
Public Hearing

before

ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

"Testimony on the Commission's proposed report and recommendations concerning risk assessment methodologies and their efficiency and applicability for establishing remediation standards and the scientific basis for the selection of a risk management standard as required by section 47 of P.L.1993, c.139"

LOCATION: State House Annex
Committee Room 11
Trenton, New Jersey

DATE: December 5, 1995
10:00 a.m.

MEMBERS OF COMMISSION PRESENT:

Michael A. Gallo, Ph.D., Chairman
Christopher P. D'Alleinne, Ph.D.
Stephen T. Boswell, Ph.D.
Richard S. Magee, Sc.D.
Rita M. Turkall, Ph.D.



ALSO PRESENT:

Judith L. Horowitz
Office of Legislative Services
Aide, Environmental Risk Assessment and
Risk Management Study Commission

New Jersey State Library

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ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

STATE HOUSE ANNEX

CN-068

TRENTON, NEW JERSEY 08625-0068

(609) 292-7676

MICHAEL A. GALLO, Ph.D.

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COMMISSIONER OF ENVIRONMENTAL
PROTECTION

NOTICE OF PUBLIC HEARING

The Environmental Risk Assessment and Risk Management Study Commission will hold a public hearing on its proposed report and recommendations concerning risk assessment methodologies and their efficiency and applicability for establishing remediation standards and the scientific basis for the selection of a risk management standard as required by section 47 of P.L.1993, c.139.

The hearing will be held on Tuesday, December 5, 1995 from 10:00 AM to 2:00 PM in Committee Room 11, (Fourth Fl., Rm 438), State House Annex, Trenton, New Jersey.

The public may address comments and questions to Judith L. Horowitz, aide to the Commission, at (609) 292-7676. Persons wishing to testify should contact Judith L. Horowitz by December 1, 1995. Written comments may be submitted and will be accepted until December 19, 1995. Fifteen copies of the comments should be provided. Oral testimony may be limited to five minutes.

The commission's proposed report and recommendations may be obtained from Judith L. Horowitz, Room 381, State House Annex, Trenton, New Jersey.

Issued 11/14/95

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MICHAEL A. GALLO, Ph.D. (Chairman): Can we get started, please?

Good morning, and welcome to the public hearing for the Environmental Risk Assessment and Risk Management Study Commission. This morning what we're going to do is, I'm going to give a very brief presentation -- a very, very broad overview of the report; most of you have seen it.

Then, we're going to have several witnesses who will have five minutes. Someone accused me of being a bit restrictive about this -- depending on how you want to define restrictive. I have a little stopwatch. So what I'll do is set the stopwatch for about four minutes. I'll let you know when there is a minute to go, and that will be it.

We have about 19 presenters. We have written comments from other individuals that are already in. The comment period is open for two weeks from today -- I believe that's correct. Any written comment can come back to Judy Horowitz.

Just as a brief introduction, many of you know that this Commission was put together quite a while back now. It seems like it was four or five years. It really wasn't quite that far. We held three public meetings before we started deliberations, collected a lot of material from most of you folks or your organizations -- we're very appreciative of that -- and we had several interesting deliberative meetings. I think the word that I used was "intellectually stimulating and contentious at times." I always believe in creative tension. Sometimes the tension got greater than the creation, but I think we've come to today.

So what I would like to do is to spend just a couple of minutes and run through a few overheads that, in my estimation, are the salient points of the report.

Before I do that, I want to thank all of the Commissioners who are here with us today: Rita Turkall, Steve Boswell, Chris D'Alleinne -- who served as Cochair -- and Dick Magee. These folks and the rest of the people on the Commission have worked very, very hard to get us to this stage.

I'd like to keep the comments brief. What we're going to do with those comments, fundamentally, is I'm hoping that the comments are going to be, basically, questions that you think we haven't addressed, or directed points of comment rather than a diatribe or a polemic of any sort. We're not about to engage in that. So I would like to have it as constructive as we can make it.

Having said that, let me just run through the few slides that I have. I thought what I would do today is-- As I said, the list of witnesses is about 19 or 20. I thought that Rick Gimello from DEP could go first, and then we'll start down the list from there.

I'm going to go to the slides now. As the Commission Chair, my first act this morning was to break the slide projector. So we'll see what happens from here. (uses overhead projector)

Is that going to record okay? (addressing hearing reporter) (affirmative response)

Somebody told me I had to do a Johnny Carson act here this morning.

This is the title of our Commission. This is our draft report that we're going to be running through today. What I want to do is go through the objectives of what this meeting is today.

First, it's to review the Commission's draft recommendations.

Secondly, it's to provide an opportunity for public comment.

Third is to obtain additional input for consideration in the final report.

Just so you know, our target date is to be finished with the final report very, very early in January -- for when the Legislature is ready to come back into session.

Now, the overriding principle of this Commission and environmental protection in New Jersey is stated here. The 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. I think that is what I want you to keep in mind. It's stated in the report, but the idea of public health and the environment was first and foremost in our deliberations from the very, very beginning.

There were two charges to the Commission, as you all know.

I guess I can pull this back. If I pull it back, it will work, I guess. (referring to table holding overhead projector)

DR. BOSWELL: No, push it forward.

DR. GALLO: Come here, muscles.

We have a very strong Commission here. That may come forward a little bit. That's not as good as I thought it would be. Now, that's a little better. Now we have almost all of it.

The charges to the Commission, as stated in the Act, are to examine and assess the scientific basis for selecting the risk management standard of one-in-a-million, which is the major charge, and also to examine--

Thank you. It's great to have engineers with you.
(referring to assistance with overhead projector)

--and assess the methodologies of risk assessment and their efficacy and applicability for the purpose of establishing remediation standards.

We spent a lot of time on both of these, as I think the report reflects. The basis for one-in-a-million -- obviously, people have been calling this "the one-in-a-million Commission," among other things. The risk assessment methodology is something that is still an important aspect of what we're trying to do.

The members of the Commission -- and, again, I want to thank them for all of their hard work. This was not an easy task. Gail Ashley from Rutgers; Steve Boswell -- this gentleman here who just moved the table -- Chris D'Alleinne, who actually served as the Cochair with me for this Commission and without whose help I never would have gotten to this stage; yours truly; Sergio Germinario; Bernie Goldstein, who happens to be in Hawaii -- I don't understand why he would want to be in Hawaii when he can be in Trenton in December -- Dave Kosson; Dick Magee, sitting over here; Rita Turkall, right behind me; and Bob Tucker and Leslie McGeorge from New Jersey DEP -- Leslie is here --

served as ex officio and were very, very helpful throughout the process.

Now, the sum and substance, this is the table -- Table 1. There are two things that I want you to read into this before you get started. It says the "Recommended Risk Management Standards." These are not the current. These are what are recommended by us.

What we did was, we looked at the classifications of carcinogens. We also looked at noncancer endpoints, because we felt that some of the noncancer endpoints, from a health point of view, were just as detrimental to the public health of the citizens of New Jersey.

We're recommending that in New Jersey the default standard be 10^{-5} , that a permanent remedy -- that is, if it's cleaned up completely by our standards -- the permanent remedy for the carcinogens would be 10^{-5} , and for a Class C carcinogen -- I don't know if you can see that -- it is 10^{-4} .

Let me just spend a second on that. Primarily, the Class C carcinogens are really regulated in many areas of the country -- in fact, in some cases, here in this State -- not so much as carcinogens, but as public health hazards for other disease states.

The next one is the one that I think may give you a little bit of pause, and that is the residual risk after exposure control remedies. This is the most strict. It is 10^{-6} , and for the Class C carcinogens it is 10^{-5} . I'm sure there are going to be some questions about that. The reason for that, basically, is that this is not a permanent remedy. This is a

permanent remedy. (indicating) This is not permanent in our eyes. (indicating)

I think the most important aspect of this table is actually in the next column, that is, regardless of what is done, whether it's exposure-- Well, if it's exposure control, you have to clean to 10^{-4} before you even think about your permanent remedies or your exposure control remedy -- particularly, your exposure control remedies.

So from a public health point of view -- and I think this is the essence of it -- we feel that these are incentives so that more sites will be cleaned up, and secondly, that for the sites where engineering controls are going to be used, at least underneath the caps or whatever it's going to be, it will have been reduced to a risk of 10^{-4} . That is quite different than what fundamentally exists in the realm today.

Based on the public comment and the deliberations, it was concluded that there were several impediments to remediation. These impediments are stated here.

One is the inability to achieve permanence and severance of liability. We felt that this was a major impediment to some of the remediations.

Secondly, one of the impediments was felt, by many of the commentators, to be the application of redundant, conservative default assumptions.

Then the third was many folks felt, as we did, that there was a lack of performance-based regulatory objectives, and that these three together served as the impediments to the remediations.

Based on that, the Commission made several recommendations. The first is to use the base available scientific information and judgement.

The second is to use site-specific data.

The third, and actually it's the overriding one, is to adopt the principles listed in Table 1 of the draft report, because these are incentives for permanent remediation.

Another recommendation is to establish a surcharge of approximately 1 percent to 5 percent on all remediations -- both permanent and exposure control. So in the remediation process, this surcharge would be charged.

Another recommendation is to develop and validate -- and this is really a research recommendation -- probabilistic approaches to risk assessment. That is a big charge, and we realize that, but I think that that is a goal that the State of New Jersey certainly has the technical ability to at least approach.

Another recommendation is to establish a central repository of all known contaminated sites. The reason for that is we are recommending for the nonpermanent remedies a declaration of environmental restrictions. These DERs are used in other instances in the State, and we felt that for the waste sites and for the sites we're talking about that a declaration of environmental restriction for any site that did not meet permanency was an important factor. It's a very important factor for the public health and well-being in the State.

The recommendations really follow a three-tiered approach. Tier 1 is to apply default standards of 10^{-5} . Currently, the default standards are fundamentally 10^{-6} . Tier 2

is to use a site-specific approach of 10^{-5} through 10^{-4} , depending -- 10^{-4} would be for all sites, 10^{-5} for site specificity, and an exposure control remedy of 10^{-6} .

The last recommendation is the establishment of an external Risk Assessment and Risk Management Scientific Advisory Board. We had long, hard debates about this, whether it should be an Advisory Board or an Oversight Commission, and I think the consensus was that it should, perhaps, be an Advisory Board.

Advisory boards are used very wisely by the State of New Jersey in other areas, and we felt that in this area, which is very, very important to public health and safety in the State of New Jersey, an Advisory Board to the DEP would be a worthwhile recommendation.

Thank you.

Now, do I have these things hooked up properly? (affirmative response) Are you getting an overtone from these two microphones? (negative response)

Dr. Magee pointed out to me that one of the things that I failed to say, which is one of our conclusions, is that as a Commission -- and I guess it became so ingrained after several meetings, I just bypassed it -- we felt there was no scientific basis for 10^{-6} . I led the caveat that there doesn't seem to be a scientific basis for many of these numbers that are used, but 10^{-6} certainly had no scientific basis.

The other thing that I failed to mention is, in the case of the deed restriction, if it is not clear-- The permanent that I'm speaking about there is a permanent for residential use. If it is permanent for industrial use, there would still be at least a statement of the deed restriction.

Okay. Having said that, I will now open it up for our witnesses. Our first witness will be Rick Gimello from DEP.

Just so you folks know what this sounds like -- let me see if I have enough battery strength here. That's it. (demonstrates timer) I love this watch.

A S S T. C O M M. R I C H A R D G I M E L L O: Am I on, Michael? I'll dispense with the niceties.

DR. GALLO: I guess these two microphones are the two that are live (indicating) and if you want to be recorded -- which I think you may want -- the microphone on that plate is the one that is activated.

ASSISTANT COMMISSIONER GIMELLO: Is it on?
(affirmative response)

It's on, Mike.

DR. GALLO: It's on. Okay. Whenever you're ready, sir.

ASSISTANT COMMISSIONER GIMELLO: Thank you.

I plan to focus today on the major policy issues in question that the DEP has based on our review. We will provide detailed, written comments by December 19. I'll start in general and move to the specific.

The Commission's comments regarding public perception of the pace of cleanups, which are an underlying premise of many of the Commission's recommendations, the Department believes strongly are unfounded and unsupported by the documentation provided by NJDEP. Indeed, what we believe is that activities in the State indicate that remediation work is ongoing at a level unprecedented in any other state.

The reduction in the level of protection from 10^{-6} to 10^{-5} or 10^{-4} , as recommended by the Commission, is indeed a public policy and not an issue of science. However, while the report goes into great detail to explain why 10^{-6} is not a scientific goal, the report does not, in our opinion, provide ample explanation about why 10^{-5} is more appropriate.

One rationale briefly discussed by the Commission is that the reduction should encourage more permanent remedies, but there are no data or case studies provided to show that the Commission's hypothesis is, in fact, valid, and we think there are serious questions about those conclusions.

In addition, under the matrix proposed by the Commission, some nonpermanent remedies would be more protective of human health and the environment than permanent remedies. I'm not sure why as a State, as a matter of policy we would want to encourage permanent remedies. This proposal has repercussions, also, for the State's groundwater and surface water quality standards.

The Commission's recommendations include flexibility standards, standards based upon use, standards which consider noncancer endpoints, allowing for permanent and nonpermanent remedies, the use of property restrictions, allowing for selection of site-specific standards, and allowing selection of natural attenuation of groundwater with monitoring where appropriate. All of this is currently available under the regulatory scheme provided in S-1070. It is not clear how or if the Commission envisions something different than is currently done.

For example, the report contains a section suggesting that DEP develop some models to describe the soil to groundwater transport pathway. DEP currently uses such models.

The Department strongly recommends that additional explanation be provided regarding the use of the risk matrix. The Commission recommends the adoption of a matrix which incorporates different risk management levels based upon the remedy selected and the carcinogenic class of the contaminants. Is it an appropriate public policy to allow residents and workers to be protected to different levels at different sites?

Our reading of the report is that the Commission is recommending a risk management goal of 10^{-5} for all carcinogens under Tier 1, but a risk management goal of 10^{-5} for Class A and Class B carcinogens and a 10^{-4} under Tier 2. The rationale for changing the risk management factor when moving from generic to specific standards is not explained.

The Commission recommends that nonpermanent remedies be 10 times more protective than permanent remedies. In addition to the other points I've raised, implementation issues will result.

For example, suppose there are two adjacent sites with similar types and distributions of contaminants. Assume that one site -- the owner of site one -- wants to do a permanent remedy, but the other wants to do a nonpermanent remedy. Under the matrix as we understand it, one site would have exposed soil at 10^{-5} with no environmental restriction, while the other site would be protective to 10^{-6} with an environmental restriction. We fail to understand the logic.

The Commission recommends-- (timer beeps)

DR. GALLO: You've got one minute, Rick.

MR. GIMELLO: The Commission recommends using cumulative risk for specific pathways not to exceed 10^{-5} . This recommendation is only included in the recommendation section. It is not discussed. We believe there are serious questions with regard to cumulative risk. It's not something that the DEP or the EPA currently uses, and it's not clear how we should apply it.

The Commission recommends that liability be severed if a permanent remedy and a surcharge be paid. We have some questions with regard to that. I'll have to highlight them later.

One of the questions is: Who pays the tax -- the surcharge? Under what conditions should it be paid? We think that needs to be further explained.

One sentence in the report mentions a surcharge reimbursement.

DR. GALLO: That's a mistake.

MR. GIMELLO: Great.

The Commission recommends that the size of population risk for a given site be included in the determination of risk-based management standards. How will one compute, calculate, or determine the exposed population factor? (timer beeps)

In closing, due to the time constraints of the oral testimony, we've tried to highlight some of DEP's major issues and questions. However, many of the issues and questions remain and will be raised in our written comments. We urge you to review them and the other testimony provided here today and

provide the clarifications necessary for the support of the report.

DR. GALLO: Thank you. Thanks, Rick, we appreciate that. You're going to have written comments?

MR. GIMELLO: Yes, sir.

DR. GALLO: Okay.

The next witness is Donald Esch, the New Jersey Area Manager, Exxon, USA.

D O N A L D E S C H: Thank you. May I start?

DR. GALLO: Yes, it's all yours.

MR. ESCH: My name, as you said, is Don Esch. I'm the New Jersey Area Manager for Exxon, USA, with primary responsibility for remediation activities at our former petroleum sites in Linden and Bayonne. I've also been a New Jersey resident for the past 24 years.

I'd like to thank the Commission for providing me the opportunity to comment on the draft report. My comments are given both on behalf of my employer and as a concerned citizen of the State.

We commend the Commission for their work on a number of key issues and support the Commission's clear and strong commitment that there is no scientific basis for 10^{-6} and its appropriate movement away from that standard.

In addition, we strongly support the Commission's recommendation to use the best available scientific information and judgment to predict hazard. We believe that this approach will be both protective of public health and will promote efficient and timely cleanups in the State of New Jersey.

Commissioner Shinn and the DEP should be complimented for their progress in striving to fulfill the statutory goals of ISRA while awaiting the recommendations of this report.

Exxon is committed to responsibly addressing our environmental concerns which may exist from historical operations, and we are hopeful that the final implementation of the Commission's recommendations, along with the work already done by the Department in implementing ISRA, will provide a safe and sensible framework for fulfilling these responsibilities.

The draft report provides a good foundation for implementing an alternative, acceptable risk scheme. However, several important issues on the use of environmental risk assessment to derive remediation standards remain, in our opinion, unresolved.

First, we encourage the Commission to strongly recommend the acceptance of valid new data and state-of-the-art methods both for developing alternative remediation standards in site-specific risk assessments and for periodic updates of generic standards.

Concerning specific risk assessments and in the spirit of ISRA, we believe that responsible parties who develop alternative remediation standards using new data and state-of-the-art methods should be able to gain approval to use such standards now.

The ability to use valid site-specific data, including actual exposure information and state-of-the-art risk assessment methods is the centerpiece of ISRA. These data and tools, which currently exist but which are not currently accepted by the DEP,

would allow us to better define the true range of exposures and risk which may exist at a site.

The Commission has recommended to delay implementation of site-specific risk assessments pending creation of a decision tree by the NJDEP and an advisory committee. We are concerned that this path will substantially delay progress in remediating sites in New Jersey. Rather, we recommend that the decision tree be developed in parallel with the approval of site-specific risk assessments.

Also, we recommend that the advisory committee itself lead the effort and other well-developed concepts, such as ASTM E 50, be considered. It is critical that the final scheme allow for use of best available scientific data and flexibility in performing site-specific risk assessments as described under ISRA.

New information on exposure assessment methods, new toxicology data, and new risk assessment technology should be incorporated quickly. Environmental risk assessment in New Jersey must be kept in synch with new developments and technologies.

Secondly, while we strongly support the inclusion of noncancer endpoints and establishing remediation targets, we would recommend that an appropriate assessment and weighing of health concerns be incorporated into their determination.

We ask the Commission to recommend that the selection of such endpoints be heavily weighted toward long-term, irreversible health effects which are well established and accepted by the majority of the scientific community and exclude or give little weight to unsubstantiated, anecdotal claims.

Finally, we support the Commission's recommendation that severance of liability should be offered as an option to responsible parties, but we feel that the surcharge should be assessed only to those parties electing the option. We strongly believe that the option to sever liabilities will in itself serve as a significant incentive to responsible parties--
(timer beeps)

DR. GALLO: You've got one minute.

MR. ESCH: --to pursue permanent remedies. However, the imposition of more restrictive standards and controls for nonpermanant remedies purely for incentive reasons is inconsistent with a concept of risk based decision making, and further it serves as an additional barrier artificially imposed to attracting business to New Jersey and keeping it here.

In many cases, there exists no cost-effective, permanent solution. A nonpermanent remedy is the only choice. The process as laid out in the report results in double jeopardy for the responsible party in such cases. First a fee is charged for which no benefit is received, and then, on top of that, a more stringent risk level is applied. Such a result is patently unfair to the responsible party.

In closing, I would like to again commend the Commission for its report and the NJDEP for its efforts to fulfill the goals of ISRA. This report is, in a sense, the missing link. Now, we believe, with a sense of urgency, the DEP should be moving forward in accepting alternative risk standards derived from site-specific risk assessments and paving the way for the safe and sensible solutions to our State's historical contamination problems.

Thank you for the opportunity to provide comments on the report.

DR. GALLO: Thank you.

MR. ESCH: We will be submitting detailed comments within two weeks.

DR. GALLO: Okay. Thank you. Right on the mark. Thank you very much. He did that one well, didn't he? (affirmative response) I'm getting a little flak up here.

Our next witness is Dwight Bedsole from the Chemical Industry Council.

A N D R E W D W I G H T B E D S O L E: Mr. Chairman, my name is Dwight Bedsole. I am Business Director of Remediation for du Pont's facilities in New Jersey. I am pleased to have the opportunity to come before this committee to provide testimony on behalf of the Chemical Industry Council of New Jersey on these extremely important issues.

In the interest of the Commission's time constraints, my testimony will provide a distilled version of a more detailed summary of comments submitted with this testimony.

The CIC and its member companies are committed to the protection of human health and the environment and believe that many of the recommendations by the Commission are in the best interest of the State's citizens and businesses. The CIC believes that the currently used one-in-a-million risk management standard, along with the overly conservative risk assumptions and methodologies currently used by the DEP, go beyond that needed for protection of human health and the environment and, thus, have the potential for misuse of society's limited resources.

We commend the Commission for clearly stating that there is no scientific basis for 1×10^{-6} and recognizing that its historical use in food safety issues should not form the basis for its use in environmental risk assessments where the potentially exposed population is extremely small.

We also commend the Commission for recommending use of best available scientific information and judgment to predict human health risk and the use of site-specific data, rather than default assumptions and scientifically defensible tools, to more accurately predict environmental risk.

The CIC also endorses the development and use of differential remediation standards that take into account the intended use of the property.

The CIC does not agree with the Commission's proposed three-tiered approach to site remediation. The CIC believes that 1×10^{-5} is the lowest lifetime cancer risk level that should determine any soil remediation standard, but disagrees with the Commission that it should apply to Groups B and C compounds. While Group A carcinogens are considered known human carcinogens, we believe that animal carcinogens that have not been proven to be human carcinogens, which are EPA's Group B and C, should not be regulated to the same risk management standard as those that are known human carcinogens. The CIC proposes that a 1×10^{-5} risk management standard apply only to Group A carcinogens, and that Group B and C compounds can be handled by a higher risk level such as 1×10^{-4} . Alternatively, remediation standards for Group C compounds can be developed using "no observed effect level." Furthermore, the same risk management

standard should apply to both the NJDEP default standard as well as site-specific risk assessments.

The Commission's proposal would require responsible parties that choose to employ exposure controls to prevent contact with contaminants of concern and, thus, eliminate risk associated with the contaminants to meet a lower, more stringent standard than responsible parties that will be able to grant unlimited access to the public and employ no site controls. Such a dichotomy in the protection of human health is illogical and difficult to understand.

The Commission also proposes that when exposure control remedies are applied, the site must also be remediated to meet standards that assume the controls someday will fail. Exposure control remedies are not designed to be temporary fixes to a contaminated site. Such remedies are designed to meet performance standards that are protective of human health. To believe that a safety net is necessary because exposure controls will always fail and always result in exposure and always cause a risk to human health is in direct contradiction to the Commission's own recommendations.

The CIC also believes that the Commission's attempt to drive the remediation process to permanent remedies will not work. The basic logic is flawed. Due to the enormous cost difference, 7 times, between implementing an exposure control remedy versus a permanent remedy, the strategy proposed by the Commission of providing an order of magnitude incentive to employ a permanent remedy will fall far short of providing any economic incentive and only succeed in adding unnecessary cost to implement exposure control remedies.

The CIC encourages the Commission to eliminate Tier 3 from its three-tiered approach to site remediation and to remove biased proposals aimed at discouraging the use of cost-effective exposure control remedies.

Thank you.

DR. GALLO: Thank you very much.

Thirty seconds short. You have another 30 seconds, if you like. (laughter)

MR. GIMELLO: Can I have that time?

DR. GALLO: No. (laughter)

MR. GIMELLO: Just trying, Mike. Just trying.

DR. GALLO: I know. I don't blame you. I've got to admire you for that one.

David Thompson?

D A V I D W . T H O M P S O N: Okay?

DR. GALLO: Anytime you're ready.

MR. THOMPSON: Good morning, Mr. Chairman and members of the Commission. My name is David W. Thompson. I am Manager of General Electric's Environmental Remediation Program for the Mid-Atlantic/Southeast Region, and I have responsibility for directing GE's site remediation efforts in New Jersey. I appreciate the opportunity to present our views today on the Study Commission's November 1995 draft report.

I wish to commend the Commission for their work on a difficult and sensitive issue. GE supports the Commission's recommendation to use the best available scientific information and judgment to predict hazard using site-specific data rather than default assumptions and the inclusion of scientifically

defensible tools such as probabilistic analysis to more accurately predict environmental risk.

GE is heavily involved in the cleanup of numerous sites in New Jersey and across the country. The Company has spent enormous resources investigating and remediating these sites. We have also devoted much effort to finding ways to improve the overall effectiveness of this program.

The selection of responsible, scientifically based risk levels and cleanup standards is absolutely critical to the success of the site remediation program, both from the standpoint of public health protection and the commitment of industry that is needed to carry out the cleanup without litigation delay.

GE endorses the general findings of this report and believes that clarification of portions of the report and recommendations can provide a realistic, workable template which is protective of human health and the environment. I would like to briefly discuss several specific topics concerning the draft report:

Number one, actual risks should be the basis for the standards. We strongly support the goal of the Study Report that parties be given the option of selecting appropriate cleanup standards based on site-specific characteristics such as nature and location of contaminants, actual exposure pathways, actual current and planned land use, and type of remedy. For too long, these cleanups have been handled with a cookie-cutter approach based on the so-called default assumptions of human exposure, health risk, and land use that have no relationship to reality. The Commission's acceptance of probabilistic analysis

as a technique for defining risk is also an important step forward.

Other states such as Pennsylvania and Massachusetts have made major legislative overhauls of their cleanup programs to require that standards be based on actual risks using realistic assumptions of human exposure and current or planned land use. GE supports legislative amendments in New Jersey to accomplish this result and to allow flexibility in the final selection of appropriate standards.

Number two, target risk: The Commission correctly identifies that the use of 1×10^{-6} is an inappropriate remediation standard which was not based on scientific study and recommends that site remediation standards be flexible and reflect future use of a site. It is interesting that even though the EPA's National Contingency Plan has allowed Superfund cleanups to achieve risks from 1×10^{-4} to 1×10^{-6} for more than 10 years, the 1×10^{-6} level continues to be used in many cases without any sound justification. New Jersey needs to step forward and establish standards in the 1×10^{-4} to 1×10^{-5} range as we are seeing emerge in other states and at the Federal level.

Number three, the report makes too great a distinction between permanent and exposure control remedies. The Table-1 tier approach makes too great a distinction between permanent remedies and exposure control remedies. We believe that all remedies which control risks, including exposure controls, should be considered on an equal footing and evaluated based on their effectiveness in protecting human health and the environment. There are very few large disposal sites where permanent remedies, as defined by the Commission, are a feasible

solution to all or even most of the contamination that is present decades after the disposal took place.

The report would deny a party protection against future liability unless it employed a permanent remedy. We see no reason why a party that achieves an acceptable level of cleanup with encapsulation or other reliable methods should not be given the full liability protection. Other factors, such as the nature of the control remedies used, deed restrictions, and deciding to cut off future liability, not just whether the remedy is classified permanent.

Risk Management Standards, Table 1: The Commission indicates a preference for permanent remedies which employ contaminant removal, destruction, irreversible transformation or irreversible immobilization by applying a more stringent risk management standard to exposure control remedies utilizing slurry walls, caps, liners, and hydraulic controls. The assumption that exposure control remedies will break down, degrade, or cannot be made permanent by proper operation and maintenance is not realistic. There are numerous exposure control remedies which are permanent by engineering standards. Application of unrealistic risk criteria or default assumptions may negate the use of these technologies.

In conclusion, GE believes that many of the risk management suggestions of the Commission are of great importance, that some should be revised, and some should be clarified. GE will be providing comments on December 19 and also offers to provide any technical assistance that the Commission may request.

Thank you.

DR. GALLO: Thank you very much.

Our next witness is George Dawson, from New Brunswick.

G E O R G E D A W S O N: (from audience) I have no statement now, but I will submit a statement later.

DR. GALLO: Okay, thank you. And Mr. Gimello, who is sitting in the back, he can't have your time either. (laughter)

DR. MAGEE: I don't know why we couldn't have left him where he was, on number seven, if he is still here. (referring to numbers assigned to the witness sign-up sheet.)

DR. GALLO: That's right.

Mark Zdepski? Is Mark here? Oh, here he is. Okay.

J. M A R K Z D E P S K I: I would like to thank you for the opportunity to speak. My name is Mark Zdepski. I'm a geologist from Flemington, New Jersey. I have a business there called JMZ Geology. It's a group of about six professionals and one nonprofessional.

I think, overall, you did a good job of looking into what you were charged with as scientists. However, I wish you had not left the writing of your report up to someone else. I think that the recommendation that was made charging the DEP to use a risk standard of 10^{-5} is a good place to start, and that 10^{-4} is also appropriate, since they run State parks that have lakes, and every day the public is exposed to a risk standard of 10^{-4} of drowning in those lakes.

I also agree that the literature has no scientific basis for the selection of one-in-a-million. I don't think you've pulled yourself out of the political controversy surrounding the one-in-a-million risk policy. I think that the report was influenced by the DEP, but after hearing the

Assistant Commissioner, maybe it was someone else. But I'll tell you what: When you look at the first five lines of the beginning of your report and compare it with the citation out of this "New Jersey Register" of November 20, it looks like the same author, the same arrangement of thoughts, the same sentence structure. To me it looks like someone else has influenced this thing that also writes for the "New Jersey Register."

I think the majority of the text found on pages 12, 13, 16, and 17 have nothing to do with the study of the scientific basis of one-in-a-million. I think that they are political in nature and that they should be deleted.

For instance, on page 12, the fifth line from the bottom states that "many properties have been capped, sealed, or otherwise delisted with a Declaration of Environmental Restriction in place," after ISRA. But when you compare it with Table 2C, on page 15, you'll see that there have actually been fewer cleanup closeouts since ISRA than there was, while the rate of administrative closeouts has remained the same.

How many of the Commission members agree with the second sentence of the report that, "Industrial activity has created a major environmental problem"? At worst, the industrial activity in New Jersey has created many contaminated sites that may even overlap in core urban areas. I think that most scientists would agree that sea-level rise or global warming are major scientific problems. I think this sensationalist introductory language should be struck. I think you should report on your study and leave the political parts of it out.

Going back to the Executive Summary: The fourth line states that "to address this problem, the Legislature passed, and the Governor signed, bill S-1070."

Dr. Gallo, ISRA in no way addresses major environmental problems in New Jersey. ISRA simply renames a former statute and regulation that was called ECRA. The renaming of ECRA was done so the DEP could change the name of it and get away from negative publicity.

Both ECRA and ISRA focus only on a small segment of the economic activity in New Jersey. ISRA is discriminatory against manufacturers. A major function of ISRA was to retroactively provide authorization for the technical requirements, NJAC 7:26E. ISRA was used by the DEP to legitimize informal policy such as the one-in-a-million risk and then, also, the technical requirements. The Commission should not allow their report to be used.

There is an inaccurate statement about the statutory history, found on page 34, that deals with ECRA. I think you need to strike those kind of things out of that--

DR. GALLO: You have one minute left.

MR. ZDEPSKI: Pardon me.

DR. GALLO: You have one minute.

MR. ZDEPSKI: Good, I'm almost done.

The lead-in to the recommendations section on pages 41 and 42 has nothing to do with Commission activities. These paragraphs simply parrot the text found on pages 12, 13, 16, and 17, only on these pages, for the first time, the subjects of environmental injustice and inequality are introduced. I think

that the text on pages 41 and 42 are political, unscientific, and also should be struck from the report.

The last recommendation, for the creation of the Science Advisory Board, is not supported anywhere in the report that was prepared. When you go into the references of this report, only 10 of the references out of the 99 are cited. There are problems in agreement with the date found in the text versus the date found in the back of the references. There are three references that are not even cited, one of which was an oral communication from Dr. William Wood. I'd like to know who had the oral communication and what Dr. Wood had to say.

I think as scientists, that you should critically examine this draft report, as you would with a paper you would be preparing. This Board has a medical doctor, seven members with Ph.D.s, six are college professors, and I would say that you would not accept a report like this from a graduate student.

DR. GALLO: Thank you.

MR. ZDEPSKI: Thank you very much.

DR. MAGEE: I don't think he liked it.

DR. GALLO: No.

DR. MAGEE: I knew we shouldn't have let you write it, Rick.

DR. GALLO: What?

DR. MAGEE: I told Rick, I knew we shouldn't have let him write it.

DR. GALLO: Okay, thank you very much.

Our next witness is Ira Whitman, from the National Association of Industrial and Office Properties.

I R A L. W H I T M A N, P.E., Ph.D.: I am Ira L. Whitman, Environmental Engineer and Principal Consultant with The Whitman Companies, Inc., an East Brunswick, New Jersey environmental consulting firm.

I am testifying today on behalf of the New Jersey Chapter of the National Association of Industrial and Office Properties -- NAIOP -- whose members are involved in the ownership, management, development, design, and construction of office, industrial, and related commercial properties. NAIOP member firms provide more than 35,000 jobs for New Jerseyans and more than \$200 million in property taxes annually.

In 1990, we began working with the Legislature and the DEP to review the many problems associated with ECRA and to propose significant changes. We worked for two and a half years to develop and present improvements to ECRA, many of which were incorporated by the Senate and the General Assembly into the 1993 ISRA law. We endorsed the creation of the Risk Management Study Commission as a means of bringing to the public's attention issues related to the 10^{-6} risk management standard and as a forum for considering and assessing alternative standards and criteria.

We believe that the Commission's report highlights many of the key issues surrounding the one-in-a-million risk standard and provides a very useful conceptual framework with your three-tiered approach.

We agree with the Commission that the 10^{-6} excess cancer risk is an issue of public policy, and not of science. We concur that there is no real scientific basis for the 10^{-6}

standard, but need to ask if 10^{-5} or any other prescribed risk level has any greater scientific basis.

We support your conclusion that site remediation standards should be flexible and reflect future use as determined by a site owner.

Apart from our general concurrence with the principles you put forth, there are some areas of your report which we find to be unclear and confusing and others with which we disagree. The time available today only allows for a brief mention of some of these.

In our opinion, the report does not clearly address the impact of the use of redundant conservative assumptions in the risk assessment process.

It is not clear to us what ground rules would be utilized in choosing between the three alternative approaches presented in Table 1. Who will make the determination and how will disputes be dealt with? Is Tier 1 voluntary? Would site owners have the right to not accept Tier 3 cleanups by tenants on their sites and the restrictions associated with nonpermanent remedies?

We question the Commission's preference for permanent remedies and the assumption made that exposure and access controls will fail. EPA is presently moving away from mandatory permanent remedies. There are many sites in New Jersey where capping improves environmental quality. The disincentive to using a nonpermanent remedy may result in no remediation and reuse whatsoever at many locations.

Our NAIOP review committee believes that the Commission's report will become an important vehicle for

communicating risk management issues between State government, the regulated community, and the public. Therefore, we recommend that you meet with interested parties, including those who are testifying here today, to find ways to clarify your report and to better present the key issues.

Since S-1070 was enacted two and a half years ago, many other states have grappled with the same risk management issues as New Jersey. Progress has been made by some states in defining their risk management strategies and developing cleanup standards. At the Federal level, EPA's policies of site remediation under CERCLA have evolved significantly, and further change may occur with congressional reauthorization of Superfund.

We suggest that the Commission and NJDEP get plugged into national developments, possibly by convening a national conference on cleanup standards and risk management. We believe that New Jersey may stand to benefit from experiences in other states which have also had to consider the balance between sound policy and good science in developing cleanup standards.

NAIOP members wear many hats as owners of properties, buyers, developers, and sellers. We are keenly aware of the value of a clean property in today's real estate market and the negatives associated with properties that are contaminated. Our members are often faced with considering the alternative consequences of engaging in a permanent remediation compared to owning properties subject to long-term engineering and institutional controls. S-1070 and your recommendations, if enacted, affect NAIOP members in many ways. We restate our

belief that a healthy environment and a healthy economy go hand in hand.

In summary, we believe that the Commission's report represents substantial progress toward developing a rational approach to risk management and remediation standards. The immediate challenge is to clarify and articulate the Commission's approach and your report, and to further the public discussion of how clean is clean and at what cost.

DR. GALLO: Thank you very much.

DR. WHITMAN: And I yield the rest of my time to Rich Gimello. (laughter)

DR. GALLO: Who is still here.

Okay, the next witness is Mr. Tom Kady, President, Handex of New Jersey, Inc.

T O M K A D Y: Good morning. I'm Tom Kady, President of Handex of New Jersey. Handex is an environmental consulting, engineering, and remediation firm. We have specialized in subsurface hydrocarbon investigation and remediation for more than 15 years in New Jersey. We understand the complexities and the practical limitations of subsurface remediation.

Handex supports the direction the Risk Management Commission is taking toward risk based corrective action in New Jersey. Society's limited resources require a practical, cost-effective, and consistent decision making framework for setting environmental priorities and remediation goals. Most importantly, this decision making framework must be scientifically defensible.

We agree with the Commission that remediation decisions need to be based on risk, not on the ability to

achieve a generic numerical value, the ability to apply a given technology, or the availability of financial resources to undertake a remediation. Remediation standards not based on risk assessment tend to drain limited funding, both public sector and private sector, from programs that are vital to protecting human health and the environment.

Through our 19 offices across the country, we are seeing an overwhelming trend of states adopting a risk based decision process for environmental remediation. Our immediate neighbors, Pennsylvania and New York, are moving toward implementation of a risk based approach toward corrective action. To remain competitive from an economic development standpoint, New Jersey should strongly consider a risk based approach as well.

In order to facilitate implementation of the Commission's recommendations, we strongly urge the Legislature, the NJDEP, and the Commission to consider ASTM Standard E-1739, entitled, "Risk Based Corrective Action Applied at Petroleum Release Sites," as a framework for decision making. The standard is being used by an increasing number of states as a framework for their own programs. We believe the standard addresses many of the issues raised in the Commission's report.

While the Commission study appeared to focus on soil remediation issues, we believe a risk based decision process should be applied to all media: soil, air, groundwater, and surface waters. An additional benefit to ASTM 1739 is that it does apply to all media.

In summary, we concur with the Commission's direction toward a risk based decision process for environmental

assessment and remediation. We urge the Commission, the DEP, and the Legislature to consider ASTM Standard E-1739 as the framework for a risk based decision process.

Thank you.

DR. GALLO: Thank you very much.

Our next witness is Jane Nogaki. Is she here? Or Dolores Philips. Is Dolores here?

UNIDENTIFIED MEMBER OF AUDIENCE: She was.

DR. GALLO: Get her off of the phone. She's in the back, on a phone. I can see.

DR. MAGEE: Why don't we just go on to the next one?

DR. GALLO: Yes, I'll just go on to the next one.

Our next witness is--

You're up, if you want to go.

D O L O R E S P H I L I P S: (from audience) Mr. Chairman, Ms. Nogaki, who is going to testify for us, is not here yet. Is it possible to defer--

DR. GALLO: Fine, sure.

Okay, our next witness is Tory Donnelly, Project Manager, Groundwater Environmental Services. (no response) Hearing none?

DR. MAGEE: Going once.

DR. GALLO: Going once, twice, gone.

Our next witness is Ed Sargent, Director of Toxicology and Environmental Health, Merck & Co., Inc.

E D W A R D V. S A R G E N T, Ph.D.: Good morning. My name is Ed Sargent. I'm the Director of Toxicology and Environmental Health at Merck. In that position, I'm responsible for conduct

of risk assessments to support remedial activity worldwide in our corporation.

As stated on page 7, the Commission was established and given charge to examine and assess the scientific basis for selecting the risk management standard of one-in-a-million and to examine and assess the methodologies of risk assessment and their efficacy and applicability for the purpose of establishing remediation standards.

On page 34 of the report and elsewhere, there is a great deal of discussion about the use of one-in-a-million as a de minimis risk level for carcinogens. It is pointed out, and correctly so, that this de minimis level is not based on sound science but rather policy. It is further pointed out that some states have adopted a one-in-one-hundred-thousand de minimis risk level without really defining its basis for adoption.

The use of de minimis risk levels other than one-in-a-million needs to be reviewed further in-depth in a report. One argument not brought out is that there are currently conflicting policies. The policy, for example, for acceptable risks for carcinogens emitted from a hazardous waste incinerator is currently 10^{-5} , whereas it is 10^{-6} for the same carcinogens under ISRA. If 10^{-5} is acceptable for one carcinogen, it should be acceptable for all of them.

One might argue that the environmental media differs for these two scenarios, but, in fact, they do not. The indirect pathways guidance for assessing risk due to incinerator emissions requires one to estimate risk due to deposition onto soil, crops, and surface water.

The Frequency of Adverse Events: This type of analysis has not normally been a part of standard corrective action risk analysis. One concern that we have is that nowhere in the document is an adverse event defined. Is it a cancer? Is it a case of noncancer illness, or is it an increased exposure probability due to a trespasser on the site?

In the latter example, is the event the trespass or the exposure? There is no guidance in the report on how this type of analysis will be conducted. If an adverse event is a cancer, how will the background incidence be taken into account? We would recommend that this type of analysis not be included in the guidance.

It appears that one incentive to select a permanent remedy is to levy a surcharge on all remediations. The selection of a permanent remedy only allows you to be eligible for a surcharge reimbursement. What are the eligibility criteria?

Explanation of surcharge reimbursement is confusing. On page 38 it states that "Sites remediated under Tiers 1 and 2 are eligible for surcharge reimbursement." This can be interpreted that if company "X" remediates its site under Tier 1 or Tier 2, it can apply to the State and receive reimbursement on the surcharge paid. It is not certain that this is exactly what the Commission had in mind.

On page 38 it is stated that a declaration of environmental restriction and listing in a proposed repository will still be required if sites are not remediated to residential criteria. A DER is essentially a deed restriction, and thus a company really does not sever its liability.

The reality is that remedies must be appropriate for the use of the site. For example, at an active industrial site, engineering controls can be used to limit access and exposure to contamination. Exposure control for such a site should be considered permanent until such time as its use changes. If the use of a site evolves to something less controlled, then the site should be reevaluated for its new intended use.

The concept of cost benefit consideration is important and a major consideration in the U.S. EPA's proposed subpart "S" Corrective Action Rule. The Commission has not gone into depth on the consideration of costs in the selection of remedies except to say that in order to select an exposure control option over a permanent option, the permanent option must be 110 percent of the exposure control option. Nowhere in this discussion is the concept of technical feasibility brought out, another key element in considering appropriate remedies under the proposed subpart "S." In terms of the cost issue, what is the basis for 110 percent?

Under generic and site-specific standards, this section appears in some way to be addressing the protection of groundwater, although it's not specifically stated. Given that groundwater protection is one of the most significant issues in any remediation strategy, further consideration should be given to such issues as defining points of compliance, establishment of groundwater standards based on risk assessment, and technical infeasibility cleanups.

The Commission recommends a risk management standard of 10^{-5} for individual carcinogens, and then confuses the issue with the next sentence. Is 10^{-5} to be applied cumulatively? It

is not clear from the way the recommendation is worded exactly what is meant. We would recommend that the language in ISRA clearly states that the health risk levels are established for any particular contaminant and not for the cumulative effects of more than one contaminant at a site.

In terms of the recommendation for an Advisory Board, we recommend that it should have industrial representation. Industrial scientists with experience in environmental risk assessment in New Jersey and elsewhere will provide the practical insights necessary for a thorough evaluation of risk assessment policy.

Thank you.

DR. GALLO: Thank you, Dr. Sargent.

Just a point of clarification -- I thought I made that in my representation -- Dr. Sargent mentioned that on page 38, the sentence reads, "Sites remediated under Tiers 1 and 2 are eligible for a surcharge reimbursement." That was obviously a typo. You don't get paid to clean them up. Actually, what that should read is, "Sites remediated under Tier 1 are eligible for severance of liability for the land use category under which"-- (timer beeps) And then, I have to stop. (laughter)

So it's not a surcharge reimbursement. That was a typo. It is my fault. It is severance of liability.

DR. MAGEE: That was the Chairman's fault.

DR. GALLO: It is always the Chairman's fault, I was just informed.

Okay, is Ms. Nogaki here?

MS. PHILIPS: No, I'm sorry.

DR. GALLO: Okay. Just holler when she comes in.

The next witness is John Dobi. He is Environmental Project Manager for PSE&G.

J O H N S. D O B I, Ph.D.: Good morning, Dr. Gallo and Risk Management Commission members. My name is Dr. John S. Dobi. I am employed as an Environmental Project Manager in the Environmental Management Department at Public Service Electric & Gas Company. In this capacity, I manage the company's Superfund and third-party sites and am responsible for managing and producing both the human health and ecological risk assessments associated with these sites.

I hold a Ph.D. in environmental science and have 25 years professional experience in environmental management. In addition, I am an Adjunct Professor at the New Jersey Institute of Technology in the Department of Chemical Engineering, Chemistry, and Environmental Science, where I teach the graduate level "Quantitative Risk Assessment" course.

PSE&G appreciates this opportunity and would like to thank the members of the Environmental Risk Assessment and Risk Management Commission for their efforts in addressing the very complex and controversial human health risk assessment process associated with soil contamination and site remediation in New Jersey. We acknowledge and appreciate that the Commission has evaluated and adopted numerous comments PSE&G submitted during the 1994 public hearings.

Conceptually we agree with and support the Commission's recommendations. We particularly support recommendation No. 3, which acknowledges a risk management standard of 10^{-5} for Class A and B carcinogens to be an objective when developing soil remediation standards. A flexible approach

to a risk management strategy would be consistent with the national Contingency Plan, such as the 10^{-4} to 10^{-6} cancer risk range accepted by U.S. EPA at CERCLA sites. If this site recommendation is accepted, New Jersey soil standards and risk management practices would be comparable to those at other sites, for example, Texas, California, Massachusetts, and Louisiana.

A practical example of a protocol for adopting a flexible risk management approach is identified in Table 1 of the Commission's report. Good science dictates that each site be assessed independently using site-specific information from which all risks are assessed. Site-specific risk assessments could significantly reduce a dependency on redundantly conservative default assumptions.

The Commission astutely embraces a tiered approach to site remediation which integrates both future land use and differential remediation criteria. An objective scientific undertaking of this nature may eventually lead to the development of screening values below which minimal risk is identified and, therefore, greatly reduce the need for a formal risk assessment.

If the acceptable risk levels, as identified by the Commission for both carcinogens and noncarcinogens, are adopted and S-1070 is amended, two objectives will be achieved. First, public health and welfare will be protected, and second, only those sites determined by their future land use options and which are determined to pose an unacceptable risk will require remediation.

We strongly recommend that probabilistic analyses such as Monte Carlo simulations, as proposed by the Commission, where possible, be applied to yield frequency distributions which will further reduce the reliance on redundantly conservative assumptions. The existing NJDEP soil remediation standards were developed through deterministic or single-point estimates which have exacerbated a dependency on employing default values and inherently redundant assumptions.

It is therefore essential that the necessary components of the risk assessment process be established during preliminary planning and scoping sessions of a remedial assessment work plan. The Commission's report appropriately identifies the significance and perspectives of valid fate and transport models to the risk assessment process.

PSE&G endorses the Risk Commission's recommendation No. 10 to establish a Risk Assessment and Risk Management Science Advisory Board to advise the NJDEP Commissioner on evolving policy based on generally accepted and peer-reviewed scientific evidence. If adopted, New Jersey citizens and elected officials will have a powerful tool to help shape environmental policies and assure that the State's resources are applied in the most effective manner.

PSE&G requests that our legislators adopt the Commission's recommended approach to developing site cleanup standards. Doing so will enhance New Jersey's position as a business and environmental leader.

Thank you very much for your time and attention.

DR. GALLO: Thank you.

The next witness is Deborah LeMonde, Jersey Central Power & Light. Obviously not.

C O L I N S W E E N E Y: I am not now, nor have I ever been, Deborah LeMonde. (laughter)

DR. GALLO: I won't comment.

MR. SWEENEY: Good morning. My name is Colin Sweeney. I am the Manager of Site Remediation for Jersey Central Power & Light Company. I am please to provide testimony today with regard to the Risk Commission's report. Due to the time constraints, this oral testimony is only designed to provide an overview of our comments. Our forthcoming written comments will provide additional details.

Jersey Central has a long-standing commitment to conduct its operations and activities in an environmentally responsible manner. We also recognize the importance of placing risks in their proper perspective, as a critical issue facing society today.

We believe that it is not only possible, but imperative to establish an approach that will be protective of human health while maintaining and promoting business in New Jersey.

Jersey Central commends the Commission for recommending the use of scientifically defensible exposure scenario alternatives such as probabilistic approaches and the use of fate and transport models which consider site-specific physical conditions. These and other recommendations made by the Commission with regard to risk methodologies establish the framework for more realistic risk assessments.

In keeping with the intent of ISRA, these methodological improvements would move the risk assessment process away from the use of redundant, overly conservative assumptions.

Jersey Central also commends the Commission for their thorough examination of the historical use of the one-in-a-million risk level, and we agree with the conclusion that, indeed, no scientific basis exists for its use in environmental risk evaluations.

The Commission has attempted to establish a mechanism designed to create a preference for permanent remedies. It has done so by suggesting the application of a more stringent risk management standard to exposure control remedies as compared with permanent remedies.

Whereas permanent remedies may be feasible and appropriate in some cases, it is likely that the remedies employing engineering and institutional controls can also be implemented to effectively eliminate any risk associated with a contaminated site and probably in a much more cost-effective manner.

To state that a less stringent risk level should be allowed when implementing a permanent remedy versus a nonpermanent remedy for the same site is hard to understand. When the NJDEP approved a Remedial Action Work Plan, including one which contains a DER as a component of the remedy, they have determined that the remedy in the RAWP is protective of human health and the environment.

The DEP stipulates the notification procedures and corrective actions required should any engineering controls be

compromised. The RAWP also specifies any monitoring and/or maintenance procedures to be conducted to ensure the integrity of engineering controls. Therefore, the assumption by the Commission that engineering controls will eventually fail is, we believe, unfounded.

Jersey Central believes that the risk level for permanent and nonpermanent remedies should be the same. We believe that a risk management standard of 10^{-5} is appropriate for EPA's Group A carcinogens. Further, we contend that the risk level of 10^{-4} is more appropriate for Group B and C compounds as they have not been proven to be human carcinogens and, therefore, should not be regulated to the same standard as Class A carcinogens.

We suggest the Commission revise Table 1 to reflect the risk management standards of 10^{-5} for Group A carcinogens and 10^{-4} for Group B and C carcinogens, regardless of whether a permanent remedy or exposure control remediation approach is used.

Whereas the severance of liability is certainly a further incentive to conduct a permanent remedy, Jersey Central believes that a surcharge of 1 percent to 5 percent proposed by the Commission should be elective and apply only to permanent remedies. To apply the surcharge to nonpermanent remedies would constitute an unnecessary financial burden and, therefore, would be inconsistent, I believe, with the intent of ISRA. (timer beeps)

Jersey Central agrees that some type of Advisory Board should be established if only to examine new trends in risk assessment and provide recommendations to the DEP. In addition,

Jersey Central recommends that such a body benchmark the progress of New Jersey in the area of risk assessment with other states' initiatives.

On behalf of Jersey Central, I want to extend our appreciation to the Commission for the opportunity to provide this testimony. We look forward to tracking the progress being made by the Commission concerning this important matter.

Thank you.

DR. GALLO: Thank you very much.

Before I go any further, I would like to recognize Senator McNamara -- who is sitting here very quietly -- as the champion of this operation. I think it bodes well for the citizens of New Jersey that the Senator is here listening to this testimony to take it back to the floor of the Legislature, because that is where this is all going to play out in the end.

I want to thank Senator McNamara for taking his time from his busy schedule to be here.

Our next witness is John Maxwell from the New Jersey Petroleum Council.

J O H N A . M A X W E L L: Good morning. I am John Maxwell. I am representing the member companies of the New Jersey Petroleum Council. We are the State affiliate of the American Petroleum Institute, and our 300 members produce and refine crude oil around the world. We transport and retail gasoline and petroleum products here in New Jersey where we have a long and proud history.

The New Jersey Petroleum Council commends the work done thus far by the Commission. Our members are proponents of risk based corrective action as the preferred approach in

dealing with contaminated environments at leaking petroleum underground storage tank sites. We believe this methodology must be broadened to govern cleanups at all contaminated sites, and the Commission's report helps to begin and continue this process.

In a perfect world, there would be all the money, technology, and trained personnel to clean up all contaminated sites. In this same world, there would have been installed, long ago, technology to prevent leaking underground storage systems or to prevent spills from occurring entirely. Although that day has not yet come, we are getting closer to these goals. In the interim, we need to face the reality that limited resources in terms of time, money, manpower, and technology exist to address environmental concerns.

A risk-based decision making approach for corrective action will allow the allocation of resources to those environmental problems that pose the greatest risk to human health and the environment. The risk at all release sites is not equal, as we know. The remedial approach should reduce the risk at a site to a level that protects the citizens affected by that site. This is discussed at length in the Risk Commission's report.

The major oil companies have long since predominately complied with the 1998 upgrade standards for underground storage tanks. However, small and/or independent businesses, municipalities, and even the State of New Jersey may face financial stress in meeting the forthcoming 1998 deadline for the retrofitting of underground storage tanks with leak detection systems.

As required work begins, the result will be that more sites with releases to soil and groundwater will be identified. The remediation of these sites will stress the limited financial resources of effected businesses, municipalities, and State agencies. There is also the need to allocate public moneys and resources for remediations of underground storage tank systems owned by the State.

The same sort of allocation of resource concerns that have been felt by the private sector, the oil industry, and small businesses with limited resources will be felt by all of those needing to perform the required upgrades and the resultant remediation. Expending public funds to achieve goals that are not risk based may well divert funds away from programs that are more effective in protecting public health and the environment.

In order to bridge between the recommendations of the Risk Commission's report and the implementation of the goals discussed therein, we urge the Commission, the Legislature, and the New Jersey DEP consider ASTM E 1739 -- risk based corrective action for petroleum releases -- as a framework for decision making. Many issues raised in the Commission's report are addressed in E-1739 making it a very good mechanism to assist in implementing the Commission's goals.

The New Jersey Petroleum Council and our member companies continue to advocate the goals of the Commission, Legislature, and the NJDEP on implementation of a risk-based corrective approach to corrective action decision making in New Jersey.

We will provide detailed written comments prior to the December 19 deadline. Thank you for your consideration.

DR. GALLO: Thank you. That was a four minute one, on the mark. Thank you very much.

The next witness is Randy Shuler.

I think I should probably leave the room. Randy is a former graduate student of our program.

DR. MAGEE: Oh, geez.

DR. GALLO: Well, that's all right. We have an NJIT person, too.

R A N D Y L. S H U L E R, Ph.D.: Good morning.

DR. GALLO: Excuse me, this is not going to be writing your thesis; four minutes is four minutes.

DR. SHULER: Very good.

My name is Dr. Randy Shuler. I am a Staff Scientist specializing in risk assessment and toxicology with Environmental Resources Management in Ewing, New Jersey.

Many of my written comments were already touched upon by others today, but I will take the few moments that I have to touch upon those that have not yet been addressed.

While the draft report does address the fact that the use of one-in-a-million excess cancer risk -- 10^{-6} -- is an issue of public policy not of science, no documentation is presented to support the Commission's position that 10^{-5} is a better standard.

One place where supporting information should be placed is on page 34 following the second full paragraph which discusses New Jersey having adopted 10^{-5} for risk management for selected environmental exposures.

In support of the 10^{-5} cancer benchmark, ERM offers the following examples of various agencies supporting cancer risk levels higher than 10^{-6} :

Federal programs have often used target risk level higher than 10^{-6} .

For example, from inside EPA's risk policy report, dated June 16, 1995, OSHA's acceptable risk range is far less stringent than the EPA's. Based on a 1980 Supreme Court ruling for a benzene standard that found a one-in-one-thousand risk to be clearly significant and a one-in-a-billion risk to be clearly insignificant, OSHA has often regulated to limit risk to 10^{-3} , which is the risk level the EPA usually considers the starting point for great controls on exposure. OSHA also faces a statutory requirement that its rules be economically feasible.

From EPA's 1990 "Guidance on Remedial Actions for Superfund Sites with PCB Contamination," "For soils, the starting point action level -- preliminary remediation goal -- is 1 ppm for sites where unlimited exposure under residential land use is assumed. Higher starting point values -- 10 to 25 ppm -- are suggested for sites where the exposure scenario is industrial. Remediation goals for groundwater that is potentially drinkable should be the proposed MCL of 0.5 ppb."

Referring to the preliminary remediation goal for PCBs in residential soils, the concentration of 1 ppm PCBs equate to approximately a 10^{-5} excess lifetime cancer risk, assuming no soil cover or management controls. The 1 ppm starting point for residential soil scenarios reflects a protective, quantifiable concentration for soil. Regarding groundwater exposure, the

proposed MCL for PCBs is 0.5 ppb reflecting a 10^{-4} excess cancer risk.

Other state cleanup programs use a 10^{-5} risk target. On June 5, 1995, the Michigan legislature enacted amendments to Part 201 of the Natural Resources and Environmental Protection Act -- 1994 PA 451 -- establishing Michigan's acceptable level of risk resulting from exposure to carcinogens at 10^{-5} for residential, industrial, and commercial sites. Previously, Michigan's cancer risk target was 10^{-6} .

A great amount of effort has been devoted to a discussion of Monte Carlo analysis in the risk assessment process. In fact, almost three entire pages were devoted to that. Is it the Commission's position that NJDEP should endorse techniques such as Monte Carlo in developing the target risk levels shown in Table 1, or has the Commission included this discussion to support the use of Monte Carlo or other techniques for quantifying uncertainty in risk assessments performed in general for the contaminated sites in New Jersey?

Specifically addressing page 38: in the Tier 1 approach the Commission indicates that 10^{-5} should be used for both residential and industrial settings. It has been ERM's experience that the U.S. EPA -- specifically region two -- will allow 10^{-4} for industrial sites. (timer beeps)

DR. GALLO: One minute, Randy.

DR. SHULER: Thus, the Commission's recommendation would, in actuality, propose a more stringent target risk level than is enforced by the U.S. EPA in some industrial situations.

Finally, from page 35, the discussion in the first full paragraph regarding the 10 cancers in 70 years versus 0.1

cancers in 70 years is unclear. Where have these numbers of 10 and 0.1 come from?

Additionally, it is important to keep in mind that 0.1 excess cancer cases per 70 years could be very important from a public health perspective to an individual living down gradient of a site with known groundwater contamination.

I thank the Commission for its time.

DR. GALLO: Thank you very much for your very pointed comments.

The next witness is Nancy Wittenberg, New Jersey Builders Association.

N A N C Y W I T T E N B E R G: Good morning. My name is Nancy Wittenberg. I'm the Director of Environmental Affairs for the New Jersey Builders Association.

I'd like to just give you the perspective from this Association. Most of the members are residential developers not industrial developers. So I think their perspective is equally important.

From the perspective of the residential development sector, application of the recommendations of this report should help to promote development of urban sites, which was the intent of ISRA -- to improve the process for defining and approving cleanup of contaminated sites and to eliminate unnecessary financial burden -- and is also current policy put forward by the Governor to redevelop our urban sites.

To redevelop such sites you need flexibility. Most residential developers shy away from such projects due to the stories they have heard in the past about the cost of such

cleanups and the relative ease of finding noncontaminated, suburban sprawl sites to develop.

The Commission's recognition that the definition of acceptable risk is a policy decision and identifying the importance of flexible site-specific cleanup requirements will go far in promoting development of such sites.

On the other hand, the report's recommendation to discriminate against the use of exposure control compared with permanent remediation and taxing or surcharging cleanups will go far in providing disincentive.

The report seems to have been authored by two groups of separate minds and, then, combined at the last minute. To the residential development community this is most confusing. If the goal is to clean up sites, then we need to talk about the risk associated with such sites and put this in perspective with other risks, be they environmental or other.

The report's lack of distinction of relative risk is troublesome. If the goal is to clean up sites and reuse them with limited health impact, then let's set up a process which promotes this without forcing expensive permanent remediation which provides little health or economic benefit. (beeper sounds)

DR. GALLO: That was a false alarm, keep going. You have plenty of time.

MS. WITTENBERG: And now I'm all in a panic.
(laughter)

If an on-site exposure control works, then promote it, don't punish it, and don't make cleanups more expensive by surcharging or taxing them.

If the goal is to get the sites cleaned up for reuse, then let the regulations and standards meet these goals. The regulations should support the spoken policies of the administration. We need to look at the costs associated with the risks and make decisions which take such costs into account.

Of course, the setting of the allowable risk is just one part of the overall process. Other factors used in models and calculations must also be estimated and how conservative or not they are should also be addressed. Without considering the impact of these factors, the definition of an acceptable risk could be of little consequence in the end.

What is the intent? To clean up sites in a cost-effective manner which protects health and the environment. Do we have to clean up the sites to prehistoric conditions, to preindustrial conditions, to some other level? The report notes that this is a policy decision, and this is good news. It is very important to separate policy from science. It is now up to the policy makers to make these decisions.

Those few residential developers who are currently involved in remediating sites have no complaints about DEP and their programs. In fact, they had nothing but very good things to say. There are, however, only very few developers who are currently doing such residential development. Residential units cannot afford to have too much increase in costs and still be saleable in this State.

The Commission's report takes some good steps towards removing the mystery from site cleanups, but could go further in making this a more straightforward process which sets its goals

to clean up sites not force permanent, more expensive remediations.

Thank you.

DR. GALLO: Thank you.

I just want to-- We've had two comments about multiple writers. My father will be very happy to know that I have a left side and a right side of my brain. Fundamentally, this is a document that was read through and written by the Commission, but I think the criticism of it is all to the Chair. I take responsibility for the writing. But I can assure you that this was not written in pieces. This was written as a whole document. I guess I ought to get my left side and right side of my brain checked out. The creative side must have gotten lost in the process.

Thank you very much.

Our next witness is Madelyn Hoffman, Director of the Grass Roots Environmental Organization.

M A D E L Y N H O F F M A N: (from audience) I just walked back in the door.

DR. GALLO: Well, that's good. Good timing.

MS. HOFFMAN: My name is Madelyn Hoffman. I'm the Director of the Grass Roots Environmental Organization in New Jersey. I have been working with citizens groups throughout the State on toxic chemical pollution problems since 1980. I appreciate the opportunity to address you this afternoon about your ongoing study on risk assessment.

I first want to say a few things about risk assessment in general, because I think it's important, given the testimony

that has preceded me, to kind of put it into some kind of perspective.

The fact is that risk assessment-- One of the questions that is never asked is: Who is being asked to take the risk, and who is getting the benefit? Risk assessments are often the risks that someone else has chosen for you to take. Risk assessments are often used to justify victimizing poor communities or communities of color. There are almost always cancer risk assessments -- although I know that this report takes into account some other kinds of health problems and I'm glad for that -- when other problems are of equal concern.

They don't take into account exposure of people who are already sensitive for other reasons, and the fact that in real life we're exposed to a complex mixture of chemicals not just a single compound. There was some testimony earlier about how we need to be looking at this. The standard needs to be applied one compound at a time not cumulatively, and I object strenuously to that. I think the cumulative impact must be considered.

I agree as well that the 10^{-6} number was not based on science. But if it were based on science in some real life situations, it would be much greater than normally calculated and much more stringent, not less the way this Commission is proposing to undertake. One-in-a-million is the minimum protective standard not one that we start with and then go to something that is less protective.

I don't think that we-- I also don't believe that science is this god that people seem to be describing it as during this morning's testimony. It's not indisputable. It's

not independent of politics, and in many instances, the kinds of conclusions that are being reached and the definitions that are being made about what is acceptable exposure and what is not are being made by those who have the money to both produce the products, create the situation, and determine how it will be cleaned up.

Those people who are left holding the bag and suffering the consequences -- the one in the one million, or the one in the one hundred thousand, or the one in the ten thousand -- they're the ones who are suffering the risks from this exposure. They are the ones whose voices need to be heard. Unfortunately, I don't think they are being heard loudly enough in this current debate.

Why do I say that? I'm looking at a couple of ways that this has played out in New Jersey over the years. Number one, my sense is -- and this is from actual experiences -- that the trend in flexible risk assessments is always in the wrong direction. It's always in the direction of saving industry money and never in the direction of being more protective of public health.

A battle that was conducted in the Legislature and, unfortunately, played out to establish dual standards for industry and residential is another example of how that works. In many of our communities in New Jersey there are situations where industries and residences abut one another. They're very close to one another. We're such a densely populated state that is, I think, foolhardy and creating needless risk to communities to have this double standard.

I understand that under Superfund it is possible, in some instances, for industrial sites to be labeled residential in order to make for a hole, a hole that needs to be cleaned up.
(timer beeps)

DR. GALLO: You have one minute.

MS. HOFFMAN: Okay.

I wanted to also speak to some extent about the chromium situation in Jersey City as another instance where this kind of political manipulation of data is being used to victimize people, but I will submit more of those comments because I don't have a whole lot of time.

But I think that with each distinction that is made -- whether that distinction be made for industrial versus residential, permanent versus temporary, this kind of inhalation route of exposure versus that kind of inhalation exposure -- you are providing greater opportunity for increased risk due to ignoring something that is important, some kind of scientific data about a chemical that would be ignored.

I believe it is more important -- I believe that it is crucial to protect the 10^{-6} standard, number one, and then, to expand it based on the kinds of ways that I suggested earlier.
(timer beeps) Right on time.

DR. GALLO: You can have one closing sentence if you want. I'm being generous.

MS. HOFFMAN: I think that my one closing sentence is that we should not forget that the end result of risk assessment is an opinion not a fact, that these opinions may be wrong, and we have to look at who the ones are who are making the opinions.

Thank you.

DR. GALLO: Thank you.

The next witness is Arnold Gray from Richard Stockton College.

You gave us a statement already, is that correct?

A R N O L D L. G R A Y: That's correct. Oh, I'll have a written statement for you later, before the 19th.

DR. GALLO: Okay, fine. Thank you. Go ahead.

MR. GRAY: I'd like to begin by just letting you know that as a college professor I would, indeed, give you a very good grade for your paper, unlike some of the previous testimony that we've heard. (laughter)

I'd like to say that while I agree that the level of 10^{-6} intended for breakfast cereal is probably not appropriate to the application of soils in an industrial establishment, I would also like to say that I'm somewhat disturbed by the degree to which the shift has been made. Going from one-in-a-million to one-in-one-hundred-thousand is rather a sharp, sharp shift, and I think I've stumbled on the problem.

I have my calculator with me, and I found that if I take a number like one-in-five-hundred-thousand and I push my log key, I will find that you can have another number for cleanup criteria such as $10^{-5.69897}$ -- which translates to one-in-five-hundred-thousand -- or even a little less stringent if you cared, $10^{-5.39794}$ gives us one-in-two-hundred-fifty-thousand. It just strikes me that we're rather stuck on round numbers in the exponent which are really quite unnecessary.

If there is going to be an error for B or C levels, I think it's really the duty of the Legislature, the Commission, and the DEP to err on the side of public health and safety. In

that respect I think that it is clear that it shouldn't be that a chemical is innocent until proven guilty, but rather it's up to the industries and the chemical societies to demonstrate that they pose no risk. It seems to me that the other way around is sort of backing into it from a very, very strange perspective.

Let's see. Another thing that I see not really covered in the rules is the mixing of contaminants. For example, if we are just below the level for BAP, dibenzo(AH)anthracene, pyrene, and a number of polycyclic organic hydrocarbons, what is it that that means in terms of how much we can leave behind? To think that these are not at least additive in their overall health effect seems to me to be quite against any logical understanding of any chemistry that I've had any experience with.

I think we're doing a disservice to industry, by the way, by creating an environment where we let the cleanup levels become too low. While it's to everybody's immediate advantage to come in with a good cost savings, in the long term I think you're opening up to long-term liabilities.

Joe Louis once said in the ring, "You can run, but you can't hide." Likewise for industry, you may escape regulation but you escape liability. Think about your long-term interests and I think it might urge you to become a little bit more on the conservative side rather than on the liberal side in establishing these cleanup criteria.

I very strongly commend the Commission for recommendation nine, talking about the central repository. It's possible today with GIS technology to do this. To take it a step further-- In fact, at Stockton on March 21 we're having a

conference on how to use GIS with other technologies to substantially cut the cost of remedial activities within the State. But with the ability of using GIS systems, we can now emphasize more risk management rather than immediate remediation.

For example, if we have a situation where we may have a serious contamination problem at a site, we can now choose -- provided there are no receptors -- to defer cleanup indefinitely until there is a cost-effective means of doing so, provided we use the technology properly.

It's just interesting to note that it's a double-edged sword; that while at the same time-- (timer beeps)

DR. GALLO: One minute.

MR. GRAY: --in the proposals you give, you at the same time help industry but hurt it. This needs to be recognized.

Understand that site-specific, once brought into the courtroom, can be translated into arbitrary and capricious. That you may be putting the DEP in a situation where it can't possibly defend the circumstances you're putting it into.

Going to a national standard doesn't mean that you've gone to a good scientific standard, and the impact of one underground storage tank in Montana might be quite different from that in New Jersey where there are many, many more storage tanks.

I would suggest tax incentives for pollution prevention. Let's try to make so companies have an incentive not to pollute in the first place. Why wait until it's a done deal?

Human health is not the only issue that should be considered. We also want lakes to swim in and streams to fish in. This is not addressed in terms of the things that were brought up in the Commission.

I would call for open public hearings with clearly articulated standards so the general public, rather than just a few environmental groups, a college professor here or there -- (timer beeps) -- and a few industrialists have the opportunity to comment on this. I'd like to hear more from the general public, and I don't believe that this format has necessarily been the best to that end.

Thank you.

DR. GALLO: You're welcome.

On that last issue: We have tried to be as inclusive as we can, with the three public hearings before -- when they only asked for one -- and other public comments.

Thank you very much.

The last listed speaker -- actually we have two -- is Eric DeGesero from the Fuel Merchants Association. I see Ms. Nogaki in the back, so we can go back to her. Did Tory Donnelly ever arrive? (negative response)

Eric, you're up.

E R I C D e G E S E R O: Thank you. Good morning. My name is Eric DeGesero. I'm an Associate Director of the Fuel Merchants Association of New Jersey. FMA represents approximately 300 independent petroleum marketers in this State.

FMA endorses the basic premise of the Environmental Risk Assessment and Risk Management Study Commission; namely,

that cleanups should be based on sound scientific standards which analyze actual risks to human health.

While the report is focused on cleanup standards for industrial sites -- as outlined in the Industrial Site Recovery Act -- FMA urges the Commission to take into account a specific circumstance when risk based cleanup criteria should be applied to residential properties; namely, incidents where there has been a discharge from an underground fuel oil tank.

FMA has been extremely proactive in its efforts to afford home owners the most protection possible in the rare instance that a fuel oil tank should have a discharge. I say rare, because a 1995 study by the Environ Corporation states that the frequency of releases from exempt USTs -- i.e. fuel oil USTs -- is less than 1 percent.

To help home owners with this, FMA has designed the Home Owners Environmental Loss Protection Program which affords home owners up to \$100,000 to clean up a discharge. However, for this program to be ultimately successful risk based cleanup standards for No. 2 fuel oil must be promulgated. Unfortunately, the current criteria is not based upon risk-based standards.

These standards must take into account the fact that the benzene present in the total petroleum hydrocarbon content of No. 2 fuel oil is in de minimis quantities. Aside from the reduced levels of benzene, No. 2 fuel oil is retained in soil to a degree four to five times that of gasoline.

FMA believes that recommendation No. 5, in which the Commission endorses the NJDEP policy of differential remediation criteria for residential and nonresidential sites should be

amended to the extent that it incorporates the thoughts reflected on page 20 and in recommendation No. 1.

Specifically, that scientific information be used to determine risk and that specific data, which incorporate the properties of No. 2 fuel oil be used in determining a cleanup standard and not a default assumption.

Deed restrictions have a far greater impact at a residential property than an industrial one. Therefore, risk-based cleanup standards are vitally important to home owners. I am certain that home owners can find a better use for \$20,000, such as sending their kids to college, than being involved in a seemingly and, in our belief, unnecessarily lengthy cleanup.

FMA will provide further comments to the Commission and looks forward to working with its members as this process advances.

Thank you.

DR. GALLO: Thank you very much.

Jane, are you here?

J A N E A . N O G A K I: (from audience) Yes, I'm here.

DR. GALLO: We had skipped over Ms. Nogaki from the New Jersey Environmental Federation.

I don't know if you were here to hear the rules, but it's four minutes, and we give you the hook. No, we actually give you one more minute after that.

MS. NOGAKI: Okay. Does my time start now?
(affirmative response)

My name is Jane Nogaki. I'm representing the New Jersey Environmental Federation, which is a statewide, nonprofit

environmental organization comprised of 94,000 members and an adjunct coalition of 74 member groups. The New Jersey Environmental Federation has historically been involved with issues of contaminated site cleanups, Superfund, and liability of responsible parties.

The New Jersey Environmental Federation wishes to thank the Commission for its efforts in attempting to answer the questions of risk assessment standards and methodology raised by ISRA, but we take issue with the recommendations and ask the Commission to reconsider and amend the report. If not, we ask that the Governor and the Legislature refute this report and maintain a one-in-a-million risk standard for contaminated site cleanups.

Specifically, the recommendations of the report exceed legislative intention and mandate and enter into areas of controversy that should be resolved through public debate due any change in public policy.

ISRA required the Commission to examine and assess the scientific basis for selecting the risk management standard of one-in-a-million and to examine risk assessment methodologies. The recommendations of the report, however, exceed the goal of the legislation.

ISRA specifically requests a review of risk assessment, while the recommendations develop an entire cleanup strategy based on a tiered approach and severing joint and several liability. These deliberations were outside of the scope of the ISRA mandate to the Commission.

No. two, the questions that have evolved over risk assessment methodology and standards remain unanswered.

Treatment, removal, technology, and liability are recommended by the Commission, but questions concerning public health risk assessment are not addressed.

Number three, weakening the one-in-a-million risk standard is unacceptable public policy and establishes a precedent for lowering other similar standards established for other media. While the Commission acknowledges that the one-in-a-million risk standard is utilized by both the FDA and the EPA for food safety and water safety, it does not make an adequate case for weakening of the standard by an order of magnitude -- one in 100,000 -- for contaminated soil.

Risk standards are not scientifically based, but public policy based and should be treated as such. The attempts by responsible parties to justify the weakening of standards by challenging the scientific justification of a one-in-a-million standard is driven by their desire to lower remediation costs. The debate over the scientific validity of a public policy risk standard has no grounds and is a contradiction in terms.

A one-in-a-million risk standard has been utilized historically to reduce risk to human health. As concern over the cumulative and current effects of toxic substances increases in scientific literature, it is imprudent to weaken a standard that will allow more risk of exposure.

Additionally, weakening the standard on the basis of population size is flawed because of concerns surrounding cumulative and concurrent interactions of substances in addition to a challenge that is necessary to the assumption that if only 500,000 people are exposed, the risk standard should be increased because of the smaller population.

All persons, regardless of population size, in the vicinity of the site should be protected from exposure by the most stringent standard possible. As a consequence, it is the New Jersey Environmental Federation's assertion that weakening the risk standard contravenes the public health protection mandate of the charge of ISRA.

Eliminating liability to theoretically enhance cleanups-- (timer beeps)

DR. GALLO: You have one minute.

MS. NOGAKI: --is not justifiable and will result in shifting the burden of funding cleanups to the public. Liability responsibility should be debated in the Legislature and exceeds the mandate of this Commission.

Differential standards for industrial and residential sites is not protective of public health. We have never agreed that there should be a two-tiered strategy for cleanup with different standards recommended.

Determination of a risk standard or recommendation for cleanup methodologies cannot adequately be made until an assessment has been made of ecosystem impact. The recommendation by the Commission fails to take into effect ecological risk, and we think those things need to be included if permanent and health based cleanup is to occur.

We do support the inclusion of noncancer endpoints to protect the most sensitive populations. We urge that the reference dose of 1 be utilized throughout any suggested cleanup paradigm. (timer beeps)

We commend the Commission for inclusion of a recommendation that risk standards apply to all cleanups, even those to be capped and paved. My time is up.

DR. GALLO: I'll give you one sentence.

MS. NOGAKI: Okay.

The New Jersey Environmental Federation does not support the creation of a Risk Assessment and Risk Management Science Advisory Board.

I'll conclude, I have my written comments here to hand in to you.

Thank you.

DR. GALLO: Thank you.

I have one comment on that. On the ecosystem question, there is, I believe, in the legislation a separate Commission that is to deal with that. That was not part of what we were asked--

MS. NOGAKI: I understand that it wasn't part of your charge, but at the same time, I think the human health and the ecological risk need to be done conjointly.

DR. GALLO: I think the Senator heard that.

MS. NOGAKI: Okay.

Thank you very much for your time and for waiting for me.

DR. GALLO: Okay.

Again, is Mr. Donnelly here or anyone from Groundwater and Environmental Services? (negative response)

If not, I want to thank all of the witnesses. I want to thank the Commission members, the members of staff, and the members of the Legislature who are here.

I think we got a lot of information to work with. Just to give you a time line, what we're going to try and do is wrap this up so we can have it ready for the next legislative session.

Thank you very much.

(HEARING CONCLUDED)

APPENDIX

**ENVIRONMENTAL RISK ASSESSMENT AND
RISK MANAGEMENT STUDY COMMISSION**

MICHAEL A. GALLO, PH.D.

PROFESSOR

UMDNJ-ROBERT WOOD JOHNSON MEDICAL SCHOOL

PISCATAWAY, NEW JERSEY

CHAIR

NOVEMBER, 1995

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ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT COMMISSION

Gail Ashley, Ph.D.

Stephen Boswell, Ph.D.

Christopher P. D'Alleinne, Ph.D.

(Co-Chair)

Michael A. Gallo, Ph.D. (Chair)

Sergio Germinario

Bernard D. Goldstein, MD

David S. Kosson, Ph.D.

Richard S. Magee, ScD.

Rita M. Turkall, Ph.D.

Robert K. Tucker, Ph.D. (Ex Officio)

Or

Leslie McGeorge, MSPH (Ex Officio)

Rutgers University

Boswell Engineering

McLaren/Hart

UMDNJ-Robert Wood Johnson

Medical School

IEC, Inc.

UMDNJ-Robert Wood Johnson

Medical School

Rutgers University

New Jersey Institute of

Technology

UMDNJ-School of Health

Related Professions

N.J. Dept. Of Environmental

Protection

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

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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

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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	Sites Under Review ³	To Be Assessed	Total Sites as of 12/31/94
10,800	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.

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

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.

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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 1×10^{-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:

$$\text{RISK} = \text{HAZARD} \times \text{EXPOSURE}$$

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, $RfD = NOAEL \text{ or } LOAEL / UF \times MF$. 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 probabilistic 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 1×10^{-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, notwithstanding 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 (K_d). Mobile chemicals (low K_d) must be treated differently from immobile chemicals (high K_d) 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 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.
- 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 1×10^{-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 1×10^{-4} to 1×10^{-5} .
- 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.

BIBLIOGRAPHY

All materials contained in this bibliography as well as other materials submitted to the Environmental Risk Assessment and Risk Management Study Commission are available through the Office of Legislative Services.

Office of Legislative Services
Ms. Judith L. Horowitz
Aides to the Commission
Environmental Risk Assessment and
Risk Management Study Commission
Legislative Office Building
CN-068
Trenton, New Jersey 08625-0068

References noted by (*) were selected from submitted public testimony

1. Allen, B.C., Crump, K.S. and Shipp, A.M. (1988).
Correlation between Carcinogenic Potency of Chemicals
in Animals and Humans, *Risk Analysis*, Volume 8, No. 4,
1988, pp.531-544.
2. American Cancer Society (1994). Cancer Facts and
Figures.
- 3.* American Industrial Health Council: On The Scientific
Basis For The Use Of 10^{-6} As A Management Standard For
Site Remediation.
4. American Industrial Health Council (AIHC) (1993).

Improving and Updating Risk Assessment: Precepts for
Legislative Proposals. pp. 1-8. Washington, D.C.

5. American Industrial Health Council Risk Characterization Guiding Principles (1993).
6. American Society for Testing and Materials (1994). ASTM Guide for Risk-Based Corrective Action. Committee E-50 on Environmental Assessment.
7. Ames, B.N., Magow, R., and Gold, L.S. (1987). Ranking Possible Carcinogenic Hazards. *Science* 236, 271-279.
- 8.* Amoco: Risk Assessment Methodologies.
9. Anderson, E.L. (1984). Risk Analysis in Environmental Health with Emphasis on Carcinogenesis Presentation, Harvard School of Public Health, Sept. 1984.
10. Anderson, E.L. (1989). Scientific Developments in Risk Assessment: Legal Implications, *Columbia Journal of Environmental Law*, 14, 411-425.
11. Ashby, J. et. al. (1990). A Scheme for Classifying Carcinogens, *Regulatory Toxicology and Pharmacology* 12, 270-295.
12. Auton, T.R. (1994): Calculation of Benchmark Doses from Teratology Data; *Regulatory Toxicology and Pharmacology* 19, 152-167.
13. Barnard, R.C. (1987). Scientific Risk Assessment and the Regulation of Human Cancer Risks: Background and New Directions. *American Industrial Hygiene Association Journal* 48, 798-803.
14. Barnard, Robert C., (1990) Some Regulatory Definitions of

Risk: Interaction of Scientific and Legal Principles,
Regulatory Toxicology and Pharmacology 11, 201-211.

15. Beck, B.D., Calabrese, E.J., and Anderson, P.D. (1989).
The Use of Toxicology in the Regulatory Process, pp. 1-
28 in *Principles and Methods of Toxicology*, Second
Edition ed. A.W. Harpes. Raven Press Ltd., N.Y.
16. Berkowitz, J.H. (1989). The Use of Risk Assessment in
Environmental Decision Making: A State Regulators
Perspective. Presented at the American Association for
the Advancement of Science. San Francisco, CA.
- 17.* Bizub, R.G., Risk Assessment & Management, Senate Bill S-
1070.
18. Brainard, Jennifer and Beck, Barbara D. (1992). A Review
of the Bioavailability of Petroleum Constituents,
Journal of Soil Contamination, 1(3): 273-307.
- 19.* Camp Dresser & McKee, Inc.: Scientific Basis for the
Selection of the One in One Million Cancer Risk:
Alternative Standards And Methodologies.
20. Comparative Environmental Risk Assessment, (1992) Ed. C.
Richard Cothorn, Lewis Publishers.
21. Crouch, E.A.C. (1992). Draft: Uncertainty in The Unit
Risk Estimate For Acrylonitrile (AN), Cambridge
Environmental Inc., March 11, 1992, pp. 1-41.
22. *Davis, R.A. (1994). Public Comments Provided to:
Environmental Risk Assessment and Risk Management Study
Commission, American Cyanamid Company, April 1994, pp.
1-7.
23. Doty, C.B., and Travis, C.C. (1990). Is EPA's National

Priorities List Correct? *Environmental Science
Technology* 24, 1778-1780.

- 24.* DuPont: Economic Impact Of One-In-One Million Risk Management Standard.
- 25.* Environmental Liability Management, Inc.: Exposure Factors Manual.
- 26. Gough, M., (1993). Chemical Risk Assessment Is Not Science, *Tappi Journal*, Volume 76, No. 7, pp.51-54.
- 27.* Grass Roots Environmental Organization: Risk Assessments: A Community Perspective.
- 28.* Hannig, John E. (1994). Comments to: Environmental Risk Assessment and Risk Management Study Commission, Exxon, April 11, 1994.
- 29.* Hanoach-Weisman, Counselors At Law: Comments On One-In-A-Million Standards Under ISRA.
- 30. Heller, Ehrman, White and McAuliffe. (11/9/93). Index to Risk Assessment Resource: File Letter of Timothy H. Butler, Seattle, Wash.
- 31. Hertzberg, R.C. and Dourson, M. L., (1993) U.S. EPA Cincinnati, OH: Using Categorical Regression Instead of a NOAEL to Characterize a Toxicologist's Judgment in Noncancer Risk Assessment.
- 32.* Hoffmann-LaRoche: On the Scientific Basis for the Selection of the Risk Level of an Additional Cancer Risk of One-In-One Million for the Remediation of Contaminated Sites.
- 33. Industrial Site Recovery Act (ISRA) New Jersey Senate

Bill 1070, (1993). (S1070) Item 47, 48. pp. 64-65.

- 34.* Jersey Central Power and Light: Environmental Risk Assessment and Risk Management Study Commission.
- 35. Kelly, K.E., and Cardon, N.C. (1991). The myth of 10^{-6} as a definition of acceptable risk. Presentation at the 84th Annual Meeting of the Air & Waste Management Association. Vancouver, B.C., Canada.
- 36. Korfiatis, GP, and Talimcioglu, N. (1994). IMPACT: A Model for Calculation of Soil Cleanup Levels, Remediation, Spring 1994, pp. 175-188.
- 37. Lloyd, K.J., Thompson, K.M., and Burmaster, D.E. (1992). Probabilistic Techniques For Backcalculating Soil Cleanup Targets, Superfund Risk Assessment in Soil Contamination Studies, American Society for Testing and Materials STP 1158.
- 38. Mantel, N., and Bryan, W.R., (1961): "Safety" Testing of Carcinogenic Agents, *Journal of the National Cancer Institute*, 27, No 2, 455-469.
- 39.* Maywood: Commission Report on Alternative Scientific Standards, Criteria and Methods for the Risk Assessment.
- 40. McKone, Thomas E. (1990). Dermal Uptake of Chemicals from a Soil Matrix, *Risk Analysis* 10 (3); 407-419.
- 41. McKone, T.E., and Bogen, K.T. (1991). Predicting the Uncertainties in Risk Assessment. *Environmental Science Technology* 25, 1674-1681.
- 42.* McLaren/Hart: Technical Comments On 1×10^{-6} As An Acceptable Risk Level For Carcinogens.

43. Minard, Richard (1991). Hard Choices: States Use Risk To Refine Environmental Priorities, NCCR Issue Paper No. 1, pp. 1-24.
- 44.* Mobil Oil Corporation: Environmental Risk Assessment And Risk Management Study.
45. Drinking Water and Health, (1977), (1980) - National Acad. Science, National Research Council, Volume I and Volume III.
46. National Research Council (1993). Issues in Risk Assessment. Committee on Risk Assessment Methodology Board on Environmental Studies and Toxicology. Commission on Life Sciences. National Academy Press, Washington, D.C.
47. National Research Council (NRC) (1994). Science And Judgment In Risk Assessment, Committee on Risk Assessment of Hazardous Air Pollutants, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, National Academy Press, Washington, D.C.
- 48.* New Jersey Business & Industry Association: The Myth of 10^{-6} as a Definition of Acceptable Risk (Or, "In Hot Pursuit of Superfund's Holy Grail").
49. New Jersey Department of Environmental Protection and Energy (1994). Review of Methodologies and Sample Approach for Soil Standards Development.
50. New Jersey Department of Environmental Protection and Energy (1994). Considerations in Selecting a Carcinogen Level and Controlling Exposure at Contaminated Sites.

- 51.* New Jersey Public Health Association Comments.
52. Nichols, A.L. and Zeckhauser, R.J. (1988). The Perils of Prudence: How Conservative Risk Assessments Distort Regulation. *Regulatory Toxicology and Pharmacology* 8, 61-75.
- 53.* Nogaki, J. (1994). Rachel's Hazardous Waste News #370, 371, 377. Resources for the Future, Winter 1994, No. 114.
- 54.* Other Written Testimony and Transcripts of Oral Testimony (1994). N.J. Department of Legislative Services.
55. Paustenbach, D.J., Shu, H.P., and Murray, F.J. (1986). A Critical Examination of Assumptions Used in Risk Assessments of Dioxin Contaminated Soil, *Regulatory Toxicology and Pharmacology* 6, 284-307 .
- 56.* Public Service Electric and Gas (April 11, 1994). Evaluation of the New Jersey Department of Environmental Protection and Energy's Proposed Minimum Remediation Soil Standards, Volumes I, IIA, 11B, and IIC.
57. Putzrath, R.M. and Ginevan, M.E. (1991). Meta Analysis: Methods for Combining Data to Improve Quantitative Risk Assessment, *Regulatory Toxicology and Pharmacology* 14, 178-188.
58. Resource Conservation and Recovery Act (RCRA) Facility Investigation (RFI) Guidance. Volume 1-4. (1989).
59. Rodericks, J.V., Brett, S.M., and Wrenn, G.C. (1987). Significant Risk Decisions in Federal Regulatory Agencies. *Regulatory Toxicology and Pharmacology* 7,

60. Rosenthal, A., Gray, George M., and Graham, J.D. (1992). Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals, *Ecology Law Quarterly*, 19 #2, 269-362.
61. Ruckelshaus, W.D. (1985). Risk, Science, and Democracy. *Issues in Science and Technology* 1, 19-38.
62. Schneider, Keith (1993). New View Calls Environmental Policy Misguided, *New York Times*, March 21, 1993.
63. School, R.A., et al. (1993). Recalculation of the Oral Arsenic Reference Dose and Cancer Slope Factor Using Revised Assumptions of Inorganic Arsenic Intake From Food, Abstract: PTI, Environmental Services, pp. 1-6.
- 64.* Shell Oil Company: Risk-Based Corrective Action. ASTM Guide for Risk-Based Corrective Action at Petroleum Sites.
65. Silbergeld, E. (1987). Responses to Editorial, Ames. et al; Wilson and Crouch, *ibid. Science* 237, 1400.
66. Skowronski, Gloria A., et al. (1994). Effects of Gender, Route of Administration, and Soil on the Bioavailability of Coal Tar Components, In: *Remediation of Hazardous Waste Contaminated Soils*, Eds: Wise/Trantolo, Marcel Dekker, Inc., NY 1994, pp 299-315.
67. Stevens, W.K. (1991). What Really Threatens the Environment?: Officials Seek to Start a Debate over the Nations Goals. *New York Times* (Jan. 29): B7(N).

68. Travis, C.C., and Hattemer-Frey, H.A. (1988). Determining An Acceptable Level of Risk. *Environmental Science Technology* 22, 873-876.
69. Travis, C.C., and Hester, S.T. (1991). Global Chemical Pollution. *Environmental Science Technology* 25, 815-819.
70. Travis, C.C., Richter, S.A., Crouch, E.A., Wilson, R., and Klema, E.D. (1987). Cancer Risk Management: A Review of 132 Federal Regulatory Decisions. *Environmental Science Technology*. 21, 416-420.
- 71.* Union County Alliance: On Risk-Based Site Remediation Cleanup Standards and Methodologies for Use under ISRA.
72. US Environmental Protection Agency (1985). Part II Office of Science and Technology Policy, Chemical Carcinogens: a Review of the Science and its Associated Principles, *Federal Register*, February.
73. US Environmental Protection Agency (1986). Guidelines for Carcinogen Risk Assessment: Final Guidelines for Carcinogen Risk Assessment. *Federal Register* 51, 33992-34003.
74. US Environmental Protection Agency (1987). The Risk Assessment Guidelines of 1986, EPA/600/8-87/045.
75. US Environmental Protection Agency (1989) Biological Data for Pharmacokinetic Modeling and Risk Assessment, EPA 600/3-90/019.
76. US Environmental Protection Agency (1989). Risk Assessment Guidance for Superfund. Volume 1: Human Health Evaluation Manual (Part A). *Interim Final*,

77. US Environmental Protection Agency Approaches to Risk Assessment for Multiple Chemical Exposures.
78. US Environmental Protection Agency (1990). The Report of the Ecology and Welfare Subcommittee. EPA SAB-EC-021 A.
79. US Environmental Protection Agency (1990). The Report of the Human Health Subcommittee. EPA SAB-EL-021 B.
80. US Environmental Protection Agency (1990). The Report of the Strategic Options Subcommittee. EPA SAB-EC-021 C.
81. US Environmental Protection Agency (1990). National Oil and Hazardous Substances Pollution Contingency Plan: Final Rule. Federal Register. 55, 8666-8853.
82. US Environmental Protection Agency (1990). Science Advisory Board. Reducing Risk: Setting Priorities and Strategies for Environmental Protection. EPA SAB-EC-90-021.
83. US Environmental Protection Agency Risk Ranking Project (1991). Region 2, Ecological Ranking And Problem Analysis. EPA 212-1003.
84. US Environmental Protection Agency (1992). Office of the Administrator. Memorandum: Guidance on Risk Characterization for Risk Managers and Risk Assessors. pp. 1-34.
85. US Environmental Protection Agency (1992). A Monte Carlo Approach to Simulating Residential Occupancy Periods and its Application to the General U.S. Population.

86. US Environmental Protection Agency (1993). Research Health Risks, U.S. Congress Office of Technology Assessment, pp. 1-228.
87. US Environmental Protection Agency (1993). Cancer Risk Assessment Guidelines. Chapter. 7, Human Health Benefits.
88. US Environmental Protection Agency (1993). Health Effects Assessment Summary Tables FY-1993 Annual, User's Guide: Chemical Toxicity, pp. 21-33.
89. Selected Publications On Risk Assessment. (1994) U.S. EPA.
90. US Food and Drug Administration (1973). Compounds Used in Food-Producing Animals: Proposed Rule. Federal Register 38, 19226-19230.
91. US Food and Drug Administration (1993), Food additives; Threshold of Regulation for Substances Used in Food-Contact Articles, Federal Register, Volume 58, No. 195, October, 1993, pp. 52719-52729.
92. United States House of Representatives (1993). Environmental Risk Reduction Act of 1993, H.R. 3111, pp. 1-43 and H.R. 2910, pp. 1-9.
93. Wester, Ronald C., et al. (1993). Percutaneous Absorption of Pentachlorophenol from Soil, *Fundamental and Applied Toxicology* 20, 68-71.
94. Wester, Ronald C., et al. (1993). In Vivo and In Vitro Percutaneous Absorption and Skin Decontamination of Arsenic from Water and Soil, *Fundamental and Applied Toxicology* 20, 336-340.

- 95.* Whelan, Elizabeth (1993). *Toxic Terror, The Truth Behind the Cancer Scares*, Prometheus Books, Buffalo, New York.
96. Whipple, C. (1984) *Nonpessimistic Risk Assessment and De Minimis Risk as Risk Management Tools in the Risk Assessment of Environmental Hazards*. Ed. D. Paustenbach. Chapter 34, pp 1105-1120. Wiley Interscience, New York.
97. Whysner, J., and Williams, G.M. (1992). *International Cancer Risk Assessment: The Impact of Biologic Mechanisms*. *Regulatory Toxicology and Pharmacology* 15, 41-50.
98. Wilson, J.D. (1991). *A Usually Unrecognized Source of Bias in Cancer Risk Estimations*, *Risk Analysis*, 11, 11-12.
99. Young, F.E. (1987). *Risk Assessment: The Convergence of Science and Law*. *Regulatory Toxicology and Pharmacology* 7, 179-184.

**ENVIRONMENTAL
RISK ASSESSMENT AND
RISK MANAGEMENT
STUDY COMMISSION
DRAFT REPORT**

**PUBLIC MEETING
December 5, 1995**



The Objectives of This Meeting Are To:

- **Review the Commission's Draft Recommendation**
- **Provide an Opportunity for Public Comment**
- **Obtain Additional Input for Consideration in the Final Report**



**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 Charges to the Commission, as Stated in the Act, are to Examine and Assess:

- **The Scientific Basis for Selecting the Risk Management Standard of One in a Million**
- **Methodologies of Risk Assessment and Their Efficacy and Applicability for the Purpose of Establishing Remediation Standards.**



COMMISSION MEMBERS

G. Ashley, Ph.D.
S. Boswell, Ph.D., PE
C. D'Alleinne, Ph.D.*
M. Gallo, Ph.D.*
S. Germinario
B. Goldstein, M.D.
D. Kosson, Ph.D.
R. Magee, ScD., P.E.
R. Turkall, Ph.D.
R. Tucker, Ph.D.+
L. McGeorge, MSPH+

Rutgers University
Boswell Engineering
McLaren/Hart Env. Eng.
UMDNJ/RWJ Med School
IEC, Inc.
UMDNJ/RWJ Med School
Rutgers University
NJIT
UMDNJ/School Health Prof's.
NJDEP
NJDEP

* Co-Chairs

+ *Ex officio* (one only)



RECOMMENDED RISK MANAGEMENT STANDARDS

USEPA Carcinogen Classification	NJDEP Default Stds.	Residual Risk After Permanent Remedy	Residual Risk After Exposure Control Remedy	Maximum Risk with Failure of Exposure Control Remedy	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	1	1	1	3	1



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After Public Comment and Commission Deliberations, It was Concluded There Were Several Impediments to Remediation:

- **Inability to Achieve Permanence and Sever Liability**
- **Application of Redundant, Conservative, Default Assumptions**
- **Lack of Performance-Based Regulatory Objectives**



RECOMMENDATIONS OF THE COMMISSION

- **Use the Best Available Scientific Information and Judgement**
- **Use Site-Specific Data**
- **Adopt Principles Listed in Table 1 of the Draft Report**
 - ❖ **These are Incentives for Permanent Remediation**



- **Establish Surcharge of Approximately 1-5% on All Remediations, Both Permanent and Exposure Control.**
- **Develop and Validate Probabilistic Approaches to Risk Assessment**
- **Establishment of a Central Repository of All Known Contaminated Sites**
- ❖ **Declarations of Environmental Restrictions**



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► **Three-Tiered Approach:**

- ❖ **Tier 1 - Apply Default Standard of 10^{-5}**
- ❖ **Tier 2 - Use Site-Specific Standard of 10^{-5} - 10^{-4}**
- ❖ **Tier 3 - Exposure Control Remedy of 10^{-6}**



- 108X
- **Establishment of an External Risk Assessment and Risk Management Scientific Advisory Board**





State of New Jersey

Christine Todd Whitman
Governor

Department of Environmental Protection

Robert C. Shinn, Jr.
Commissioner

December 19, 1995

Dr. Michael A. Gallo, Ph.D.
Chairman, Environmental Risk Assessment
Risk Management Study Commission
UMDNJ-Robert Wood Johnson Medical Center
Piscataway, NJ

Dear Dr. Gallo:

The Site Remediation Program (SRP) and Division of Science and Research (DSR) have reviewed the draft report and recommendations of the Environmental Risk Assessment and Risk Management Study Commission (the Commission). I would like to take this opportunity to relay to the Commission the comments and thoughts of SRP and DSR on the draft report.

I look forward to reviewing the final draft of the Commission's report. In the meantime, if you have any questions on our comments, please feel free to contact me at (609) 292-1250.

Sincerely,

Rick Gimello
Assistant Commissioner

c: R. Shinn
M. Smith
L. Nagy
L. McGeorge
S. Boyle
A. Farro
R. Fabricant
J. Horowitz

Post-It® Fax Note	7671	Date	12/19/95	# of pages	12
To	Judy Horowitz	From	Doug Barry		
Co./Dept.	Env. Section	Co.	DEP		
Phone #	292-7676	Phone #	292-1250		
Fax #	292-0561	Fax #			

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**Comments to the Draft Report
of the Environmental Risk Assessment and Risk Management Study Commission
December 19, 1995**

1. The Commission's report contains minimal specific guidance on many important questions of the application of risk assessment methodology to the development of cleanup standards. Based on the charge of the Commission, "...To examine and assess methodologies of risk assessment and their efficacy and applicability for the purpose of establishing remediation standards," we had hoped that the Commission would have provided more guidance on appropriate exposure pathways, exposure, and fate-and-transport models, toxicity and exposure assumptions, etc. In April of 1994, the Department submitted a White Paper to the Commission entitled a "Review of Methodologies and a Sample Approach for Soil Standards Development." This document contained a review of the various approaches currently employed or under consideration for determining soil cleanup standards nationwide and a detailed approach, which, we believed provided a reasonable framework for New Jersey. Where the Commission has not made a specific recommendation, does the Commission support the general approach submitted by DEP in the above referenced paper?

The Department had also submitted to the Commission a paper entitled "Considerations in Selecting a Carcinogen Level and Controlling Exposure at Contaminated Sites." This document described the relationship between the risk management criteria currently used among the various DEP programs. What is the relationship (if any) between the proposed risk management matrix and the current risk management criteria used by the various DEP programs?

2. The Commission recommends, among other things: flexible standards; standards based upon use; standards which consider non-cancer end-points; permanent and non-permanent remedies; use of "deed restrictions"; site specific standards for soil and groundwater; and selection of a natural attenuation/groundwater modeling remedy where appropriate. All of this is currently available under the statutory scheme of P.L.1993, c.139. It is not clear how, or if the Commission envisioned something different than is currently done, or if the Commission is supporting the programmatic tools which are already available. This should be clarified.

The report also omits an option currently available under P.L.1993, c.139; specifically, the development of an alternate cleanup standard based upon a site specific risk assessment using USEPA's CERCLA protocols. Did the Commission unintentionally omit this option or is the Commission recommending its deletion?

Overall, it would be optimal if the Commission would reconcile its risk assessment recommendations with the various options and guidance provided by P.L.1993, c.139.

3. The Commission's recommendation to change the risk management goal to $10(-5)$ has potential repercussions for the DEP groundwater and surface water quality standards. While groundwater and surface water standards are arguably outside of the scope of the Commission's charge, a change in the DEP default value for soil would logically imply a need to reexamine these other media standards. For example, the NJ Safe Drinking Water Act incorporates a $10(-6)$ cancer risk goal as a mandatory starting point for MCL development. If the practical quantitation limit (PQL) is less than the criterion, and if the substance is treatable, then the MCL is derived based upon $10(-6)$. The use of this risk level goal for carcinogens in public water supplies has proven to be one which is implementable in this state. The Ground Water Quality Standards incorporate this policy because the groundwater quality standards primarily protect drinking water. In addition to the $10(-6)$ risk level for individual contaminants, the Ground Water Quality standards consider the potential for additivity by allowing for additional actions if total risk exceeds $10(-4)$. Most carcinogens have criteria below the PQL, and the PQL levels present cancer risks greater than $10(-6)$ and in some cases greater than $10(-5)$. How does this information factor into the Commission's recommendations?
4. The report should acknowledge that ecological receptors must be considered. Nowhere in the report are standards protective of ecological receptors discussed. Although ecological standards are clearly the charge of a separate task force, the report should be clarified to recognize that the DEP must consider ecological impacts on a case-by-case basis as currently provided for in P.L.1993,c.139. This consideration may be particularly important when issues such as severance of liability are discussed.

In addition, the report focuses on direct contact issues with little attention given to the fact that many contaminants have solubilities which result in cleanup levels lower than those concerns related to direct contact with contaminants (i.e., protection of ground water and surface water). The report should clarify that there is the potential for cleanup levels lower than the direct contact concerns.

5. In finalizing its recommendations, the commission should consider USEPA's Superfund risk policy. If the risk policy ultimately recommended by the Commission is less stringent than the USEPA policy, the potential for future federal involvement at a site will remain. This would be inconsistent with the Commission's efforts to provide finality.
6. DEP and USEPA Region II have an agreement that under the current SRP program, USEPA will accept a DEP approved cleanup as satisfying the requirements of RCRA corrective action. Because the proposed risk policy in the Commission's report ($10(-5)$) is less stringent than the federal RCRA corrective action requirements ($10(-6)$), USEPA may not continue to accept DEP approved cleanups as acceptable under the RCRA Corrective Action Program. This is inconsistent with the Commission's efforts to provide finality.

7. The SRP and DSR support the Commission's recommendations to use scientifically defensible tools such as probabilistic modeling, physiologically based pharmacokinetic modeling, mechanistic toxicology, etc. However, development of these approaches will take time, money and research. What are the Commission's recommendations regarding how to proceed with risk assessment in the interim as these approaches are being developed, and are these specific recommendations as to the development of a resource base for necessary state expertise to incorporate these new tools in a meaningful manner into future remediation standards?

8. While stating (correctly) that there is no scientific basis for a 10(-6) risk level, or any other numeric level, the Commission, nonetheless, recommends a basic risk level of 10(-5). This may or may not be appropriate, but why? The Report assumes that this change coupled with a more stringent risk level for non-permanent remediations (10(-6)) should encourage more permanent remedies, but offers no data to show that the decreased cost associated with the less stringent risk level will offset the cheaper cost of non-permanent remedies. If this cost difference is not offset, the effect of this option may be to drive more remedies toward non-permanent solutions.

The report proposes to change the current cost-based preference for permanent remedies from 50% to 10%. Does the Commission have data to show that reducing the cost-based preference will result in any permanent remedies? A 10% difference is so negligible as to be meaningless. Reasonable estimates for remedial costs will certainly vary by at least 10%. How will the DEP ever be able to show that a 10% difference does not exist?

9. The Commission recommends adoption of a matrix which incorporates risk management levels of 10(-4), 10(-5) or 10(-6) depending on carcinogenic class and remedy type. The matrix also incorporates a hazard quotient not to exceed 1 or 3 depending on the type of remedy selected.

As the Report points out, selection of a risk management goal is public policy. But, is it appropriate public policy to allow residents and workers to be protected to different levels depending on where they live, work or play? Should all persons be protected to the same level?

Further, if a non-permanent remedy carries a lower risk to human health as proposed in the matrix, why should the DEP prefer, as a matter of public policy, permanent remedies?

10. Please clarify in the matrix which columns represent Tiers 1, 2 and 3, if indeed any relationship does exist. Also clarify how the table will be applied to develop differential cleanup criteria for residential and non-residential sites. Also clarify whether column IV will be used to develop standards for potential impact to off-site receptors where exposure controls are used (see page 39). Finally, please clarify

whether column V will be used to develop standards for soils remaining on site where exposure controls are used (see page 35, third paragraph).

11. Our reading of the Report is that commission is recommending a "risk management" factor of 10(-5) for all carcinogens under Tier 1, but a "risk management" factor of 10(-5) for Class A and B carcinogens and 10(-4) for Class C carcinogens under Tier 2. What is the rationale (scientific or otherwise) for changing the "risk management" factor for class C carcinogens when moving from the "generic" standards to site-specific standards?
12. The Commission recommends for Class A and B carcinogens that contaminant levels no more than 100 times the applicable health based soil cleanup criterion be left behind (assuming that the 10(-5) listing for class C carcinogens in column II of Table 1 is a typo and should be 10(-4)), see comment 11 above). This however, seems illogical. Why would we want to leave behind levels of more carcinogenic contaminants (A and B) than less carcinogenic contaminants (C)? It would seem more logical if reversed.
13. Under the Matrix, a Class C carcinogen must be remediated to a 10(-4) risk level prior to implementing a permanent remedy. However, the risk level for Class C carcinogens for permanent remedies is also 10(-4). Therefore, the Report infers that a permanent remedy must be employed for all Class C contaminants.
14. The Report states that "Tier 3 builds upon Tier 2 and provides alternative methods to derive site specific cleanup criteria". This implies that a different set of models/equations are used to derive cleanup standards for Tier 3 (engineering control) cleanups. Is the cleanup standard under Tier 3 the Tier 1 standard adjusted by new "risk management factor" or a site-specific cleanup standard determined by Tier 2 and then adjusted by the new risk management factor? Or, could either approach be used?

The Commission states in the Report (pg. 38 - 39 and 43 - 44) that Tier 3 - the most site specific approach - applies only to non-permanent remediations (Columns IV and V of Table 1) while Tiers 1 and 2 apply to permanent remediations (Columns II and III of Table 1). Is this intended?

15. The Commission recommends that non-permanent remedies be 10X more protective than permanent remedies. Again, we are not sure that it is appropriate to protect residents to different degrees, nor have we seen any data to show that this approach will actually encourage permanent remedies. But, there are also implementation issues which arise. For example, suppose there are two adjacent sites with similar types and distribution of contamination. Assume that a site owner wants to do a permanent remedy, but the other wants to do a non-permanent remedy. Using the risk commission strategy, one site would have EXPOSED soil at 10(-5) with no declaration of environmental restriction, while the other site would be protective to 10(-6) WITH a restriction. From a public policy perspective, is this logical?

16. The Commission supports a risk management standard of 10^{-5} for Class A and B carcinogens for calculation of soil remediation standards where permanent remedies will be used; and further recommends that cumulative risk for using specific pathway should not exceed 10^{-5} . The Commission states that previous discussions have demonstrated that USEPA endorses and utilizes a flexible risk management structure. The Commission states that this flexible approach is supported by the NCP risk management guidance values of 10^{-4} to 10^{-6} .

The Commission recommends using **cumulative** risk for specific pathways not to exceed 10^{-5} . This recommendation is only included in the "recommendations" section of the report and is not discussed in the body of the report. This concept has major implications and will result in more stringent cleanups IF more than one contaminant is present at a site. Cumulative exposure pathway risk has a completely different meaning than exposure pathway risk for a single contaminant. For example, assume there are 3 carcinogens in soil, each contaminant posing a risk of 1×10^{-5} . While on a single contaminant basis, the risk level is 1×10^{-5} , the cumulative risk is 3×10^{-5} (assuming the Commission is recommending that the DEP use a simple additive approach). This would be an unacceptable risk and the total risk would need to be reduced three-fold. The major effect of requiring cumulative risk is that site specific risk assessments would have to be performed at all sites to determine cumulative exposure risks. This may be appropriate for the limited universe of NPL sites (as is currently done), but will be costly and time consuming for the 6,000 active non-NPL cleanups. It should also be noted that while the above example uses a simple additive approach for determining cumulative risk, there is currently no scientific basis for determining cumulative risk.

Also, it is not clear whether the "cumulative risk" as used by the Commission applies only to cumulative risk of different contaminants from the same exposure pathway or also to cumulative pathway risk for the same chemical. The combination of both approaches may significantly increase the calculated risk.

The Commission's recommendation to consider cumulative risk is specific to carcinogens. Does the Commission also recommend consideration of cumulative impact for non-carcinogens. If so, another implication of this approach is that the Commission provides no guidance on how to regulate non-carcinogens for cumulative hazard, especially if exposure to two contaminants result in the same adverse impact. Because the Commission recommends changing the risk goal for carcinogens by a factor of 10, but also recommends keeping the current approach for non-carcinogens under most scenarios (hazard quotient not to exceed 1) more cleanups may be driven by non-carcinogenic endpoints.

It should also be noted that **current law prohibits DEP from considering cumulative risk** in the development of cleanup standards. This provision was placed in the law because it was felt at the time that there was not enough scientific information on the

cumulative and synergistic impacts of multiple contaminants at a site to perform an accurate/realistic analysis of cumulative risk. This concern remains.

Finally, the report confuses the concept of USEPA's acceptable risk range of 10(-4) to 10(-6) for cumulative site risk using baseline conditions to determine the need to remediate a site under the NCP with the concept of an acceptable risk level to develop individual remediation goals. USEPA's Superfund program currently uses 10(-6) as a starting point in developing remediation goals and departs from that level based on technical feasibility and other considerations. Therefore, the comparison used to justify the matrix is invalid.

17. 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 is an intriguing idea. How much of a surcharge, who pays the surcharge, and how that surcharge ties with the existing Remediation Funding Source surcharge are not discussed in the report.

The Commission recommends that liability be severed if a permanent remedy (defined by implication in the report as treating/removing contamination to the residential or non-residential standard) and that a surcharge be paid to the state. The surcharge is to be dedicated for costs of additional remediation if cleanup standards change by an order of magnitude or more AND for contamination not previously discovered. How would this last provision apply under scenarios where a contaminant previously found at acceptable levels were found to have converted over time to unacceptable levels?

In one part of the report, the Commission recommends that those who permanently remediate a site pay the surcharge. If so, isn't this a penalty for those who permanently remediate? Does the Commission recommend abolishing all contribution rights against the original discharger? Why should this surcharge be used to cleanup contamination not discovered? Is this an incentive to "hide" problems? What if property was treated to the industrial standard, and the surcharge paid, but a prospective purchaser wants the property for residential use? Is the DEP compelled to go in and use the fund to remediate to the residential standard at the whim of the timing of the real estate transaction? Can the DEP use the fund to cap to the standard, or must DEP permanently remediate the site? How does this proposal fit within the current innocent purchaser defense in S1070?

On what is the surcharge imposed? Who pays the surcharge? Those who permanently remediate or all remediations (the report seems to say different things in different places)? Answers to these questions will dramatically influence the amount of monies in the fund. For example, using ISRA only as an example, in 1994, \$113 million dollars was the total for cleanups completed that year. Using 1% and 5% the surcharge would generate \$1.3 M or \$6.3M respectively. However, if the surcharge were an

annual surcharge based upon the total costs of cleanup (remediation funding source) the monies would be much greater. But, this would be a duplication of the surcharge already imposed in S1070.

One sentence in the report mentions a surcharge "reimbursement". No where else in the report is this reimbursement mentioned or discussed. What is this reimbursement?

18. 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.

The Department currently works with the scientific and academic community within and out of the state therefore, it is not clear that this body is needed. However if such a board is created we strongly recommend that, criteria for membership should be very carefully considered and developed -- perhaps limited solely to the academic community. Clearly demonstrated professional experience in risk assessment should be a primary criteria for membership. We would also recommend that NJDEP be a voting member.

One of the recommended functions of this board is site reutilization. Why would a risk assessment board advise DEP on site reutilization? The Site Remediation Program already uses its Site Remediation Advisory Group (comprised of representatives of the environmental community and business and consulting industries) to seek advice and recommendations on this and other similar subjects. If the recommendation for this Board remains, this function should be deleted.

19. The Commission strongly suggests that remedial risk management standards be established based on the data which best characterizes these sites.

While noting elsewhere in the report that the choice of a risk management standard (e.g., one-in-one-million risk level) is **policy-based**, the Commission nonetheless recommends that such standards be based on data which best characterizes the sites (i.e., objective judgement). This is not only confusing, but opens the door to the incorrect conclusion that whatever risk level the Commission recommends in place of the current policy-based risk management level of one-in-a-million risk is, in contrast, scientific and objective. In fact all such "acceptable" risk levels are, of necessity, subjective and policy based and therefore, no risk management level is more inherently valid than any other. Ultimately, the choice of a risk management standard is one of policy and not of science. In contrast, the determination of the level of chemical in the soil which corresponds to the risk management standard is based on scientific modeling and calculation and it is **these** determinations which should be based on "the data which best characterize the sites." This issue should be clarified in the report.

20. The Commission recommends that the size of the population at risk from a given site be included in the determination of the risk-based management standard.

This concept represents a major change in the way site-related risk is viewed. While the idea may have some merit, it presents major policy difficulties which the Commission has not addressed. Unlike the physical characteristics of a site (e.g., soil type, depth to groundwater), the size of the population at, or near a site is not fixed. How the size of the population will be projected into the indefinite future, and what to do if the size of the population increases after a cleanup is completed with a risk level appropriate for a smaller population presents major areas for subjective policy dispute.

The report included "total population impacted" as a factor that must be considered when establishing site remediation standards. This is a new concept that to date, neither the EPA or DEP have ever used. The report recommends what appears to be a "normalization" of cancer to 1 event every 70 years based upon population. While this could theoretically be done, it will have the effect of producing a variable risk management level based on population. For example, normalizing a large population (of 10,000,000 people) to 1 excess cancer risk results in an effective risk management level of 1×10^{-7} for each individual while normalizing a smaller exposed population (of 100,000 people) results in an effective risk management level of 1×10^{-5} for each individual.

Furthermore, for non-carcinogens the risk, as defined in the RfD approach, is not expressed in terms of the population at risk (e.g., one cancer per million exposed population). Therefore, the approach of adjusting the risk level to the population at risk cannot be employed for non-carcinogens.

However, the commission recommends using this normalization only in those situations where the total number of excess cancers exceeds the nominal risk management level. In the example above, the large exposed population would be normalized to 1 excess cancer risk resulting in an effective risk management level of 1×10^{-7} . However, the smaller exposed population would not be normalized, therefore retaining the nominal risk management level of 1×10^{-6} . Would this approach result in more stringent standards in densely populated areas, such as our cities?

As such, the information presented in Table 1 of the report is confusing. The table should clearly note that the appropriate remediation standards should be the lower of the standard derived in columns derived in columns II, II, or IV (whichever is being used) versus the standard derived in column VI.

How will one compute/calculate/determine the population exposure factor? As EPA doesn't follow this approach, the DEP would have to develop one. Did the commission envision we use census data based on an area surrounding a given site? Since residential standards are based on exposures to children, will only population data for

children be considered? What happens if there are population changes? Will we change standards? Would we then go back and make facilities do additional cleanups.

21. In its recommendation section, the Commission lists "multiple redundant default assumptions" in the derivation of site remediation standards among the impediments to remediation.

Without clearly stating so, this statement implies that the DEP's current cleanup standards are, in fact, multiply redundant and therefore unnecessarily stringent. However, this assertion is inserted among the recommendations without any previous discussion of such practices by the department and without providing evidence of the use of such multiple redundant assumptions. In fact, elsewhere in the report, the Commission endorses standards based on EPA toxicity factors and exposure assumptions apparently unaware that the DEP's standards are, in fact, based largely on such EPA guidance.

22. The report consistently uses the term "deed restriction".

The DEP is currently precluded by P.L.1993, c.139 from using DERs. If the Commission is recommending that the current practice be changed, the report should so note.

23. Several sections of the report state that "deed restrictions" (declarations of environmental restrictions) should not be required where a remedy treats/removes contamination to the industrial standard. In other sections, the commission states that a "deed restriction" (declaration of environmental restriction) should be required when anything but treating/removing to the residential standard is used.

The report should be clarified so that a DER is required whenever anything other than treating/removing to the residential standard is used.

24. The Commission recommends that under certain circumstances, i.e. if a contaminant can be shown to degrade in 30 years, monitoring should be allowed in lieu of active remediation.

DEP currently allows Classification Exception Areas (CEAs) pursuant to the GWQS. However, the 30 year criteria is not considered, and is likely, in our opinion far too long. Contaminants are mobile. How far could a contaminant spread in 30 years. Would well restrictions need to be placed for the zone of probable impact for 30 years and what action would then be permitted if contaminants were detected in the monitoring wells? How would this impact land use/water use/property values? What if there are currently no receptors, but, a residential development is planned and there

are no public water supplies? Why is this recommendation needed? What specifically does not work with the current CEA process?

25. On page 12, paragraph 1, the report notes that most of the remaining sites are relegated to the NJ ISRA law. This statement is incorrect. ISRA is only one program. The sites may also be addressed under the Voluntary Cleanup Program, Spill Act Enforcement program, or the Underground Storage Tank Program.
26. The report notes that "few" ECRA sites have been remediated. Yet the table in the report shows over 61% of the known contaminated sites have been remediated. According to Table 2B, 7200 ISRA sites have met criteria for NFAs. Table 2C indicates that for 1984 - 1995, 85% of all ISRA cases have been closed out. These numbers do not justify the pervasive theme in the report that something major is "broken" in the Site Remediation Program which must be fixed to encourage additional cleanups. This is not to say that there is no room for improvement in the program. However, these unsupported statements and this wording only serves to negatively impact public perception of the Site Remediation Program.

There were also some errors in the UST information provided to the Commission. The following are corrections.

On page 15, the title of the Table should be changed to read "Status of UST cases by Fiscal Year". This change is needed to reflect the fact that other units other than Bureau of UST review UST work. In keeping with this change, the table should be modified as follows:

	Cases Received	Closed Cases	Ending Balance
92	1663	1749	200
93	2880	1717	1363
94	2843	1531	2675
95	2855	2746	2784

Finally, in Table 2B on page 14, the number of UST NFAs-PA/SI only should be changed from 2,800 to 3,000. The number of UST NFAs-Cleanup required should be changed from 2,400 to 3,900.

27. On page 23, paragraph 3, it should be noted that for the inhalation pathway, reference concentrations (RfCs) are developed.
28. On page 38, paragraph 2, the sentence mentioning surcharge reimbursement implies that a surcharge is imposed on cleanups to the non-residential remediation standards. As

this report recommends that surcharges be imposed on permanent remediation, one could infer that cleanups conducted according to non-residential standards are permanent. This is not consistent with the Department's current definition of "permanance" and should be clarified.

29. On page 36, does the Commission have any data to show that the existing liability scheme is a "substantial impediment" to the remediation of contaminated sites? If the Commission does not have any reference or source for this statement it is recommended that it be deleted.

COMMENTS ON
ENVIRONMENTAL RISK ASSESSMENT AND
RISK MANAGEMENT STUDY COMMISSION
FINAL DRAFT

NOVEMBER, 1995

ANDREW DWIGHT BEDSOLE
E. I. DUPONT DE NEMOURS & CO., INC.

PREPARED BY: THE CHEMICAL INDUSTRY COUNCIL OF
NEW JERSEY, RISK ASSESSMENT TASK FORCE

TESTIMONY PROVIDED TO THE
ENVIRONMENTAL RISK ASSESSMENT AND
RISK MANAGEMENT STUDY COMMISSION
ON ITS PROPOSED REPORT AND RECOMMENDATIONS
CONCERNING RISK ASSESSMENT METHODOLOGIES
AND THEIR EFFICIENCY AND APPLICABILITY
FOR ESTABLISHING REMEDIATION STANDARDS AND THE
SCIENTIFIC BASIS FOR THE SELECTION OF A
RISK MANAGEMENT STANDARD AS REQUIRED BY
SECTION 47 OF P.L. 1993, C.139

DECEMBER 5, 1995

ANDREW DWIGHT BEDSOLE
E. I. DUPONT DE NEMOURS & CO. INC.

Mr. Chairman:

My name is Dwight Bedsole. I am Business Director of Remediation for DuPont's facilities in New Jersey. I am pleased to have the opportunity to come before this committee to provide testimony on behalf of the Chemical Industry Council of New Jersey on these extremely important issues.

In the interest of the Commission's time constraints, my testimony will provide a distilled version of a more detailed summary of comments submitted with this testimony.

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The CIC/NJ and its member companies are committed to protection of human health and the environment and believe that many of the recommendations by the Commission are in the best interest of the State's citizens and businesses. The CIC/NJ believes that the currently used "one-in-one million" risk management standard along with the overly conservative risk assumptions and methodologies used by the NJDEP go beyond that needed for protection of human health and the environment and thus have the potential for misuse of society's limited resources.

We commend the Commission for clearly stating that there is no scientific basis for 1×10^{-6} and recognizing that its historical use in food safety issues should not form the basis for its use in environmental risk assessments where the potentially exposed population is extremely small.

We also commend the Commission for recommending use of best available scientific information and judgment to predict human health risk. The use of site specific data, rather than default assumptions and scientifically defensible tools such as probabilistic analysis, physiologically based / pharmacokinetic modeling, mechanistic toxicology, bioavailability, and environmental fate and transport modeling to more accurately predict environmental risk.

The CIC/NJ also endorses the development and use of differential remediation standards that take into account the intended use of the property.

The CIC/NJ does not agree with the Commissions proposed three tiered approach to site remediation. The CIC/NJ believes 1×10^{-5} is the lowest lifetime cancer risk level that should determine any soil remediation standard but disagrees with the Commission that it should apply to Groups B and C compounds. While Group A carcinogens are considered known human carcinogens, we believe that animal carcinogens that have not been proven to be human carcinogens (EPA's Group B and C) should not be regulated to the same risk management standard as those that are known human carcinogens. The CIC/NJ proposes that a 1×10^{-5} risk management standard only apply to Group A carcinogens and that Group B and C compounds can be handled by a higher risk level such as 1×10^{-4} . Alternatively, remediation standards for Group C compounds can be developed using NOEL's. Furthermore, the same risk management standard should apply to both the NJDEP default standard as well as site-specific risk assessments.

The Commission's proposal would require responsible parties that choose to employ exposure controls to prevent contact with contaminants of concern and thus eliminate risk associated with the contaminants, to meet a lower, more stringent standard than responsible parties that will be able to grant unlimited access to the public and employ no site controls. Such a dichotomy in the protection of human health is illogical and difficult to understand.

The Commission also proposes that when exposure control remedies are applied, the site must also be remediated to meet standards that assume the controls someday will fail. Exposure control remedies are not designed to be temporary "fixes" to a contaminated site. Such remedies are designed to meet performance standards that are protective of human health. To believe that a "safety net" is necessary because exposure controls will always fail and always result in exposure and always cause a risk to human health is in direct contradiction to the Commission's own recommendations, "The Commission recommends using the best available scientific information and judgment to predict hazard. The use of site specific data, rather than default assumptions is embraced by the Commission."

The CIC/NJ also believes that the Commission's attempt to drive the remediation process to permanent remedies will not work. The basic logic is flawed. Due to the enormous cost difference (7X) between implementing an exposure control remedy versus a permanent remedy, the strategy proposed by the Commission of providing an order of magnitude incentive to employ a permanent remedy will fall far short of providing an economic incentive and only succeed in adding unnecessary cost to implement exposure control remedies.

The CIC/NJ encourages the Commission to eliminate tier 3, from its three-tiered approach to site remediation and to remove biased proposals aimed at discouraging the use of cost effective exposure control remedies.

COMMENTS ON
ENVIRONMENTAL RISK ASSESSMENT AND
RISK MANAGEMENT STUDY COMMISSION
FINAL DRAFT

NOVEMBER, 1995

PREPARED BY: THE CHEMICAL INDUSTRY COUNCIL OF
NEW JERSEY, RISK ASSESSMENT TASK FORCE

86X

PREFERENCE FOR PERMANENCE

The Commission's preference for permanence and attempts to drive remedial actions away from institutional and engineering controls to more costly permanent remedies by requiring inconsistent risk management standards will slow the reuse and redevelopment of brownfields across the state.

The Commission Report is silent on the NJDEP's vain attempts over the last fifteen years to force "permanent" remedies. This attempt most often has created gridlock, since human health risks are minimal and costs extraordinary compared to land values.

ISRA was created out of recognition that ECRA had gone off track. Ten years of ECRA showed that the law had to be changed to promote efficient and timely cleanups, and to eliminate any unnecessary financial burdens of remediating contaminated sites. ISRA recognized that engineering and institutional controls could be a cost effective remedy, protective of human health and the environment, that would place brownfields back into productive use in a timely manner. It also provided protection against the NJDEP forcing permanent remedies by establishing a cost test.

Costs do matter, so does urban renewal, jobs, and a tax base, yet none of this is discussed in the Commission Report.

An estimate of the cost burden to implement a permanent remedy versus an exposure control remedy is shown in Figure 1. As an example, the cost to install an impermeable cap over soil contaminated with heavy metals can range from \$90,000 to \$160,000 per acre while the cost to excavate the material, treat and dispose can cost from \$655,000 to \$1,155,000 per acre; a 7-fold increase of \$565,000 to \$995,000 higher cost for the "preferred permanent remedy". Also note that the total remedial cost for the permanent remedy (including delineation/reports, etc.) would be 12X to 15X higher than the land value. Hardly an incentive to recycle and reuse brownfields.

FIGURE 1
EXPOSURE CONTROL VERSUS PERMANENT REMEDY COST COMPARISON

EXPOSURE CONTROL REMEDY			
ITEM		COST RANGE (\$/ACRE)	
		LOW	HIGH
REPORTS			
	RI/Delineation (2)	\$20,000	\$60,000
	Work Plans (2)	\$50,000	\$100,000
	Reports (2)*	\$200,000	\$1,000,000
	Total	\$270,000	\$1,160,000
FENCE		\$8,400	\$12,500
COVER			
	Soil/Grass	\$45,000	\$75,000
	Aggregate	\$30,000	\$45,000
CAP			
	RCRA	\$175,000	\$260,000
	Impermeable	\$90,000	\$160,000
SLURRY WALL			
	Soil/Bentonite	\$300,000	\$500,000
MARKET VALUE		\$80,000	\$150,000

PERMANENT REMEDY			
ITEM		COST RANGE (\$/ACRE)	
		LOW	HIGH
REPORTS			
	RI/Delineation (2)	\$20,000	\$60,000
	Work Plans (2)	\$50,000	\$100,000
	Reports (2)*	\$200,000	\$1,000,000
	Total	\$270,000	\$1,160,000
EXCAVATION & DISPOSAL			
	Excavation	\$15,000	\$30,000
	Disposal	\$250,000	\$500,000
	Backfill	\$45,000	\$75,000
	Total	\$310,000	\$605,000
STABILIZATION			
	Excavation & Treatment	\$360,000	\$580,000
	Disposal	\$250,000	\$500,000
	Backfill	\$45,000	\$75,000
	Total	\$655,000	\$1,155,000
LOW TEMPERATURE THERMAL DESORPTION			
	Excavation & Treatment	\$500,000	\$1,210,000
	Disposal	\$250,000	\$500,000
	Backfill	\$45,000	\$75,000
	Total	\$795,000	\$1,785,000
INCINERATION			
	Excavation & Treatment	\$1,210,000	\$5,808,000
	Disposal	\$250,000	\$500,000
	Backfill	\$45,000	\$75,000
	Total	\$1,505,000	\$6,383,000
MARKET VALUE		\$80,000	\$150,000

* - high end report cost based on investigation report for large facility.

Fencing cost assumes 840 foot length.

Soil cover assumes 1.5 feet fill, 0.5 feet topsoil.

Aggregate cover assumes 1 foot aggregate.

Slurry wall cost assumes 30 foot depth and 840 foot length.

Treatment remedies assume 2 foot depth excavation, 1.5 tons per cubic yard.

Disposal cost assumes material is non-hazardous and can be deposited in an industrial landfill. Hazardous waste disposal costs are considerably higher.

The Union County Model Site Redevelopment Project identified 185 sites, totaling over 2500 acres of redevelopable land in the county. This study concluded that the average site size was 14 acres. If one assumes this to be indicative of the over 6600 contaminated sites in N.J., and assumes that only half of the site acreage will require remedial action, the additional cost for permanence could range from \$26 BBL to \$46BBL. Where will such money come from? Likely deep pockets own no more than a few percent of this land. The remainder are owned by people without a hope of paying for such costly cleanups, or abandoned. Since the NJDEP has very limited resources, the only hope for cleanups will be investors encouraged to "adopt" such parcels. Rather than acknowledge this dilemma, the Commission Report would mandate that "Exposure Control Remedies", often the only ones affordable, must meet an order of magnitude more stringent standard than that required for a permanent remedy.

Due to the enormous cost difference (7X) between implementing an exposure control remedy versus a permanent remedy, the strategy proposed by the Commission of providing an order of magnitude incentive to employ a permanent remedy (2X) will fall far short of providing an economic incentive and only succeed in adding unnecessary cost to implement exposure control remedies.

New Jersey State Library

SEVERANCE OF LIABILITY

The CIC agrees with the Commission that liability into the indeterminate future provides a substantial impediment to the cleanup of contaminated sites. While ISRA recognized the problem and addressed the issue by requiring at least an order of magnitude decrease in remedial standards and a determination that the original remedy is no longer protective before the responsible party would be required to revisit the cleanup, considerable uncertainty over future liability still exists and provides a disincentive for timely remediation.

The CIC supports a proposal that would allow the responsible party, choosing to implement a permanent remedy, the option to pay a 1% surcharge to completely and permanently sever future liability. It should be recognized that while this proposal may protect the responsible party from further action by the NJDEP at some future date, no party is protected from suits for personal injury, so complete relief is not possible.

While severing long term liability does reduce the potential for future costs, this "potential future cost avoidance" will be more than off-set by the extraordinarily high cost 7X to implement a "permanent" versus a "non-permanent" remedy. Clearly, only for very simple, straight-forward remediations, or under "unique" situations would a responsible party choose to pursue a permanent versus a non-permanent remedy; therefore, the option to pay into a fund must be at the responsible parties choice and not required of all remediations.

We question how many responsible parties are willing to pay any tax for whatever minimal additional comfort they may get from severed long term liability from the NJDEP after they have achieved the highly conservative cleanup levels, and extraordinarily high cost to achieve a "permanent" remedy.

Remediations in N.J., except those being performed voluntarily, or with a self-guarantee are already required to pay a 1% annual surcharge. Additional taxes, surcharges, etc., should not be levied on the regulated community. The CIC disagrees with the proposal by the Commission that a surcharge of approximately one to five percent should be assessed on ALL remediations both permanent and non permanent.

RISK MANAGEMENT STANDARD

- A. Use of a Risk Management Standard of 1×10^{-5} for Class B&C carcinogens for calculation of soil remediation standards is overly protective.

We commend the Commission for stating that there is no scientific basis for 1×10^{-6} and for recognizing that the historical use of 1×10^{-6} in food safety issues should not form the basis for its use in environmental risk assessments where the potentially exposed population is much smaller than the general population exposed to food additives. We also commend the Commission for proposing an alternate acceptable risk scheme based on EPA weight of evidence classifications.

The adoption of a 1×10^{-5} or 1×10^{-4} risk level would result in risk reduction of only 0.001 or 0.01 of a hypothetical cancer case per year for the population of the state of New Jersey compared to 0.0001 for 1×10^{-6} . These hypothetical fractions can be compared to the actual incidence of 42,000 (1994) new cancer cases in the State of New Jersey as reported by the American Cancer Society. Clearly the choice of 1×10^{-5} or 1×10^{-4} versus 1×10^{-6} risk level will not appreciably affect the public health of the citizens of New Jersey (i.e., 42,000.001 for 1×10^{-5} and 42,000.01 for 1×10^{-4}).

A one-in-one million risk level is needlessly stringent, does not match up with other societal risks and has been chosen historically in an arbitrary manner as a basis for regulation. While the risk of dying from a falling airplane is four times greater than 1×10^{-6} , the public has viewed such risks as inconsequential; yet, industry has been forced to spend enormous sums to reduce risks to that level.

A primary objective of ISRA "is to reform the site remediation process in order to promote faster cleanups of contaminated property while at the same time furthering the State's economic well-being and development by improving the State's business climate". The CIC considers the proposed use of a 1×10^{-5} risk management standard for A carcinogens consistent with the intent of ISRA. Applying a 1×10^{-6} risk management standard results in needless expenditure of hundreds of millions of dollars for little or no incremental reduction in risk. The members of the CIC Risk Assessment Task Force estimate that the difference between a 1×10^{-6} and a 1×10^{-5} risk management level will reduce remediation cost by a minimum of 2 to 3-fold for those sites choosing not to employ engineering controls. A study that looked at nine sites in the Chemical and Petrochemical industries undergoing remediation showed that for these sites a 1×10^{-5} versus a 1×10^{-6} risk management standard could reduce overall remediation costs by greater than \$250MM. Please note that there are currently over 6600 known contaminated sites in New Jersey.

The CIC believes 1×10^{-5} is the lowest lifetime cancer risk level that should determine any soil remediation standard but disagrees with the Commission that it should apply to Groups B and C compounds as proposed in Table 1 (p.11), Column II. While Group A carcinogens are considered known human carcinogens, we believe that animal carcinogens that have not been proven to be human carcinogens (EPA's Group B and C) can be handled by a higher risk level. The CIC believes that Group B and C carcinogens that are classified with such a high degree of uncertainty should not be regulated to the same risk management standard as those that are known human carcinogens. Therefore, the CIC proposes that a 1×10^{-5} risk management standard only apply to Group A carcinogens and that Group B and C compounds can be handled by a higher risk level such as 1×10^{-4} . Alternatively, remediation standards for Group C compounds can be developed using NOEL's.

TABLE 1 - RISK MANAGEMENT STANDARDS

- A. Column II - Group B and C carcinogens are not known human carcinogens and should not be regulated to the same risk management standard as those that are known human carcinogens - Group A.

The CIC does not agree that a 1×10^{-5} risk management standard should apply to Groups B and C compounds. While Group A carcinogens are considered known human carcinogens, we believe that animal carcinogens that have not been proven to be human carcinogens (EPA's Group B and C) can be handled by a higher risk level. The CIC believes that Group B and C carcinogens that are classified with such a high degree of uncertainty should not be regulated to the same risk management standard as those that are known human carcinogens. Therefore, the CIC proposes that a 1×10^{-5} risk management standard only apply to Group A carcinogens and that Group B and C compounds can be handled by a higher risk level such as 1×10^{-4} . Alternatively, remediation standards for Group C compounds can be developed using NOEL's.

- B. Column III - The Commissions proposal creates a dual standard for permanence.

In Tier 2, the Commission allows site specific physical characteristics and exposure information to be considered with NJDEP default assumptions and assigns risk management standards of 1×10^{-5} for A and B carcinogens and 1×10^{-4} for C carcinogens. Both tier 1 and 2 are considered by the Commission as permanent remedies and could result in the severance of future liability. The Commission has created a dual standard for permanent remedies and severance of liability. For a responsible party completing a remediation, including site specific data will always allow cleanup levels for C carcinogens to increase by an order of magnitude. By creating this dual standard, the Commission has intertwined the practices of risk assessment and risk management and created a prejudice against NJ Default Standards.

The CIC suggests that Table 1 be revised to have all permanent remedies meet the same risk management standards. Those standards should be 1×10^{-5} for A carcinogens and 1×10^{-4} for B and C carcinogens.

- C. Columns IV and V - It is illogical to require exposure control remedies to meet a lower, more restrictive risk management standard than required for permanent remedies.

The Commission attempts to create a preference for permanent remedies by applying a more stringent risk management standard to remediations that employ exposure control methods than those that apply permanent remedies. Exposure control methods are described by the Commission as "those that prevent contact between contaminants of concern and the human population." Responsible parties that wish to prevent contact with contaminants of concern and thus eliminate risk associated with the contaminants are required to meet a lower, more stringent standard than responsible parties that will be able to grant unlimited access to the public and employ no site controls. Such a dichotomy in the protection of human health is difficult to understand.

Permanent remedies may be applicable to many sites within the state however the Commission's preference for permanence attempts to severely limit the reuse of industrial sites with proper exposure control remedies. In Column V, the Commission suggests that when exposure control remedies are applied, the site must also be remediated to meet standards that assume the controls someday will fail. Exposure control remedies are not designed to be temporary "fixes" to a contaminated site. Such remedies include slurry walls, liners, caps, all designed to meet performance standards that are protective of human health. In addition to these controls, Declarations of Environmental Restrictions are always applied. These restrictions define where and what concentration are left at the site and requirements to maintain the "controls". In the event of failure of the exposure control, such information can be used to define new or better controls. To believe that a "safety net" is necessary because exposure controls will always fail and always result in exposure and always cause a risk to human health is in direct contradiction to the Commission's own recommendations, "The Commission recommends using the best available scientific information and judgment to predict hazard. The use of site specific data, rather than default assumptions is embraced by the Commission."

This requirement would highly impact all landfills in New Jersey. Although these landfills may be lined, capped and contain a leachate collection system, under the Commission's assumptions, every landfill in New Jersey would be required to:

1. Treat all wastes within the landfill to a concentration so that direct contact with the wastes for 70 years would not cause an increase in cancer above 1×10^{-4} .
2. In order to show that this concentration has been met, all the treated wastes would have to be sampled and analyzed to prove that such a concentration has been met.

This example illustrates that the requirement in Table 1 would do little to further the use of permanent remedies at landfills, but at a minimum would create increased hazards and safety concerns by causing all landfills to start remediating their wastes.

The CIC hopes that the Commission will apply a consistent risk management standard to both permanent and exposure control remedies as well as remove column V of table 1. Requiring more stringent remediation standards on sites that employ exposure controls will not, by itself, improve the environmental quality of New Jersey. Instead, this additional requirement will require responsible parties to spend their resources in unnecessary remedial actions, slow the pace of remediation and discourage the redevelopment and reuse of these sites.

- D. Column VI - This column should be deleted. There is no explanation of its use and it is inappropriate given the small population that are affected by the remediation standards proposed in the legislation.

The discussion on p. 35 should indicate that all anticipated scenarios covered by a 1×10^{-5} upper limit risk level would result in much less than an upper limit of one event per 70 years (or the average population lifetime) for any conceivable effected population by any site potentially covered in the legislation. Only 0.2% of the US population has been found to be impacted by contaminated sites studied by the Agency for Toxic Substances and Disease Registry (ATSDR, 1993), most of which are Superfund sites. Most hazardous waste sites do not impact large numbers of people and 1% of New Jersey residents is a reasonable upper limit estimate for all sites. If one assumes that 1% of the state-wide population, or 70,000 citizens, would be potentially exposed, the 1×10^{-5} and 1×10^{-4} risk levels would be associated with 0.001 and 0.01 of a hypothetical cancer case per year (Whyser, 1994). Due to all of the health protective assumptions involved in the overall risk calculations, the real risks would be much less than these estimates, and realistically there may be no risk at all. Consequently, there is no need to further consider the population at risk in the delineation of a risk-based standard.

96X

SITE SPECIFIC RISK ASSESSMENTS

- A. Site Specific RA should not be limited in use to only developing alternative standards for protection of groundwater. (p.37)

ISRA allows use of site specific risk assessments to define "alternative remediation standards". The Commission Report only recognizes site specific factors impacting "groundwater" and thus proposes to limit the use of site specific risk assessments.

Site specific factors can also impact direct soil contact criteria, such as:

- Soil contamination at "depth" represents a different exposure frequency than do "surface soils".
- Form of contaminant in soil can impact its bio-availability and hence risk to human health and the environment.

Site specific factors can impact both exposure routes and should be considered in the development of alternative standards.

- B. Do not delay use of site specific risk assessments until a "decision tree" has been developed.

Site specific risk assessments are clearly provided for under ISRA. Waiting for the development of a "decision tree" will cause additional delays in remediating sites in New Jersey pp.35(f), in ISRA requires that the risk assessment protocol must be consistent with the guidance and regulations for exposure assessment developed by the United States Environmental Protection Agency pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980.

These methodologies are the only "approved and acceptable" methods for conducting risk assessments. It is not apparent what additional information could be provided by a decision tree and an oversight committee.

C. Monte Carlo probabilistic approaches should be used by the NJDEP in calculating their default soil remediation standards.

The Commission, in recommendation 8 of their report, supports the development and validation of standard probabilistic approaches to better define risk. The CIC supports this approach and believes that it is technically superior to using point estimates since probabilistic approaches such as Monte Carlo use distributions that describe the range of anticipated exposure conditions for a broad range of population characteristics. This approach also reflects the current scientific trend in risk assessment toward the use of best available exposure factors to define risk. EPA has endorsed the use of Monte Carlo probabilistic approaches in their Guidelines for Exposure Assessment (1994). The CIC believes that the Monte Carlo or probabilistic approaches should be used by NJDEP in calculating their default soil remediation standards as well as utilizing this approach in site specific risk assessments.

If conservative point estimates are used in developing New Jersey's default soil remediation standards, the result will be the development of unnecessarily stringent standards that do not reflect realistic exposure assumptions. Excessively stringent standards, in turn, will precipitate a large number of unnecessary cleanups taking place, diverting resources from other potentially more significant sources of risk.

OTHER COMMENTS ON RECOMMENDATIONS

RECOMMENDATION (1)

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.

The Commission is inconsistent in this recommendation with statements made in Section VI on page 28. On page 28, the Commission states that "in the absence of other methodologies the USEPA derived CSFs (potency factors) are recommended by the Commission for use by the NJDEP. The CSFs use PBPK modeling, mechanistic toxicology, and chemical specific bioavailability to a limited or almost non existent degree so it is difficult to see how these two statements are compatible.

RECOMMENDATION (2)

THE COMMISSION RECOMMENDS ADOPTION OF THE PRINCIPLES PUT FORTH IN TABLE 1. THESE PRINCIPLES PROVIDE INCENTIVE FOR PERMANENT REMEDIATION AND IN THE OPINION OF THE COMMISSION ARE PROTECTIVE OF PUBLIC HEALTH.

The principles put forth in table 1 are not clearly represented and apply the very opposite of the principles put forth by the Commission in this paper. Using a bright line of residual risk for a permanent or exposure control remedy suggests that a single point estimate of risk must be determined and used despite the Commission's own statement, "that 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." (p.23) Using a risk level of 1×10^{-4} assuming failure of exposure

control, is significantly more stringent than Superfund's range of 1×10^{-4} being the trigger for remediation. The use of a decreased factor of 10 in carcinogenic risk and three fold decrease in non cancer endpoints seems extremely conservative in light of the statements by the Commission that in the use of slope factors alone, the overestimate of risk is 15 to 10, 800 fold. The RfDs used by USEPA carry an uncertainty factor of 10 to 10,000.

The suggestion by the Commission that "any remedy that still results in one or more adverse events every 70 years, notwithstanding the success in achieving the individual risk based standards, would not be acceptable," is unclear in how such an event would be calculated and lacks any precedent or clear understanding of the overall value or protection of public health that would be achieved.

RECOMMENDATION (4)

THE COMMISSION STRONGLY SUPPORTS A RISK MANAGEMENT STANDARD OF 1×10^{-5} FOR CLASS A&B CARCINOGENS FOR CALCULATION OF SOIL REMEDIATION STANDARDS. CUMULATIVE RISK FOR USING SPECIFIC PATHWAY SHOULD NOT EXCEED 1×10^{-5} . PREVIOUS DISCUSSIONS HAVE DEMONSTRATED THAT USEPA ENDORSES AND UTILIZES A FLEXIBLE RISK MANAGEMENT STRUCTURE. THIS FLEXIBLE APPROACH IS SUPPORTED BY THE NCP MANAGEMENT GUIDANCE VALUES OF 1×10^{-4} TO 1×10^{-6} .

The first and second sentence of this recommendation do not agree. If the risk management level for each carcinogen is 1×10^{-5} then a cumulative risk for each pathway cannot also equal 1×10^{-5} if there is more than one constituent. The mention of EPA's risk management structure is not found within this document.

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RECOMMENDATION (5)

THE COMMISSION ENDORSES THE NJDEP POLICY OF DIFFERENTIAL REMEDIATION CRITERIA FOR RESIDENTIAL AND NON-RESIDENTIAL SITES, CONSISTENT WITH TABLE 1.

Table 1 does not mention residential or non residential use in defining residual risk.

RECOMMENDATION (8)

THE COMMISSION RECOMMENDS THE DEVELOPMENT AND VALIDATION OF STANDARD PROBABILISTIC APPROACHES THAT CAN BE USED TO BETTER DEFINE RISK.

Since the science of performing such analysis is still evolving, it is premature to attempt to standardize these techniques or to arrive at default methodology. A better approach would be to promote the incorporation of the best methodologies into risk assessments.

RECOMMENDATION (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.

The creation of a risk assessment advisory group that will aid in the use of risk assessment cannot be limited just to site remediation but should address all issues related to risk assessment. Such a group should not be created to review site specific risk assessments.



David W. Thompson
Manager, Mid-Atlantic/Southeast Region
Environmental Remediation Program

General Electric Company
640 Freedom Business Center
King of Prussia, PA 19406
610 992-7890, Dial Comm: 8*566-7890
Fx: 610 992-7898

**Statement of
David W. Thompson
Manager, Mid-Atlantic/Southeast Region
Environmental Remediation Program
General Electric Company**

**Before the
Environmental Risk Assessment and
Risk Management Study Commission
State of New Jersey**

December 5, 1995

Good morning Mr. Chairman and Members of the Commission. My name is David W. Thompson. I am Manager of GE's Environmental Remediation Program for the Mid-Atlantic/Southeast Region, and I have responsibility for directing GE's site remediation efforts in New Jersey. I appreciate the opportunity to present our views today on the Study Commission's November, 1995 draft report.

I wish to commend the Commission for their work on a difficult and sensitive issue. GE supports the Commission's recommendation to use the best available scientific information and judgment to predict hazard using site specific data rather than default assumptions and the inclusion of scientifically defensible tools such as probabilistic analysis to more accurately predict environmental risk.

GE is heavily involved in the cleanup of numerous sites in New Jersey and across the country. The Company has spent enormous resources investigating and remediating these sites. We have also devoted much effort to finding ways to improve the overall effectiveness of this program. The selection of responsible, scientifically-based risk levels and cleanup standards is absolutely critical to the success of the site remediation program -- both from the standpoint of public health protection and the commitment of industry

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that is needed to carry out the cleanup without litigation delay. GE endorses the general findings of this report and believes that clarification of portions of the report and recommendations can provide a realistic workable template which is protective of human health and the environment. I would like to briefly discuss several specific topics concerning the draft report:

1. Actual Risks Should be the Basis for Standards

We strongly support the goal of the Study Report that parties be given the option of selecting appropriate cleanup standards based on site-specific characteristics, such as nature and location of contaminants, actual exposure pathways, actual current and planned land use, and type of remedy. For too long these cleanups have been handled with a "cookie cutter" approach based on the so-called "default assumptions" of human exposure, health risk and land use that have no relationship to reality. The Commission's acceptance of "probabilistic analysis" as a technique for defining risk is also an important step forward.

Other states, such as Pennsylvania and Massachusetts, have made major legislative overhauls of their cleanup programs to require that standards be based on actual risks using realistic assumptions of human exposure and current or planned land use. GE supports legislative amendments in New Jersey to accomplish this result and to allow flexibility in the final selection of appropriate standards.

2. Target Risk

The Commission correctly identifies that the use of 1×10^{-6} is an inappropriate remediation standard which was not based on scientific study and recommends that site remediation standards be flexible and reflect future use of a site. It is interesting that even though the EPA's National Contingency Plan has allowed Superfund cleanups to achieve risks from 1×10^{-4} to 1×10^{-6} for more than ten years, the 1×10^{-6} level continues to be used in many cases without any sound justification. New Jersey needs to step forward and establish standards in the 1×10^{-4} to 1×10^{-5} range as we are seeing emerge in other states and at the Federal level.

3. The Report Makes too Great a Distinction Between Permanent and "Exposure Control" Remedies.

The Table 1 "Tier" approach makes too great a distinction between "permanent remedies" and "exposure control remedies." We believe that all remedies which control risks, including "exposure controls" should be considered on an equal footing and evaluated based on their effectiveness in protecting human health and the environment. There are very few large disposal sites where permanent remedies (as defined by the Commission) are a feasible solution to all or even most of the contamination that is present decades after the disposal took place. The Report would deny a party protection against future liability unless it employed a permanent remedy. We see no reason why a party that achieves an acceptable level of cleanup with encapsulation or other reliable methods should not be given the full liability protection. Other factors, such as the nature of the control remedies used, deed restrictions and other institutional controls should be taken into account in deciding to cut off future liability, not just whether the remedy is classified permanent.

4. The Report Should Address Groundwater as well as Soil Risk Standards.

The Report focuses on soil cleanup but does not address the groundwater standards. Attempts to remediate groundwater contamination, often occurring deep in bedrock formations, have caused costs of cleanup to skyrocket at many sites. The Commission should apply the same risk management principles in its final Report for groundwater as well as soil, i.e., use of 1×10^{-4} and 1×10^{-5} risk levels as appropriate. If there is no exposure to unacceptable risk now or in the reasonably foreseeable future, groundwater pumping should not be required.

5. Risk Management Standards - Table 1

The Commission indicates a preference for "permanent remedies" which employ contaminant removal, destruction, irreversible transformation or irreversible immobilization by applying a more stringent risk management standard to "exposure control" remedies utilizing slurry walls, caps, liners and hydraulic controls. The assumption that exposure

control remedies will break down, degrade or cannot be made permanent by proper operation and maintenance is not realistic. There are numerous exposure control remedies which are "permanent" by engineering standards. Application of unrealistic risk criteria or default assumptions may negate the use of these technologies and approaches and slow the remediation process.

GE recommends that the Commission apply risk management standards in the 1×10^{-4} to 1×10^{-5} range as appropriate for both permanent and exposure control remedies.

Conclusion

In conclusion, GE believes that many of the risk management suggestions of the Commission are of great importance, that some should be revised and some should be clarified. The goal, of course, is to apply the best available scientific information and judgment to the site-specific circumstances. GE believes that action is needed by the legislature to establish these principles to all cleanups in the state and by the Commission or its successor board (which GE supports) to give more specific guidance as to how exposures and risks are calculated or assumed. GE will expand upon these remarks in its written comments on December 19. Also GE offers to provide technical assistance to the Commission on this issue.

BEFORE THE NEW JERSEY
ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT
STUDY COMMISSION

COMMENTS OF
GENERAL ELECTRIC COMPANY

Draft Report of the Environmental
Risk Assessment and Risk Management Study Commission
November, 1995
Pursuant to P.L. 1993, c.139, § 47

General Electric Company
Corporate Environmental Programs
640 Freedom Business Center
King of Prussia, Pennsylvania 19406
(610) 992-7970

December 19, 1995

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INTRODUCTION

General Electric Company ("GE") is pleased to have the opportunity to submit the following Comments with respect to the November, 1995 Draft Report of the New Jersey Environmental Risk Assessment and Risk Management Study Commission. The Commission's Report is issued pursuant to P.L. 1993, c.139, § 47, the Industrial Site Recovery Act ("ISRA"). The specific legislative charter to the Commission was to examine and assess the scientific basis for selecting the 1×10^{-6} risk standard, to assess alternative scientific standards, and to examine methodologies of risk assessment and their efficacy and applicability for the establishment of remediation standards.

GE wishes to commend the Commission for its work on this difficult and sensitive set of issues. Risk Assessment is at the heart of the remedial process and its importance cannot be overstated. GE supports the risk-based remedy selection process, and encourages the Commission's efforts to improve the science of risk assessment and promote a risk-based remedy selection process for New Jersey's site remediation programs. GE supports the Commission's recommendation to use the best available scientific information and judgment to predict actual risks using site-specific data rather than default assumptions.

GE is heavily involved in the clean-up of numerous sites in New Jersey and across the country. The Company has spent enormous resources investigating and remediating these sites, and GE currently spends over \$100 million a year on its remedial program. We have also devoted much effort to finding ways to improve the overall effectiveness of this program. The selection of responsible, scientifically-based risk levels and clean-up standards is absolutely critical to the success of the site remediation program -- both from the standpoint of public health protection and the commitment of industry that is needed to carry

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out the clean-up without litigation delay. GE endorses the general findings of this report and makes the following specific recommendations.

I. STANDARDS BASED ON ACTUAL RISK

GE strongly supports the goal of the Commission Report that parties be given the option of selecting appropriate clean-up standards based on site-specific characteristics, such as the nature and location of contaminants, actual exposure pathways, current and planned land use, and type of remedy. For too long these clean-ups have been handled with a "cookie cutter" approach based on the overly conservative and unrealistic "default assumptions" of human exposure, health risk and land use.

As the Commission notes in this report and extensive bibliography, there is a substantial body of scientific information documenting the inappropriate application of default assumptions and overly conservative risk projections. These data are helpful in developing a basis for predicting risks at sites. In fact, many of the references cited in the Report's bibliography show that the use of less extreme assumptions resulted in more realistic assessment of risk and successful remediations. The Commission's recommendation of the development of probabilistic analysis will enhance the quality of risk assessment.

Other states have made major legislative overhauls of their clean-up programs to require that standards be based on actual risks and realistic assumptions of human exposure and current or planned land use. GE supports legislative amendments in New Jersey to accomplish a similar result to ensure that resources are focused on fixing real problems and protecting the public from actual rather than hypothetical risks.

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GE notes that the Commission's concluding recommendations (Report, Section X, pp. 41-45) do not contain a specific statement that assumptions for land use should be based on "current and planned land use" for the site. This concept is certainly implied in the body of the Report, but GE believes that the statement should be expressed in order to preclude the continued application of hypothetical uses in estimating health risks. Other states have codified this type of language regarding land use.¹

II. THE INAPPROPRIATENESS OF 1×10^{-6}

The Commission correctly identifies that the use of 1×10^{-6} is an inappropriate remediation standard created from other non-remedial programs and was not based on scientific study. The inappropriateness of the 1×10^{-6} standard has been highlighted in an earlier article ². GE supports the Commission's recommendations that site remediation standards be flexible and reflect current and planned use of a site. It is interesting that even though the EPA's National Contingency Plan has explicitly allowed Superfund clean-ups to protect against risks in the 1×10^{-4} to 1×10^{-6} range for more than five years, the 1×10^{-6} level continues to be used in many cases without any sound justification. Even this risk range is based on overly conservative assumptions. Other federal programs use risk ranges that are more moderate than those used by EPA.³ Several states

¹ See, OHIO REV. CODE ANN. § 3746.07(A)(2)(B) (Anderson 1995) (assumptions are to be based on "current and proposed uses").

² Kelly and Cardon, The Myth of 10^{-6} As a Definition of Acceptable Risk (or, "In Hot Pursuit of Superfund's Holy Grail") (1991). (Copy attached hereto).

³ Science Applications International Corporation, Analysis of the Use of Risk Levels by Government Agencies (1995) (Nuclear Regulatory Commission uses risk levels 1×10^{-3} to 1×10^{-4}).

have legislatively embraced a risk level of 1×10^{-5} .⁴

As the Report notes, establishing conservative risk goals of 10^{-6} is not based on any validated scientific principles. Attaining such goals is often economically and scientifically unachievable and accomplishes little toward the real reduction in public health risk. This has been documented in several recent studies (National Research Council, Valuing Health Risks, Costs, and Benefits for Environmental Decision-making (1992); Chemical Manufacturers Association, Assessment of Cost Savings resulting from Implementation of the CMA Remedy Selection Approach (1995).

The Commission should recognize that many old industrial sites are often widely contaminated due to a long history of human activity and will remain contaminated to some degree for the foreseeable future. Neither technology nor sufficient funds exist to clean these sites to near pristine conditions nor is such a clean-up even appropriate for the uses at most sites. It is often said that it takes 10% of the cost to reduce risk by 90% from baseline and 90% of the cost to reduce the remaining 10% of the risk. The public health will be best served by devoting limited resources to reducing the maximum amount of risk at the largest possible number of sites.

III. THE DISTINCTION BETWEEN "PERMANENT" AND "EXPOSURE CONTROL" REMEDIES

The Commission Report offers several alternative approaches for establishing risk criteria for so-called "permanent" and "exposure control" remedies. GE believes that the Report makes too great a distinction between so-called "permanent"

⁴ OR. ADMIN. R. 340, Table 1 (residual contamination in soil not to exceed 1×10^{-5}); Mass. Regs. Code Tit. 310, § 40.0902(2)(b) (1995) (cumulative cancer risk 1×10^{-5}).

and "exposure control" remedies. This distinction continues to support the preference for treatment that evolved during the political debate of the 1980's regarding amendment to the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA"). Extensive research and engineering experience since that time has shown that public health can be well protected by exposure control remedies that employ engineering and institutional controls. It is not feasible technically or economically to destroy or remove all or even most of the wastes from many of these old disposal sites.

Further, treatment and off-site disposal remedies carry their own inherent risks. For example, on-site incineration remedies have been opposed by many local communities. Worker exposure during excavation is a significant and often unnecessary risk. The risks from off-site transportation of hazardous wastes occasionally outweigh the risks of a well-engineered exposure control remedy.

The regulatory experience with site remediation at the federal level has been broad-based and has encompassed programs under CERCLA and the Resource Conservation and Recovery Act ("RCRA"), including the underground storage tank ("UST") program. A list of guidance manuals under these programs that deal directly with "exposure control" remedial methods is set forth below.⁵

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Table A. Guidance Manuals Relying on Exposure Control Methods

Design and construction of RCRA/CERCLA final covers. EPA/625/4-91/125.

Requirements for Hazardous Waste Landfill design, Construction and Closure. EPA/625/4-89/022

RCRA Corrective Action Stabilization Technologies. EPA/625/R-92/014

Ground Water and Leachate Treatment Systems. EPA/625/R-94/005

RCRA Corrective Action Interim Measures Guidances. EPA/530/G-88/003

RCRA Corrective Action Plan. EPA/530-SW-88-028

Continued on next page

Many of the technologies utilized in exposure control remedies effectively provide permanent solutions to the problems posed. There is no question that there has now been wide acceptance by the scientific and regulatory community of the principles of site remediation by means of eliminating exposure through source removal, waste isolation, and containment and institutional and engineering controls. Unrealistic risk criteria or default assumptions should not negate the use of these technologies.

The line drawn by the Commission between so-called permanent and exposure control remedies may have theoretical meaning but is not based on any practical difference between the real-world health impacts of clean-up methods. All remedies that control risks, including exposure controls, should be considered on an equal footing and evaluated based on their effectiveness in protecting human health and the environment. There are very few large disposal sites where treatment ("permanent") remedies (as defined by the Commission) are a feasible solution to all or even most of the contamination that is present decades after the disposal took place. Since exposure control remedies have been shown to be reliable and effective, there is no reason why the Report (Table 1, Column IV) should set a higher risk management standard (1×10^{-6}) for these remedies than for others.

It should be recognized in establishing risk criteria, that the assumption that exposure control remedies will break down, degrade or otherwise fail is both unrealistic and

Continued from previous page

Guidance on Remedial Actions for Contaminated Ground Water at
Superfund Sites. EPA/530/G-88/003

How to Evaluate Clean-up Technologies for Underground Storage Tank
Sites. EPA 510-B-95-007

Construction Quality Management for Remedial Design and Remedial
Design Waste Containment Systems. EPA/540/R-92/073

Superfund Remedial Design and Remedial Action Guidance. OSWER
9355.0-4A

simplistic. Due to advancement in technology, materials development and field application experience, many exposure control remedies are now recognized to be permanent. Engineering components of the remedy can now be specified to sustain weathering, accidents, and material failure; these components can be supplemented with appropriate operations and maintenance specifications to ensure long life. The net effect is that the bright-line distinction drawn by the Commission between permanent and exposure control remedies does not have scientific validity.

GE recommends revision to the Table 1 Risk Management Standards. The concept of permanent vs. exposure control remediation as defined in the Commission Report needs to be discarded. Based on the increasing number and technical efficacy of exposure controls, there should be a single basis for risk management set as follows:

PROPOSED REVISED TABLE 1
RISK STANDARDS

I	II	III	IV
USEPA Carcinogen <u>Classification</u>	NJDEP Default <u>Standard</u>	Residual <u>Risk</u>	Maximum risk with <u>failure of remedy</u>
A	10 ⁻⁵	10 ⁻⁵	10 ⁻⁴
B	10 ⁻⁵	10 ⁻⁵	10 ⁻⁴
C	10 ⁻⁵	10 ⁻⁴	10 ⁻⁴
Non-Cancer Endpoints	1	1	3

The revised Table 1 represents a unified risk management standard that should apply to all environmental media, including groundwater, and should provide a single standard of measurement for all remedies.

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IV. SEVERANCE OF LIABILITY

GE agrees with the Commission's recommendation that a party that achieves clean-up to the standards set by the Department should also achieve protection against future liability for clean-up at the same site. However, the Report would deny a party protection against future liability unless the remedy employed is a permanent remedy. We see no reason why a party achieving an exposure control remedy clean-up (e.g. 10^{-5} risk) with encapsulation or other reliable methods should not be provided the full liability protection. Other states, such as Pennsylvania, have legislatively cut off any future clean-up liability for parties that meet approved standards, regardless of the type of remedial method employed. The method by which a party achieves these standards should not affect the liability for future claims at the site.

V. GROUNDWATER STANDARDS

The Report focuses on soil clean-up standards but does not address groundwater standards. Attempts to remediate groundwater contamination, often occurring deep in bedrock formations, have caused costs of clean-up to skyrocket at many sites. If the Report does not address groundwater risks, it will have omitted one of the most critical issues posed by site remediation in New Jersey. The Commission should apply the unified risk management standard set forth above for groundwater as well as soil, considering site-specific factors such as the nature and timing of the use of groundwater.

VI. "SURCHARGE" FUND FOR FUTURE REMEDIATION

The Draft Report recommends that a surcharge be imposed on all clean-ups in the amount of from one (1) to five (5) percent of clean-up costs. The "surcharge" is simply another form of tax

that would be imposed on private parties who are dedicating their resources to the clean-up of New Jersey sites. The surcharge would apply to all remedies, both permanent and exposure control, and the proceeds would be dedicated entirely to the future remediation of closed sites.

The Commission's proposed surcharge appears designed to protect against both an increase in the cost of remediation before final closure and a future change in clean-up standards that might trigger yet additional response action long after the site has been closed. As to any potential increase in cost before final closure, one New Jersey statute already in effect, ISRA, requires financial assurance to be posted by the owner that covers the entire clean-up cost. Thus, the pre-implementation surcharge is not needed at ISRA sites.

GE strongly opposes the use of any surcharge for additional remediation that may result from changes in the land use classification that occur after the implementation of a clean-up and that allow development to take place on the property. Parties contributing to clean-up of a site should not be taxed for the cost of a future land development benefitting others.

If, subsequent to site remediation, new health effects information causes the Department to reduce a clean-up standard for a particular substance in order to ensure that risk levels of 1×10^{-5} are maintained, GE believes that monetary funds should be available for additional remediation. GE does suggest that the ISRA trigger mechanism of a minimum order of magnitude change in the standard be applied here. GE does not oppose the establishment of a limited surcharge fund for this purpose provided that the surcharge is imposed in an evenhanded manner and takes into account factors such as the degree of reliability of the remedy.

The Commission should consider further how and when the surcharge would be imposed. The Commission gives no guidance as to how the precise surcharge percentage (i.e., 1%-5%) would be selected. If clean-up costs were \$50-\$100 million at a site, the total surcharge would be from \$500,000 to \$5 million, a very substantial amount of money. Any surcharge that is not based on a rational system considering the factors set forth above would be an arbitrary and unfair exercise of the state's taxing power.

For these reasons, GE proposes that the surcharge concept be examined thoroughly before it is adopted in New Jersey.

VII. OTHER RISK ASSESSMENT FACTORS

GE strongly supports the Commission's endorsement of the use of Monte Carlo type risk analyses. The goal is to make risk assessments more reflective of actual, site-related health risks. To the same end, GE suggests that the Commission make note of other factors that should be considered in determining actual (as opposed to theoretical) risk. For example, most of the toxicology database is based on toxicology testing with water soluble material. However, many contaminants in soil are relatively insoluble. Society coexists with numerous minerals in soil, often naturally occurring, which in their mineralized or complexed state will never be bioavailable. Because a water-soluble derivative of the element or compound may have exhibited an effect in a toxicology test does not mean that the same material in soil, mineralized to other salts and elements, will be capable of exerting an adverse effect.

Obviously, GE cannot set forth in these comments an all-inclusive list of these types of technical factors to consider in performing a risk assessment. We recognize that the Table 1

approach of the Commission does allow a party to apply site-specific factors. However, GE recommends that the Commission expand its discussion of these factors, perhaps by illustration, in support of the conclusion that parties will be afforded flexibility in making these critical assumptions.

VIII. SCIENCE REVIEW BOARD

GE recommends that a Science Review Board be established with continuing jurisdiction to interpret and oversee the implementation of the risk management standards at the state level. The absence of such a Science Review Board that has expertise in toxicology has been a serious hindrance to the implementation of site remediation programs at both the federal and state levels. All parties would benefit from the availability of such a body to assist in this technical program.

CONCLUSION

In conclusion, GE supports the recommendation that parties undertaking remediation at New Jersey sites be allowed to select appropriate clean-up levels based either on a generic standard of 1×10^{-5} with realistic (not overly conservative or compound⁶) default assumptions or individual risk management standards using site-specific factors. The Report should expressly recommend the application of "current and planned" land use classification.

"Exposure control" remedies should be evaluated in the same manner as "permanent" remedies to determine whether they provide the degree of reliability and protection needed at a site.

⁶ In some instances, the regulatory agencies have created multiple or compound risk assumptions from a series of individual, unrealistic assumptions, thereby skewing the assessment.

The Commission should re-examine the necessity of imposing a surcharge of 1-5% on parties that undertake clean-ups in New Jersey and meet the approved standards. Although it is not within the Commission's charter to recommend specific legal provisions for cutting off future liability of responsible parties, the Report should make the general recommendation that parties meeting the risk assessment standards at particular sites be released from all future liability for clean-up under state law. Because of the multiplicity of different regulatory programs in New Jersey affected by these recommendations, the Report should note that legislative amendments are necessary to carry out these changes. Finally, GE supports the creation of a Science Review Board at the state level that would be charged with interpreting and overseeing the implementation of the risk management standards.

December 4, 1995

Mr. Michael A. Gallo, PhD; Chairperson
Environmental Risk Assessment and
Risk Management Study Commission
C/O Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, NJ 08625-0068

RE: Comment Upon "Report and Recommendations of the...Commission"

Dear Dr. Gallo:

Thank-you for the opportunity to provide both oral and written comment on the important topic considered by the Commission. It is obvious from examination of the Report that you have considered your task as scientists and have taken a logical approach. The conclusions of the Commission that acceptable risks of clean up includes a range starting with a 10^{-5} risk, and then building a three-tiered, approach are commendable. You have put some thought into your work.

This recommendation for the NJDEP to use a range of risks as a basis for decision making especially makes sense, because this same agency operates State parks with lakes; Lakes where the public is exposed to a 10^{-4} life-time risk of drowning. The Commission 'hit the nail on the head' when they say:

"...the literature revealed no scientific basis for the selection of one in a million as the criterion for developing remediation standards for environmental pollutants".

However, the Commission has not lifted itself above the political cloud surrounding 'one-in-a-million' risk policy. The writing of the Commission's report has obviously been influenced by the NJDEP. The influence of the NJDEP is so strong that one need only read the first few lines of the Commission's 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."

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and then compare it some text found in the November 20, 1995 New Jersey Register, authored presumably by employees of NJDEP:

CITE 27 N.J.R. 4516 "Over the last century, New Jersey has been a leader in industrial manufacturing. However, years of improper disposal, treatment, and handling of chemicals have resulted in the existence of thousands of contaminated sites throughout New Jersey.

The similarity of sentence structure and the sequence of thoughts expressed are not coincidental.

As independent scientists who actually study things, I suggest that you study how this document was prepared. The majority of the text on pages 12, 13, 16 and 17 has nothing to do with studying the scientific basis for 'one-in-a-million', but rather shifts the responsibility for this risk policy to the Legislature.

The text on these pages should be deleted, it is all political. For instance, on page 12, fifth line from the bottom the Commission's Report states that since ISRA "...many properties have been capped, sealed or otherwise delisted with a Declaration of Environmental Restriction in place. But, on Table 2C, page 15, the Commission presents data showing that there have been fewer cleanup closeouts, while the rate of administrative closeouts has remained constant since passage of ISRA.

The insertion of 'one-in-a-million' into Bill S-1070 actually occurred during the latest revisions of the bill. It was most likely placed in the bill by representatives of the Florio Administration in exchange for something they viewed as a concession, during one of the "private room" negotiating sessions that take place outside of the public view.

How many of the Commission members agree with the second sentence of the report that "... this industrial activity has created a major environmental problem."? At worst the industrial activity in New Jersey has created many contaminated sites that may even overlap in the core urban areas. I think most scientists think that sea-level rise, or global warming are 'major environmental problems'. This sensationalist introductory language should be struck. Please only report on your study, don't provide someone's political view on how manufacturing is responsible for New Jersey's problems.

Returning back to the Executive Summary of the Commission's Report, the fourth line states, "To address this problem the legislature passed and the Governor



signed Senate Bill S-1070 on June 16, 1993". Dr. Gallo, ISRA in no way addresses major environmental problems in New Jersey. ISRA simply renames a former statute and regulation that was called ECRA. The renaming of ECRA was done because the NJDEP was tired of the negative publicity coming from this statute and regulations.

But, both ECRA and ISRA focus on only a small segment of the economic activity in New Jersey. ISRA is discriminatory against manufacturers. Exempt from complying with this law are many other potential polluters. For instance: gasoline stations, heavy engine repair, trucking-transfer operations, dry cleaners, military installations, public works garages and other polluting industries, are all exempt from ISRA.

A major function of the ISRA Statute is to retroactively provide authorization for the Technical Requirements NJAC 7:26E. ISRA was used by NJDEP to legitimize informal policy such as one-in-a-million risk standards and the Technical Requirements. The Commission should not allow the NJDEP to use its report as another forum for advancing informal Department policy.

An inaccurate statement of statutory history is made on page 34 of the Commission Report where it states:

"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 [sic] 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."

Perhaps the Commission should re-examine the ECRA statute, because it is dated December 31, 1983, and it contains no one-in-a-million goal.

The lead-in to the Recommendations section on pages 41 and 42 has nothing to do with the Commissions activities. These paragraphs simply parrot the text found on pages 12, 13, 16 and 17, only for the first time are the subjects of environmental inequality and injustice introduced; the text on pages 41 and 42 are political, unscientific, and also should be struck from this report.

The last Recommendation of the Commission's Report has no basis. No where in the report does the Commission present evidence that a Science Advisory Board is needed, tell us what the Board would do, you do not discuss who should be

appointed to this group, and you offer no standard of performance for this group. This recommendation is weak and without justification.

The references, both in the text and listed in the Bibliography at the end of the report, will require a shrewd editor to fix as this document is finalized. Only 10 of the 99 references were cited in the text. You should make sure all the dates for citation correspond with a Bibliography entry. In my professional opinion, this report is weak on providing proper citations. A number of the USEPA citations have multiple documents with the same publication year. For instance USEPA (1990) could be one of four documents found in the Bibliography. Three references cited in the text do not make it into the Bibliography; on page 22 NRC (1984), on page 30 (personal communication, Dr. William Wood, 1995), and on page 34 (USEPA/600/BP-92/003, August, 1994). None of these appear in the Bibliography. Could you please find out to whom Dr. William Wood personally communicated? And then share it with us?

The scientists on the Commission should critically examine this draft report and absolutely insist upon the removal of all the politically motivated text. A professor would not tolerate a report of this caliber, if it were produced by a graduate student, similarly the NJDEP would no doubt criticize the regulated community for producing such a weakly-cited position paper that was to be used for setting risk goals. This Commission has one medical doctor, seven members with doctorate degrees and six college professors. As educators and scientists please critically examine the level of scholarship that is found in your report. We in the regulated community will have to live by the law and the resulting regulations, do not hand your responsibility for producing a report to the NJDEP.

This criticism of the Commission Report should not be taken in a totally negative manner. The Commission clearly articulated that there was no scientific basis for using a 10^{-6} cancer risk for setting remedial standards. The thoughts expressed in this draft report provides a point of departure, that I would hope will result in the introduction of new legislation removing the 'one-in-a-million' cancer risk as the only remedial goal for environmental cleanups in New Jersey.

Thank-you for the opportunity to express my views.

Sincerely,


J. Mark Zdepski, CPG
President, JMZ Geology



TESTIMONY BY DR. IRA L. WHITMAN, P.E.

TO THE

**ENVIRONMENTAL RISK ASSESSMENT AND
RISK MANAGEMENT STUDY COMMISSION**

DECEMBER 5, 1995

TRENTON, NEW JERSEY

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New Jersey State Library

**NEW JERSEY NAIOP TESTIMONY TO
ENVIRONMENTAL RISK ASSESSMENT AND
RISK MANAGEMENT STUDY COMMISSION**

BY DR. IRA L. WHITMAN, P.E.

DECEMBER 5, 1995

Thank you for this opportunity to testify before your Commission today.

I am Ira L. Whitman, Environmental Engineer and Principal Consultant with The Whitman Companies, Inc., an East Brunswick, NJ environmental consulting firm.

I am testifying today on behalf of the New Jersey Chapter of the National Association of Industrial and Office Properties (NAIOP), whose members are involved in the ownership, management, development, design and construction of office, industrial, and related commercial properties. NAIOP member firms provide more than 35,000 jobs for New Jerseyans and more than \$200 million in property taxes annually.

In 1990, NJ-NAIOP began working with the legislature and the Department of Environmental Protection to review the many problems associated with the ECRA law, and to propose significant changes. We worked for 2½ years to develop and present improvements to ECRA, many of which were incorporated by the New Jersey Senate and General Assembly into the 1993 ISRA law, Senate Bill 1070. We endorsed the creation of the Risk Management Study Commission as a means of bringing to the public's attention issues related to the 10^{-6} risk management standard, and as a forum for considering and assessing alternative standards and criteria.

- We believe that the Commission's report highlights many of the key issues surrounding the one in a million risk standard and provides a very useful conceptual framework with your three-tiered approach to site remediation as presented in Table 1.
- We agree with the Commission that the 10^{-6} excess cancer risk is an issue of public policy, and not of science. We concur that there is no real scientific basis for the 10^{-6} standard, but need to ask if 10^{-5} or any other prescribed risk level has any greater scientific basis.
- We support your conclusion that site remediation standards should be flexible, and reflect future use as determined by the site owner.

Apart from our general concurrence with the principles you put forth, there are some areas of your report which we find to be unclear and confusing, and others with which we disagree. The time available today only allows for a brief mention of some of these, but we will be pleased to provide you with comments in greater detail.

- The report does not clearly address the impact of the use of redundant conservative assumptions in the risk assessment process. Do these assumptions result in standards in which the conservative factors are compounded?
- It is not clear what ground rules would be utilized in choosing between the three alternative approaches presented in Table 1. Who will make this determination and how will disputes be dealt with? Is Tier II voluntary? Would site owners have the right to not accept Tier III cleanups by tenants on their sites and the restrictions associated with non-permanent remedies?
- We question the Commission's preference for permanent remedies, and the assumption made by the Commission that exposure and access controls will fail. EPA is presently moving away from mandatory permanent remedies. There are many sites in New Jersey where capping improves environmental quality. The disincentive to using a non-permanent remedy may result in no remediation and reuse whatsoever at many locations.
- We support your recommendation on the severance of liability. We agree in theory with the surcharge concept you recommend, but believe that it is not likely to be workable or equitable.

Our NAIOP review committee believes that the Commission's report will become an important vehicle for communicating risk management issues between state government, the regulated community, and the public. Therefore, we recommend that you meet with interested parties, including those who are testifying here today, to find ways to clarify your report and to present the key issues.

Since S1070 was enacted 2½ years ago, many other states have grappled with the same risk management issues as New Jersey. Progress has been made by some states in defining their risk management strategies and developing cleanup standards. At the federal level, EPA's policies of site remediation under CERCLA have evolved significantly, and further change may occur with Congressional reauthorization of Superfund.

We suggest that the Commission and NJDEP get "plugged into" national developments, possibly by convening a national conference on cleanup standards and risk management. We believe that New Jersey may stand to benefit from experiences in other states which have also had to consider the balance between sound policy and good science in developing cleanup standards.

NAIOP members wear many hats as owners of properties, buyers, developers, and sellers. We are keenly aware of the value of a clean property in today's real estate market, and the negatives associated with properties that are contaminated. Our members are often faced with considering the alternative consequences of engaging in a permanent remediation compared to owning properties subject to long-term engineering and institutional controls. S1070 and your recommendations, if enacted, affect us in many ways. We restate our belief that a healthy environment and a healthy economy go hand in hand.

In summary, we believe that the Commission's report represents substantial progress toward developing a rational approach to risk management and remediation standards. The immediate challenge is to clarify and articulate the Commission's approach, and to further the public discussion of how clean is clean, and at what cost.



**Oral Comments of HANDEX of New Jersey Inc before the New Jersey Environmental Risk Assessment and Risk Management Study Commission, December 5, 1995, Trenton, NJ
Presented by Tom Kady, President, Handex of New Jersey, Inc.**

Good Day. My name is Tom Kady. I am President of Handex of New Jersey.

Handex is an environmental consulting, engineering and remediation firm. We have specialized in subsurface hydrocarbon investigation and remediation for more than 15 years in New Jersey. We understand the complexities and practical limitations of subsurface remediation.

HANDEX supports the direction the Risk Management Commission is taking toward risk-based corrective action in New Jersey.

Society's limited resources require a practical, cost-effective, and consistent decision-making framework for setting environmental priorities and remediation goals. Most importantly, this decision-making framework must be scientifically defensible. We agree with the Commission that remediation decisions need to be based on risk, not on the ability to achieve a generic numerical value, the ability to apply a given technology, or the availability of financial resources to undertake a remediation. Remediation standards not based on risk assessment tend to drain limited funding, both public and private, from programs vital to protecting public health and the environment.

Through our 19 offices across the country, we are seeing an overwhelming trend of states adopting a risk-based decision process for environmental remediation. Our immediate neighbors (PA and NY) are moving toward implementation of a risk-based approach toward corrective action. To remain competitive from an economic development standpoint, New Jersey should strongly consider a risk-based approach as well.

In order to facilitate implementation of the Commission's recommendations, we urge the Legislature, the NJDEP and the Commission to consider ASTM Standard E - 1739 entitled "*Risk Based Corrective Action Applied at Petroleum Release Sites*" as a framework for decision making. The standard is being used by an increasing number of states as a framework for their own programs. We believe Standard E-1739 addresses many of the issues raised in the Commission's report.

While the Commission's study appeared to focus on soil remediation issues, we believe a risk-based decision process should be applied to all media -- soil, air, groundwater, and surface waters. An additional benefit to ASTM Standard E-1739 is that it does apply to all media.

In summary, we concur with the Commission's direction toward a risk-based decision process for environmental assessment and remediation. We urge the Commission, the NJDEP and the Legislature to consider ASTM Standard E-1739 as the framework for a risk-based decision process.

Thank you.

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December 13, 1995

Judith Horowitz
Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, NJ 08625

Dear Ms. Horowitz:

Attached are the written comments of Handex of New Jersey, Inc. on the report of the Environmental Risk Assessment and Risk Management Commission. This is in addition to our oral comments presented at the December 5, 1995 hearing.

In support of our oral comments, Handex of New Jersey is presenting some additional information on ASTM E-1739 and why we believe it should be the cornerstone of any risk based corrective action plan in New Jersey. Although E-1739 was developed for application at petroleum sites, the principles of risk assessment and the decision making process could be applied to other sites. We believe this Standard addresses many of the issues raised by the Commission and will help resolve conflicts between policy and science.

ASTM E-1739 (*Risk Based Corrective Action Decision Making Applied at Petroleum Release Sites*) or RBCA (pronounced "Rebecca") would address a number of the issues and concerns raised by the Commission including:

Acceptance

- Prepared and peer reviewed by a multidisciplinary team of experts and backed by a respected professional standards organization (American Society for Testing and Materials).
- Allows states to set acceptable levels of risk (ie 10^{-6} , 10^{-5} etc) since these are policy decisions.
- Used by states as a framework for their own programs. New Jersey can look at the experiences of other State agencies.
- Follows US EPA risk assessment and exposure assessment guidance documents which are also used by NJDEP.

- Encourages use of site specific data as recommended by the Risk Commission

Flexibility

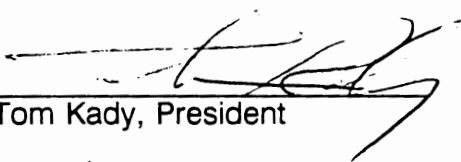
- Provides a framework for states to build their own program around
- Uses a 3 tiered screening and classification system, allowing for continuous improvement and sophistication of the risk assessment process.
- Encourages states to develop their own Tier 1 default values for soil, air and groundwater

Support

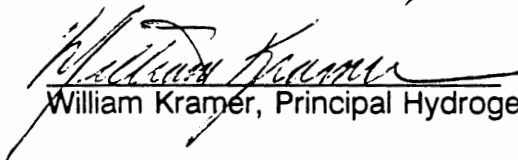
- Improvement of the Standard thru the ASTM process and committee E-50
- Support of the RBCA process by US EPA
- Availability of support systems (e.g. software) built around the Standard
- Ability to integrate the RBCA process with other ASTM environmental standards

Handex of New Jersey, Inc. is available to assist the Commission, the Legislature and the DEP on implementation of a risk based corrective action program for New Jersey.

Very truly yours,



Tom Kady, President



William Kramer, Principal Hydrogeologist

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Edward V. Sargent, MPH, Ph.D.
Diplomate, American Board of Toxicology,
Director of Toxicology and
Environmental Health

Merck & Co., Inc.
One Merck Drive
P.O. Box 100, WS2F-45
Whitehouse Station NJ 08889-0100
Fax 908 735 1388
Tel 908 423 7906



December 4, 1995

Risk Assessment and Risk
Management Study Commissioner
Trenton, New Jersey

Dear Commissioner:

Attached are comments prepared by Merck & Co., Inc. on the Risk Assessment and Risk Management Study Commission Report. Merck & Co., Inc. manufactures and markets human and veterinary health pharmaceuticals and is headquartered in Whitehouse Station, New Jersey.

Any questions related to the attached comments should be addressed to Dr. Edward Sargent at the above address. Thank you for the opportunity to present our comments.

Sincerely,

A handwritten signature in black ink that reads "Edward V. Sargent". The signature is fluid and cursive, with a large, stylized "E" and "S".

Edward V. Sargent, MPH, Ph.D.

/lbr
Attach.

139X

COMMENTS ON THE RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION REPORT

VI. EXAMINATION AND ASSESSMENT OF RISK ASSESSMENT METHODOLOGIES

Uncertainty Analysis and Conservatism:

This section does not address the broader issues of either of these topics but rather narrowly makes a statement that probabilistic approaches need to be developed and validated and that they eventually can be used to better define risk. This section could be expanded to include several key areas. First it must provide more discussion of the relationship between the over conservative nature of point estimates of risk and the use of standard default assumptions. Discussion in this area would go a long way in further supporting the need for probabilistic analysis. The other issue not discussed in this section is the fact that there are impediments to the use of probabilistic analysis. One of the major problems facing probabilistic risk analysis is that the risk managers who must use the output of the risk assessment to make decisions really do not understand how to interpret probabilistic data. Current practitioners in our estimation have not been good communicators of the technique. Added to this is that there is no incentive for risk managers to learn new techniques like this one and in some instances regulatory policy even precludes its use. The Commission recommends the development and validation of probabilistic approaches. This should go further to recommend improvement in the risk management decision making process to incorporate this type of information.

Environmental Fate and Transport Considerations:

It must be pointed out in any discussion of Environmental Fate that biodegradation should be considered a potential permanent remedy. Studies done to evaluate site specific biodegradation capability should provide data to support an argument that if the contamination can be contained for X number of years, that the compound will be degraded and rendered harmless to human health and the environment during that time period. This is a permanent remedy, but one which will perhaps require more time. The amount of time required to achieve a permanent remedy is mentioned in this draft under Section IX as possibly requiring 30 years. It appears however that this proposal only applies to groundwater and would not be considered a permanent remedy. We recommend that biodegradation be considered a permanent remedy that can be applied to both soil and groundwater.

VII. RECOMMENDED SITE REMEDIATION STANDARDS

As stated on page 7, the 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."

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The Study supports the USEPA risk assessment paradigm - stating reservations regarding 'broad based application of conservative assumptions' and strongly endorses the use of probabilistic risk assessment, however, the three-tiered approach to remediation standards provides a total disincentive to conduct a site specific assessment. Application of site specific physical parameters into the NJDEP proposed soil clean-up criteria algorithms (Tier 2) is not a site specific risk assessment. The equations, models and assumptions established by NJDEP in 1992 are set in time and make no allowance for the use of more scientifically defensible approaches in the evolving science of risk estimation. The Commission has made an unreasonable assumption that if the NJDEP default standards reinstated at $10E-05$ or some variation of the existing standards with site specific parameters are not met (Tiers 1 and 2), then the only alternative is an exposure control remedy in which liability is not severed and the clean-up is not permanent.

On page 34 and elsewhere there is a great deal of discussion about the use of 1 in a million as a de minimis risk level for carcinogens. It is pointed out, and correctly so, that this de minimis level is not based on sound science but rather policy. It is further pointed out that some states have adopted a one in 100,000 de minimis risk level without really defining the basis for it's adoption. The use of de minimis risk levels other than one in a million needs to be reviewed. In particular the basis for the decision to use 10^{-5} whether it be scientific or policy needs to be explored. This was one of the primary objectives of the Commission and therefore it must provide greater support for its recommendation. By not exploring the basis in sufficient depth the necessary support for a new risk level is not given. Subsequently it is going to be very difficult for the DEP to defend a relaxation of the 10^{-6} to 10^{-5} risk level to the public. The point in fact is that there really is no basis for either. One argument not brought out is that there are currently conflicting policies. The policy for acceptable risk for carcinogens emitted from a hazardous waste incinerator is 10^{-5} whereas it is 10^{-6} for carcinogens released in a spill to soil or groundwater. One might argue that the environmental media differs for the two scenarios. In fact however, they do not. The Indirect Pathways Guidance for assessing risk due to incinerator emissions requires one to estimate risk due to deposition onto soil, crops and surface water.

Frequency of Adverse Events:

This type of analysis has not normally been a part of standard Corrective Action risk analysis. One concern we have is that nowhere in the document is an adverse event defined. Is it a cancer, is it a case of non-cancer illness, or is it an increased exposure probability due to a trespasser on site. In the latter example is the event the trespass or the exposure. There is no guidance in this report on how this type of analysis will be conducted. If an adverse event is a cancer how will the background incidence be taken into account? We would recommend that this type of analysis not be included in this guidance.

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Permanent versus Exposure Control Remedies:

It appears that one incentive to select a permanent remedy is to levy a surcharge on all remediations.

The selection of a permanent remedy only allows you to be "eligible" for a surcharge reimbursement. What are the eligibility criteria? Explanation of surcharge reimbursement is confusing. On page 38 it states that "Sites remediated under Tiers 1 and 2 are eligible for surcharge reimbursement..." This can be interpreted that if Company X remediates its site under Tier 1 or 2, it can apply to the state and receive a reimbursement on the surcharge paid. It is not certain that this is exactly what the Commission had in mind when making this statement, thus the language needs to be clarified.

On page 38 it is stated that a Declaration of Environmental Restriction and listing in a proposed repository will still be required if sites are not remediated to residential criteria. A DER is essentially a deed restriction and thus a Company really does not sever its liability. The reality is that remedies must be appropriate for the use of the site. For example, at an active industrial site, engineering controls can be used to limit access and exposure to contamination. Exposure control for such a site should be considered permanent until such time that its use changes. If the use of the site evolves to something less controlled then the site should be re-evaluated for its new intended use.

Cost Benefit Considerations:

The concept of cost benefit consideration is important and a major consideration in the USEPAs Proposed Subpart S Corrective Action Rule (July, 1990). The Commission has not gone into depth on the consideration of costs in the selection of remedies except to say that in order to select an exposure control option over a permanent option, the permanent option must be 110% of the exposure control option. Nowhere in this discussion is the concept of technical feasibility brought out, another key element in considering appropriate remedies under the proposed subpart S. In terms of the cost issue, what is the basis for 110%?

IX. RECOMMENDED RISK ASSESSMENT APPROACHES

Generic and Site Specific Standards

This section appears in some way to be addressing protection of groundwater, although it's not specifically stated. Given that groundwater protection is one of the most significant issues in any remediation strategy further consideration should be given to such issues as defining points of compliance, establishment of groundwater standards - based on risk assessment (i.e., considering current and potential future exposures), and technically infeasibility to cleanups.

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Recommendation 4:

The Commission recommends a risk management standard of 10-5 for individual carcinogens and then confuses the issue with the next sentence. Is 10-5 to be applied cumulatively? It is not clear from the way the recommendation is worded, exactly what is meant. The last part of Recommendation 4 further confuses the issue by bringing in the USEPA flexible risk management structure. What was the purpose of doing this? Does this mean that the USEPA structure is being endorsed for cumulative risk? We would recommend that the language in ISRA clearly states that the health risk levels are established "for any particular contaminant and not for the cumulative effects of more than one contaminant at a site".

Recommendation 6:

There is no discussion about the surcharge reimbursement here. It is recommended that the method of surcharge reimbursement be clarified and repeated in this recommendation.

Recommendation 8:

This should go further and provide for support for improving the decision making process using probabilistic analysis. If this is not done Monte Carlo and the like will just continue to be nothing more than academic statistical exercises.

Recommendation 10:

The Advisory Board should have industrial representation. Industrial scientists with experience in environmental risk assessment in New Jersey and elsewhere will provide the practical insights necessary for a thorough evaluation of risk assessment policy. Precedence for industrial participation can be found in many New Jersey Advisory Groups including the Governors Right to Know Advisory Commission and the NJ DOH Occupational Disease Advisory Group.

COMMENTS TO THE ENVIRONMENTAL RISK ASSESSMENT
AND RISK MANAGEMENT COMMISSION

By:

Public Service Electric and Gas Company

December 5, 1995

144X

Good Morning Dr. Gallo and Risk Management Commission members. My name is Dr. John S. Dobi. I am employed as an Environmental Project Manager in the Environmental Management Department at Public Service Electric and Gas Company. In this capacity I manage the Company's superfund and third party sites and am responsible for managing and producing both the human health and ecological risk assessments associated with these sites. I hold a Ph.D. in Environmental Science and have twenty five years professional experience in environmental management. In addition, I am an Adjunct Professor at the NJIT in the Department of Chemical Engineering, Chemistry and Environmental Science where I teach the graduate level "Quantitative Risk Assessment" course.

PSE&G appreciates this opportunity and would like to thank the members of the Environmental Risk Assessment and Risk Management Commission (Commission) for their efforts in addressing the very complex and controversial human health risk assessment process associated with soil contamination and site remediation in New Jersey. We acknowledge and appreciate that the Commission has evaluated and adopted numerous comments PSE&G submitted during the 1994 public hearings.

Conceptually we concur with and support the Commission's recommendations. We particularly support recommendation three (#3), which acknowledges a risk management standard of 10^{-5} for Class A&B

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carcinogens to be an objective when developing soil remediation standards. A flexible approach to a risk management strategy would be consistent with the National Contingency Plan, such as the 10⁻⁴ to 10⁻⁶, cancer risk range accepted by USEPA at CERCLA sites. If this recommendation is accepted, New Jersey soil standards and risk management policies would be comparable to those in other states, e.g., Texas, California, Massachusetts and Louisiana. A practical example of a protocol for adopting a flexible risk management approach is identified in Table 1 of the Commissions report. Good science dictates that each site be assessed independently using site-specific information from which all risks are assessed. Site-specific risk assessments could significantly reduce a dependency on redundantly conservative default assumptions.

The Commission astutely embraces a tiered approach to site remediation which integrates both future land use and differential remediation criteria. An objective scientific undertaking of this nature may eventually lead to the development of "screening" values below which minimal risk is identified and therefore greatly reduce the need for a formal risk assessment.

If the "Acceptable Risk Levels" as identified by the Commission for both carcinogens and non- carcinogens are adopted and S-1070 (ISRA) is amended, two objectives will be achieved; first, public

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health and welfare will be protected, and, second only those sites determined by their future land use options and which are determined to pose an unacceptable risk will require remediation.

We strongly recommend that probabilistic analyses such as Monte Carlo simulations, as proposed by the Commission, where possible be applied to yield frequency distributions which will further reduce the reliance on redundantly conservative assumptions. The existing NJDEP soil remediation standards were developed through deterministic or single point estimates which has exacerbated a dependency on employing default values and inherently redundant assumptions. It is therefore essential that the necessary components of the risk assessment process be established during preliminary planning and scoping sessions of a remedial assessment work plan. The Commission's report appropriately identifies the significance and perspectives of valid fate and transport models to the risk assessment process.

PSE&G endorses the Risk Commission's recommendation (#10) to establish a "RISK ASSESSMENT AND RISK MANAGEMENT SCIENCE ADVISORY BOARD" to advise the NJDEP Commissioner on evolving risk policy based on generally accepted and peer-reviewed scientific evidence. If adopted, New Jersey citizens and elected officials will have a powerful tool to help shape environmental policies and assure that the State's resources are applied in the most effective manner.

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PSE&G requests that our legislators adopt the Commission's recommended approach to developing site cleanup standards. Doing so will enhance New Jersey's position as a business and environmental leader.

Thank you for your time and attention.

148X



Public Service Electric and Gas Company 80 Park Plaza, Newark, NJ 07102-4194

Environmental Management

December 19, 1995

Ms. Judy Horowitz
Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, New Jersey 08625

Dear Ms. Horowitz:

**WRITTEN COMMENTS IN SUPPORT OF THE ENVIRONMENTAL RISK
ASSESSMENT AND RISK MANAGEMENT COMMISSION BY PUBLIC SERVICE
ELECTRIC AND GAS (PSE&G)**

In support of our oral testimony on the aforementioned report at the Public Hearing on December 5, 1995, PSE&G is presenting additional written comments on the Risk Commission Report.

PSE&G's written comments are offered to assist the Risk Commission in developing a risk-based corrective action strategy for New Jersey. As such, while PSE&G agrees with the Risk Commission in principle, that remediation decisions need to be based on risk and future land use, we also suggest certain approaches be considered by the Commission, which take into account the practical limitations of subsurface remediation and the need for agreement with USEPA policies and procedures.

In summary, while we concur with the Commission's direction toward a risk-based management process for environmental assessment and remediation, PSE&G is prepared to work with the Commission, Legislature, and the NJDEP to develop site specific alternatives to protect the public health and the environment. Should you have any questions regarding our written comments, please contact Dr. John Dobi at (201) 430-8036 or Mr. Thomas Costantino at (201) 430-5869.

Sincerely,

A handwritten signature in black ink, appearing to read "E. B. Svenson", is written over the typed name.

Eric B. Svenson
Manager - Environmental
Strategy & Policy

attachment

The power is in your hands.

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COMMENTS TO THE ENVIRONMENTAL RISK ASSESSMENT
AND RISK MANAGEMENT COMMISSION

BY

PUBLIC SERVICE ELECTRIC AND GAS COMPANY

DECEMBER 19, 1995

150X

Dr. John S. Dobi of Public Service Electric and Gas Company (PSE&G) presented oral testimony before the Environmental Risk Assessment and Risk Management Commission (Commission) in Trenton, New Jersey on December 5, 1995 (Attachment #1). The following written comments provide additional information which supplement our oral testimony and elaborate on technical issues which PSE&G is confident that the Commission will consider during preparation of the final report.

As we testified, PSE&G conceptually concurs with and supports the Commission's recommendations. However, a number of the ten recommendations are ambiguous and may be difficult to implement if not clarified and further refined before legislative action is taken.

COMMISSION RECOMMENDATION #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 probabilistic analysis, physiological based/pharmacokinetic modeling, mechanistic toxicology, bioavailability (particularly from soil and sediment materials), and environmental fate and transport modeling to more accurately predict environmental risk.

PSE&G'S COMMENTS

PSE&G concurs with the Commission's Recommendation #1 and offers the following comments to identify some of the issues that may

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arise during implementation. The Commission acknowledges the applicability of the USEPA procedures for risk assessments performed at the 108 New Jersey Superfund sites. PSE&G's position is that for consistency and reproducibility the USEPA procedures should be incorporated within the New Jersey site specific risk assessments in their entirety.

Recommendation #1 lists several scientific tools which should be considered in developing site specific risk assessments. In the Report (page 28) the Commission considers only one toxicity model used to assess carcinogenic agents, i.e., the linearized multistage model (LMS). Numerous other toxicity models may be more appropriate depending on site specific data, such as the Weibull, Probit, Logit and Time-to-Tumor models. The toxicity assessment conclusions of the risk assessment will differ as a function of employing a more appropriate, though less conservative model.

The Commission appropriately acknowledges that USEPA risk estimates based on the LMS upper bound are high and that the unknown true risk may be as low as zero. When site specific data are incomplete or poorly distributed, the point estimate may be the only number available for use in the risk assessment. The most applicable toxicity model should be used to objectively and realistically estimate risk.

Establishing consistency between USEPA and New Jersey risk procedures will facilitate the risk based remedial option selection by both regulatory agencies and Potentially Responsible Parties (PRPs). This will certainly help assure that only scientifically defensible remedial options and actions are implemented to protect human health and the environment.

Congress is currently evaluating the reauthorization of Superfund legislation. A Congressional Committee proposes that states be delegated the authority to implement the Superfund regulations. If such a plan is adopted, risk assessment procedures would be more effectively implemented if both state and federal regulatory agencies used consistent processes.

Adopting regulatory consistency would significantly reduce policy differences at sites where both EPA and NJDEP and PRPs participate. Site specific risk issues would be based on "the best available scientific information and judgement to predict human health risk" as proposed by the Commission's Recommendation #1.

COMMISSION RECOMMENDATION #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.

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PSE&G'S POSITION

PSE&G concurs with the concept of developing a table as guidance for selecting remedial alternatives. However, PSE&G wants the Commission to modify Table 1 so that the complexities and ambiguities are removed.

The principles in Table 1 call for an acceptable risk range of 10^{-4} to 10^{-6} for carcinogens which is consistent with the risk range identified in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) and therefore are consistent with EPA's risk management strategy at Superfund sites. However, the requirements for a permanent remedy along with the associated incentives can lead to a confusing interpretation of the "Risk Management Standards" in Table 1.

The present configuration of Table 1 does not consider cross media contamination. Many sites have cross media contamination, i.e., ground water to surface soil to subsurface soil, as well as numerous types of contaminants, i.e., polycyclic aromatic hydrocarbons (PAHs) total petroleum hydrocarbons, metals or chlorinated solvents. When a site assessment at a complex site is conducted, the application of the risk based objectives of Table 1 becomes difficult. For example, soil matrix contamination at one site can become a groundwater problem at an adjacent site. PSE&G does not perceive a distinct advantage to implement a "permanent remedy" at a site only to become potentially

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responsible for off- site contamination from a remediated site in another media.

Many states, including New Jersey have CERCLA sites which have remained on the National Priority List (NPL) for over twelve years because the original remedial action did not achieve the remedial goal. The 1986 Superfund Amendments and Reauthorization Act (SARA) mandates that EPA demonstrate a preference for and select permanent on-site remedies in contrast to off-site treatment and disposal. Consistent with this policy EPA has pursued "permanent remedies" very similar to those identified by the Commission's footnote 1 to Table 1. Unfortunately the implementation of a true "permanent remedy" is a very elusive objective. Many complex federal and state sites involve industrial fill with numerous contaminants, are near residential or urban areas and other systems such as rivers, lakes, aquifers, and other natural resources.

If, for example, during or after the implementation of an EPA selected remedy, unanticipated contamination of other media are identified, regardless of having been identified as a contaminant of concern and remedial goal during the Remedial Investigation and risk assessment, EPA has available a number of policy options to respond to such a situation. These options exist because historically new and expanded site specific information is discovered during the implementation of a selected

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"permanent remedy". The final result can range from a complete Remedial Investigation with a new risk assessment through a focused Feasibility Statement with a new risk assessment.

The Commission must clarify Table 1 to account for a situation where the physical boundaries and contaminants at a "permanent remedy" selected site where liability has been severed, changes from the limits established in the Remedial Action Work Plan (RAWP). Many times during the site investigation phase of a project the original work plan is modified in response to newly discovered site conditions.

PSE&G recommends the scope of the "severed liability" option in footnote #1 be better defined by the Commission. Without a more descriptive definition of a site in regards to the "permanent remedy" option, implementation of Table 1 will be difficult. The Commission's explanation of a permanent remedy versus exposure control remedy on page 35 defines only the Commission's preference without incorporating the complex issues addressed in the section of the Report entitled "Environmental Fate and Transport Considerations in Risk Assessment" (page 31) and in the paragraphs under the section "Generic Standards" and Site Specific Standards" (page 39).

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COMMISSION'S RECOMMENDATION #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 standards 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 use 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.

PSE&G'S POSITION

PSE&G agrees with the adoption of a combined 10-5 residential and non-residential soil clean-up standard as the Commission's Recommendation #3 proposes. A New Jersey risk management strategy for contaminated soil of 10-5 is a much more practical approach to risk management than the current scientifically unsubstantiated 10-6 soil standard. However, it is not practical to assume that a PRP could "screen" the site against Tier 1 criteria and decide if remediation is necessary as the Report (page 38) implies. Table 1 is more applicable at sites with minimal contamination or at sites where a permanent remedy may be achieved.

The Commission's Tiered approach overlain by Table 1 is an attempt to be a decision tree matrix where risk management evaluations and remediation decisions must be made before the necessary site specific data are available and without having

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performed a risk assessment. The factors mentioned in the above paragraphs on defining the site for a permanent remedy is even more applicable to the "Exposure Control" scenario of footnote 2 of Table 1. Without risk assessment results, it would be difficult to determine the appropriate USEPA Carcinogen Classification (Column 1) which could ultimately affect the acceptability of an appropriate risk level, such as 10^{-4} or 10^{-5} .

A site selected under Tier 2 is also considered a permanent remedial option with severed liability. The Report correctly describes how and why "site specific analysis minimizes the application of NJDEP default assumptions and reduces the uncertainty of the assessment" (page 38). Once liability is severed at a Tier 2 site, it would not be necessary to record the site or impose a Declaration of Environmental Restriction (DER) even if the "site" is not remediated to residential standards. The level of remediation should be selected by determining the human health risks associated with a site. A remedial action decision made with the results of a risk assessment which is permanent and includes severed liability should not require compliance with residential standards. Selecting a Tier 3 "Exposure Control" option at a site can result in two risk Tiers applying at the same site.

The Tier 3 option which incorporates columns IV and V in Table 1 includes the largest range of risk from 10^{-4} through 10^{-6} . The

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amount of scientific site-specific exposure and fate and transport information required for Tier 3 is, by far, the most extensive and results in a complex risk assessment. Risk should drive site specific remedial options, not generate data to determine where a site fits on a matrix.

The requirements for Tier 3 are; "the cost of Tier 1 and 2, (permanent remediation) must exceed the cost of Tier 3 by 110%, it must be demonstrated that off-site receptors are not impacted by on-site contaminants (don't exceed Column IV in Table 1) and there is no severance of liability". The burden of these requirements makes Tier 3 the most difficult to achieve, even though it is the Tier that allows a lower risk, such as 10^{-4} for Class C carcinogens. The cost of remediating a site using Soil Vacuum Extraction technology can be one third the cost of incineration or excavation. When the remedial costs differ by two to three orders of magnitude, a permanent remedy would exceed the Tier 3 requirement by significantly more than the recommended 110%.

At many sites more than one form of remedial action may be necessary. USEPA has developed "Treatment Trains" under their Superfund Innovative Technologies Evaluation (SITE) Program primarily to respond to the sequencing of various technologies to remediated sites.

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Nowhere in the Commission's report are guidelines which describe how Tier 3 would be applied. PSE&G urges the Commission to provide clearer requirements for the application of the three Tiers in the final Report. The last sentence in the Report Section IX "Recommended Risk Assessment Approaches" (page 39) is "clean-up may result in sites that are utilizable for non-residential, as well as selected residential usage such that exposure to soils can be controlled". The relationship between the background technical information provided in the Report and the development of the risk values in Table 1 should be explained more definitively.

COMMISSION'S RECOMMENDATION #4

The Commission strongly supports a risk management standard of 10^{-5} for Class A&B carcinogens for calculation of soil remediation standards. Cumulative risk for using specific pathways 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 Substance Pollution Contingency Plan (USEPA, 1990) risk management guidance values of 10^{-4} to 10^{-6} .

PSE&G'S POSITION

PSE&G endorses the approach of a flexible management structure, with identified data quality requirements. At complex sites analytical results could significantly limit the possibility of achieving a cumulative 10^{-5} carcinogenic risk. The concentrations of many organic compounds are difficult to identify because constituents are very often masked by matrix interferences or by physical and chemical processes. For example, unless special acid

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washing techniques are employed early in the analytical process, the concentrations of constituent PAHs in a clay matrix could be incorrectly identified. The consequence could result in a gross over estimation of the contaminants and their concentrations leading to significant distortion of the actual risk to human health and the environment.

At Superfund sites, the data quality requirements in risk assessments is of paramount importance. As the Commission identifies in the Report (page 31), the ability to use probability analysis which yield "more realistic estimates of risk is dependent on the quality of input information". Without good quality data the risk assessment must be performed with much less accurate default values and point estimates.

Recommendation #4, if adopted, would help assure that the USEPA and New Jersey follow a similar flexible risk management strategy. However, for the process to be truly comparable, New Jersey would need to require similar data quality stipulations to those established by USEPA.

COMMISSION'S RECOMMENDATION #5

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

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PSE&G'S POSITION

PSE&G supports the concept of differential remediation criteria as a function of both risk and land use. However, Table 1, as currently composed, does not allow for the determination of residential and non-residential remediation criteria.

Differential remediation criteria are related to cancer classification and the three Tiers without a consideration for site land use objectives. The Commission should also clarify the non-carcinogenic risk segment of Table 1 to be better understand how differential remediation criteria would be applied at a site contaminated with both carcinogens and non-carcinogens. PSE&G strongly supports the position that differential site remediation criteria should be developed and consider both risk exposure and future land use.

COMMISSION'S RECOMMENDATION #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 clean-up, insure complete and comprehensive remediation, and provide a mechanism to protect human health and the environment.

PSE&G'S POSITION

PSE&G does not support the Commission's Recommendation #6. Recommendation #6 should be rewritten only after the surcharge issue has received an depth analysis and before any financial option or obligation is tied to a selected remedy.

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A company or Potentially Responsible Party (PRP) which is capable of providing a financial guarantee bond or is self-insured, should have the option of not paying a surcharge. Both technical and legal interpretations much be developed on the mechanism to implement a surcharge before the issue becomes final.

The likelihood of implementing a "truly" permanent remedy at complex sites is not very high. Many of the difficult scientific issues that must be evaluated during a site assessments to determine the nature and extent of contamination have been explained in our comments to Recommendation #1. Fate and transport issue reduce the probability of true permanent remediation. Scenarios such as the following could easily develop. The mechanism for liability protection against future PRP claims to someone who has incurred the expense of a "permanent remedy", paid the surcharge according to Recommendation #6 and received a severance of liability must be explained. The reverse scenario must also be evaluated in the context of applying a surcharge, e.g., off-site contaminants migrating onto a permanent remedy site. PSE&G encourages the Commission to explain a method by which the "initial responsible party", as identified in the Report (page 37), will be protected from other third party claims.

Recommendation #6 must better explain the purpose, the calculation process, how the surcharge will be applied and the

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how the dollars will be collected and administered. Unless the purpose and the objectives of establishing a surcharge are better explained, it can be perceived that the surcharge fund can be used to create a State Superfund to support NJDEP remediation strategies.

COMMISSION'S RECOMMENDATION #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 adoption of this report. The commission recognizes that complete severance of long terms 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.

PSE&G'S POSITION

PSE&G can not support Recommendation #7 without much more explanation on the methods to implement the surcharge.

Considerable technical and legal analysis must be performed before the contents of Recommendation #7 are adopted. The comments PSE&G made on Recommendation #6 also apply for the surcharge assessment in Recommendation #7.

Many selected and implemented remedial actions at Superfund sites did not achieve the remedial goals and objectives. As part of the remedial alternative evaluation of the Feasibility Study, several expensive treatability can be performed at a site. Consequently the "one to five percent assessed on all

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remediation" must be based on a specific cost estimate which Recommendation # 7 does not allow for. The total cost of site remediation very often includes significant NJDEP over-sight costs at both New Jersey Spill Act sites and New Jersey Superfund sites. The PRP or company that is assessed the one to five percent could essentially be double billed, first for the remediation over-sight costs then if the surcharge includes all remediation costs, a surcharge on the amount they originally paid. The options available to USEPA that enable them to respond to an unsuccessful remediation are included in our comments on the Commission's Recommendation #1. The basis for the one to five percent surcharge must be identified. The surcharge will disappear quickly especially if the physical limits of the site and the health risks at the site are not established early. The Commission's endorsement of Recommendation #7 indicates they recognize the likelihood that the permanent and exposure control remedies may not be "truly permanent". PSE&G encourages the Commission to resolve the technical and risk assessment issues before the financial and surcharge considerations are addressed.

COMMISSION'S RECOMMENDATION #8

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

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PSE&G'S POSITION

PSE&G supports the use of probabilistic analysis whenever possible to estimate human health risk with greater accuracy and precision. Risk assessments using exposure assessments derived from mechanistic point estimates can overstate risk issues and result in greater remediation than may be necessary to protect human health and the environment.

Probabilistic analysis, such as Monte Carlo, Latin Hypercube or similar computational models, requires very specific and high quality data as identified in the Report (page 31).

PSE&G encourages the Commission to specify data quality criteria requirements and incorporate same into the Report.

The data quality objectives, remedial goals and objectives, and future land use should be developed during the early RAWP scoping sessions. The more complex a site, the more important risk assessment will be. Probabilistic analysis will help achieve established remedial site objectives.

COMMISSION'S RECOMMENDATION #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 residential clean-up criteria.

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PSE&G'S POSITION

PSE&G concurs with the Commission's Recommendation #9. The relationship between a Tier 1 "permanent remedy" and the residential clean-up criteria should be made clear and incorporated into Table 1 as per Recommendation #5 comments.

COMMISSION RECOMMENDATION # 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.

PSE&G'S POSITION

PSE&G agrees with the Commission's Recommendation #10. The composition of an Advisory Board should include qualified scientists representing the industrial constituency.

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ATTACHMENT

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COMMENTS TO THE ENVIRONMENTAL RISK ASSESSMENT
AND RISK MANAGEMENT COMMISSION

By:

Public Service Electric and Gas Company

December 5, 1995

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Good Morning Dr. Gallo and Risk Management Commission members. My name is Dr. John S. Dobi. I am employed as an Environmental Project Manager in the Environmental Management Department at Public Service Electric and Gas Company. In this capacity I manage the Company's superfund and third party sites and am responsible for managing and producing both the human health and ecological risk assessments associated with these sites. I hold a Ph.D. in Environmental Science and have twenty five years professional experience in environmental management. In addition, I am an Adjunct Professor at the NJIT in the Department of Chemical Engineering, Chemistry and Environmental Science where I teach the graduate level "Quantitative Risk Assessment" course.

PSE&G appreciates this opportunity and would like to thank the members of the Environmental Risk Assessment and Risk Management Commission (Commission) for their efforts in addressing the very complex and controversial human health risk assessment process associated with soil contamination and site remediation in New Jersey. We acknowledge and appreciate that the Commission has evaluated and adopted numerous comments PSE&G submitted during the 1994 public hearings.

Conceptually we concur with and support the Commission's recommendations. We particularly support recommendation three (#3), which acknowledges a risk management standard of 10-5 for Class A&B

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carcinogens to be an objective when developing soil remediation standards. A flexible approach to a risk management strategy would be consistent with the National Contingency Plan, such as the 10^{-4} to 10^{-6} , cancer risk range accepted by USEPA at CERCLA sites. If this recommendation is accepted, New Jersey soil standards and risk management policies would be comparable to those in other states, e.g., Texas, California, Massachusetts and Louisiana. A practical example of a protocol for adopting a flexible risk management approach is identified in Table 1 of the Commissions report. Good science dictates that each site be assessed independently using site-specific information from which all risks are assessed. Site-specific risk assessments could significantly reduce a dependency on redundantly conservative default assumptions.

The Commission astutely embraces a tiered approach to site remediation which integrates both future land use and differential remediation criteria. An objective scientific undertaking of this nature may eventually lead to the development of "screening" values below which minimal risk is identified and therefore greatly reduce the need for a formal risk assessment.

If the "Acceptable Risk Levels" as identified by the Commission for both carcinogens and non- carcinogens are adopted and S-1070 (ISRA) is amended, two objectives will be achieved; first, public

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health and welfare will be protected, and, second only those sites determined by their future land use options and which are determined to pose an unacceptable risk will require remediation.

We strongly recommend that probabilistic analyses such as Monte Carlo simulations, as proposed by the Commission, where possible be applied to yield frequency distributions which will further reduce the reliance on redundantly conservative assumptions. The existing NJDEP soil remediation standards were developed through deterministic or single point estimates which has exacerbated a dependency on employing default values and inherently redundant assumptions. It is therefore essential that the necessary components of the risk assessment process be established during preliminary planning and scoping sessions of a remedial assessment work plan. The Commission's report appropriately identifies the significance and perspectives of valid fate and transport models to the risk assessment process.

PSE&G endorses the Risk Commission's recommendation (#10) to establish a "RISK ASSESSMENT AND RISK MANAGEMENT SCIENCE ADVISORY BOARD" to advise the NJDEP Commissioner on evolving risk policy based on generally accepted and peer-reviewed scientific evidence. If adopted, New Jersey citizens and elected officials will have a powerful tool to help shape environmental policies and assure that the State's resources are applied in the most effective manner.

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PSE&G requests that our legislators adopt the Commission's recommended approach to developing site cleanup standards. Doing so will enhance New Jersey's position as a business and environmental leader.

Thank you for your time and attention.

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New Jersey State Library

**JERSEY CENTRAL POWER & LIGHT COMPANY'S
ORAL TESTIMONY ON THE ENVIRONMENTAL RISK ASSESSMENT
AND RISK MANAGEMENT STUDY COMMISSION REPORT
December 5, 1995**

Good morning, my name is Colin Sweeney and I am the Manager of Site Remediation for Jersey Central Power & Light Company (Jersey Central). I am pleased to provide testimony today with regard to the Environmental Risk Assessment and Risk Management Study Commission (Commission) Report. Due to the time constraints, this oral testimony is only designed to provide an overview of Jersey Central's comments. My forthcoming written testimony will provide additional and more detailed comments.

Jersey Central has a long-standing commitment to conduct its operations and activities in an environmentally responsible manner. We also recognize that the importance of placing risks in their proper perspective is a critical issue facing society today. How successful we are in doing so will have a major impact on our ability to properly prioritize and utilize limited available resources. We believe that it is not only possible, but imperative to establish an approach that will be protective of public health while maintaining and promoting business in New Jersey.

Jersey Central commends the Commission for recommending the use of scientifically defensible exposure scenario alternatives such as probabilistic approaches, and the use of fate and transport models which consider site-specific physical conditions. These, and other recommendations made by the Commission with regard to risk methodologies, establish the framework for more realistic risk assessments. In keeping with the intent of ISRA, these methodological improvements would

move the risk assessment process away from the use of redundant, overly conservative assumptions. Jersey Central endorses the use of the site-specific risk assessment process which calls for using the best scientifically sound methodologies available. We believe that the use of site-specific assessments should move forward without delay.

The Commission was 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". Jersey Central commends the Commission for their thorough examination of the historical use of the 1×10^{-6} risk level and we agree with the conclusion that indeed no scientific basis exists for its use in environmental risk evaluations.

The Commission has attempted to establish a mechanism designed to create a preference for permanent remedies. It has done so by suggesting the application of a more stringent risk management standard to exposure control remedies as compared with permanent remedies. Whereas permanent remedies may be feasible and appropriate in some cases, it is likely that remedies employing engineering and institutional controls can also be implemented to effectively eliminate any risk associated with a contaminated site, and probably in a much more cost-effective manner. To state that a less stringent risk level should be allowed when implementing a permanent remedy versus a non-permanent remedy for the same site is hard to understand. When the NJDEP approves a Remedial Action Workplan, including one which contains a Declaration of Environmental Restriction (DER) as a component of the remedy, they have determined that the remedy described in the RAWP is protective of human health and the

environment. The DER stipulates the notification procedures and corrective actions required should any engineering controls be compromised. The RAWP also specifies any monitoring and/or maintenance procedures to be conducted to ensure the integrity of engineering controls. Therefore, the assumption by the Commission that engineering controls will eventually fail is, we believe, unfounded. Jersey Central believes the risk level for permanent and non-permanent remedies should be the same. We believe that a risk management standard of 1×10^{-5} is appropriate for EPA's Group A carcinogens. Further, we contend that a risk level of 1×10^{-4} is more appropriate for Group B and C compounds as they have not been proven to be human carcinogens and, therefore, should not be regulated to the same standard as Group A carcinogens. We suggest the Commission revise Table 1 to reflect that risk management standards of 1×10^{-5} for Group A carcinogens and 1×10^{-4} for Group B and C carcinogens be utilized, regardless of whether a permanent or exposure control remediation approach is used.

Whereas the severance of liability is certainly a further incentive to conduct a permanent remedy, Jersey Central believes that the surcharge of 1% to 5% proposed by the Commission should be elective and apply only to permanent remedies. To apply the surcharge to non-permanent remedies would constitute an unnecessary financial burden and, therefore, would be inconsistent with the intent of ISRA.

Jersey Central commends the Commission for its recognition that current and future site use should be considered in the risk management scheme and it is our hope that the NJDEP is receptive to the application of less stringent risk levels for sites designated for industrial use.

Jersey Central agrees that some type of Advisory Board should be established if only to examine new trends in risk assessment and provide recommendations to the NJDEP. In addition, Jersey Central recommends that such a body benchmark the progress of New Jersey in the area of risk assessment with other States' initiatives.

On behalf of Jersey Central, I want to extend our appreciation to the Commission for the opportunity to provide this testimony. We look forward to continuing to track the progress being made by the Commission concerning this important matter.

**JERSEY CENTRAL POWER & LIGHT COMPANY'S
COMMENTS ON THE ENVIRONMENTAL RISK ASSESSMENT
AND RISK MANAGEMENT STUDY COMMISSION REPORT
December 19, 1995**

Introduction

Jersey Central Power & Light Company (JCP&L) is pleased to provide comments to the Environmental Risk Assessment and Risk Management Study Commission Report (Report). The Commission was 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". JCP&L commends the Commission for their thorough examination of the historical use of the 1×10^{-6} risk level and we agree with the conclusion that indeed no scientific basis exists for its use in environmental risk evaluations.

JCP&L has a long-standing commitment to conduct its operations and activities in an environmentally responsible manner. We also recognize that the importance of placing risks in their proper perspective is a critical issue facing society today. How successful we are in doing so will have a major impact on our ability to properly prioritize and utilize limited available resources. We believe that it is not only possible, but imperative to establish an approach that will be protective of public health while maintaining and promoting business in New Jersey.

Risk Assessment Methodologies

JCP&L commends the Commission for recommending the use of scientifically defensible exposure scenario alternatives such as probabilistic approaches (e.g., Monte Carlo, Latin Hypercube), and the use of fate and transport models which consider site-specific physical conditions. These, and other recommendations made by the Commission with regard to risk methodologies, establish the framework for more realistic risk assessments. In keeping with the intent of Industrial Site Recovery Act (ISRA), these methodological improvements would move the risk assessment process away from the use of redundant, overly conservative assumptions. However, the Report does not adequately endorse those alternative risk assessment methodologies which have been found to be based in sound science. An endorsement by the Commission, even if qualified with precautions would provide responsible parties, as well as the New Jersey Department of Environmental Protection (NJDEP), with the framework to conduct site-specific risk assessment with the attendant result being the timely remediation of a larger number of sites.

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We would like to point out an apparent inconsistency in the Report. The Commission promotes the use of sound, peer reviewed toxicological data, physiologically based pharmacokinetics (PBPK) and mechanistic toxicology. However, at the same time the Commission recommends the use of EPA Cancer Slope Factors and Reference Doses which are not reviewed outside of the EPA. This inconsistency, we believe, will be misinterpreted by the NJDEP as an opportunity to continue with the "status quo" of applying redundant, overly conservative assumptions.

JCP&L endorses the use of the site-specific risk assessment process, as allowed under ISRA, which calls for using the best scientifically sound methodologies available. However, we do not believe that the application of site-specific risk assessment should be delayed any further by awaiting the development of a "decision tree"; this will only serve to further delay the cleanup of sites

With respect to site-specific risk assessment, the Report appears only to consider groundwater contamination. We submit that all environmental media must be addressed. JCP&L commends the Commission for their recognition that the current and anticipated use of the site must be considered. Former industrial properties that will be used in the future for industrial/commercial purposes should not be required to meet soil standards calculated using improbable future residential exposures.

Permanent versus Exposure Control Remedies

The Commission has attempted to establish a mechanism designed to create a preference for permanent remedies. It has done so by suggesting the application of a more stringent risk management standard to exposure control remedies as compared with permanent remedies. Whereas permanent remedies may be feasible and appropriate in some cases, it is likely that remedies employing engineering and institutional controls can also be implemented to effectively eliminate any risk associated with a contaminated site, and probably in a much more cost-effective manner. To state that a less stringent risk level should be allowed when implementing a permanent remedy versus a non-permanent remedy for the same site is illogical. When the NJDEP approves a Remedial Action Workplan, including one which contains a Declaration of Environmental Restriction (DER) as a component of the remedy, they have determined that the remedy described in the RAWP is protective of human health and the environment. The DER stipulates the notification procedures and corrective actions required should any engineering controls be compromised. The RAWP also specifies any monitoring and/or maintenance procedures to be conducted to ensure the integrity of engineering controls. Therefore, the assumption by the Commission that engineering controls will eventually fail is, we believe, unfounded. JCP&L believes the risk level for permanent and non-permanent remedies should be the same.

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Column V of Table 1 implies that, in order to implement a non-permanent remedy, the site must be remediated to a 10^{-4} risk level before the remedy is implemented. Again, the Commission is apparently (and in our strong opinion mistakenly) assuming the exposure control remedy will fail. ISRA specifies that non-permanent remedies are acceptable and clearly demonstrates a strong interest in ensuring that remediations are considerate of cost-effectiveness by specifying that the NJDEP cannot require the responsible party to implement a permanent remedy if the cost to implement it is more than twice the cost of the non-permanent remedy. Column V is blatantly at odds with this provision in ISRA and, as such, we propose that it be deleted from Table 1. JCP&L does not understand the rationale provided for establishing Column VI in Table 1. It is unclear what, if any, additional protection of human health would be derived with the application of such a risk standard. We recommend that Column VI be deleted from Table 1.

Whereas the severance of liability is certainly a further incentive to conduct a permanent remedy, JCP&L believes that the surcharge of 1% to 5% proposed by the Commission should be elective and apply only to permanent remedies. To apply the surcharge to non-permanent remedies would constitute an unnecessary financial burden and, therefore, would be inconsistent with the intent of ISRA.

Risk Management Standard

JCP&L believes that a risk management standard of 1×10^{-5} is appropriate for EPA's Group A carcinogens. In fact, policy makers now consider that an excess cancer risk level of 1 in 10,000 provides an adequate level of protection for small populations. This viewpoint is supported by the work of Dr. Curtis Travis and associates who in 1987 examined the basis for the most recent 132 health-based regulatory decisions made by the Federal government [Travis, 1987]. The regulatory decisions evaluated in Travis's study covered the broad spectrum of both public and occupational exposures for populations ranging from 9,700 to 230 million people. Dr. Travis found that where the estimated risk to a small population was less than 1 in 10,000, regulatory action was never taken. Conversely, for effects resulting from exposures to the entire U.S. population, the level of acceptable risk was usually set at one in one million. Clearly, the size of the potentially exposed population, as well as the level of individual risk, is being considered by public officials when making regulatory decisions.

Also, a directive from the Deputy Administrator of the U.S.EPA's Office of Solid Waste and Emergency Response (OSWER Directive 9355.0-30), noted that some action is warranted at Superfund sites when a cumulative site risk to an individual exceeds 1 in 10,000. These data are critical when examining the issue of acceptable risk levels for contaminated sites in New Jersey, since impacts from these site typically affect a limited geographic area, where the total potentially affected population is small. The Federal decisions and directives support the viewpoint that an appropriate risk for contaminated

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sites in New Jersey is 1 in 10,000 when site specific characteristics are considered. Such is the case when a quantitative risk assessment is performed.

Another major finding of the Travis study is that when the cancer risk is estimated to be between one in one million and 1 in 10,000, the primary determinant for regulation became cost effectiveness. A guidance document prepared by the EPA Deputy Administrator to EPA Regional Administrators on risk management, states that decision-makers should not be a captive of the numbers and should expect the same level of rigor from the economic analysis as they receive from the risk analysis (Habicht, 1992). Clearly, the EPA feels that cost is an important consideration in determining which levels of risk should trigger remedial actions. JCP&L believes that the Commission has not adequately examined the cost benefit issues as they relate to reducing overall risk from contaminated sites in New Jersey. The implementation of an exposure control remedy can effectively eliminate risk at less cost. We believe this will lead to more sites being remediated in a manner protective of human health and the environment and return such sites to productive use.

We contend that a risk level of 1×10^{-4} is more appropriate for Group B and C compounds as they have not been proven to be human carcinogens and, therefore, should not be regulated to the same standard as Group A carcinogens. We suggest the Commission revise Table 1 to reflect that risk management standards of 1×10^{-5} for Group A carcinogens and 1×10^{-4} for Group B and C carcinogens be utilized, regardless of whether a permanent or exposure control remediation approach is used.

Summary

The Commission has overstepped its charge by stating a preference for permanent remedies and, in particular, by creating an approach which would likely lead to further delays in cost-effective remediation.

JCP&L agrees that some type of Advisory Board should be established to identify and evaluate new trends in risk assessment and provide recommendations to the NJDEP. The advisory board should not review risk assessments submitted to the NJDEP. In addition, JCP&L recommends that such a body benchmark the progress of New Jersey in the area of risk assessment with other States' initiatives.

The Report contains inconsistencies in some key areas; the danger of this is that the NJDEP may continue to conduct "business as usual". We believe the Commission needs to provide language and cite currently accepted methodologies to combat this possibility.

JCP&L appreciates the opportunity to provide these comments to the Commission. We look forward to continuing to track the progress being made by the Commission concerning this important matter.

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References:

Graham, John D., 1993. (Center Director of the Harvard School of Public Health) "The legacy of one in a million". Risk in Perspective, Harvard Center for Risk Analysis, Volume 1, Number 1, March.

Travis, Curtis C. PhD.et. al, 1987. "Cancer risk management". ES&E Features, Environmental Science and Technology, Vol 21, No 5.

Henry F. Habicht, Deputy Administrator U.S.EPA. OSWER Directive 9355.030. Role of the Baseline Risk Assessment in Superfund Remedy Selection Decision. 1991.

Henry F. Habicht, Deputy Administrator U.S.EPA. (Guidance on Risk Managers and Risk Assessors. 1992.

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NEW JERSEY PETROLEUM COUNCIL

A DIVISION OF THE AMERICAN PETROLEUM INSTITUTE

150 WEST STATE STREET TRENTON NEW JERSEY 08608

TELEPHONE (609) 392-0800 FAX (609) 392-0775

J.E. BENTON, Executive Director
J.F. HOLTZ, Associate Director
J.A. MAXWELL, Associate Director

December 20, 1995

Judith L. Horowitz
Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, NJ 08625

Dear Ms. Horowitz:

The New Jersey Petroleum Council, the state affiliate of the American Petroleum Institute, compliments the Environmental Risk Assessment and Risk Management Study Commission on their efforts thus far.

We believe that incorporating site specific risk based corrective action decision making into corrective action programs in New Jersey is a much needed common sense and sound policy decision that will result in more remediation activity throughout our state, while protecting public health and the environment.

We offer the following observations on the Commission's Report:

- It appears to us that the report is focused on soil remediation standards as a result of the history of the ECRA/ISRA program and their emphasis on soil sampling and remediation. The Commission should emphasize that the risk management principles discussed apply to all media and all DEP remedial programs. Standards in Tier 1 should be expanded to include groundwater, air and soil exposure pathways. All relevant exposure pathways should be identified in Tier 1.
- It appears that the Commission's mission was clouded by several issues that are not related to risk based corrective action decision making, namely liability, and a preference for "permanent" as opposed to "non-permanent remedies".
- Current NJDEP philosophy is resistant to moving beyond numerical cleanup criteria that are comparable to Tier 1 default cleanup values. Often there is no site specific risk at Tier 1 because the exposure or potential for exposure is absent. Tier 1 should be a screening criteria, not necessarily a remediation trigger.
- The Commission should review and recommend that ASTM E-1739

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Risk Based Corrective Action Applied at Petroleum Release Sites be utilized as the basis for implementation of the Commissions recommendations. Although E-1739 is focused on petroleum release sites, the decision making principles and processes can be applied to other corrective action programs. An ASTM Committee is currently working on a modified risk based corrective action guide for application at non-petroleum sites.

- The ASTM E-1739 RBCA standard provides an effective approach for dealing with petroleum release sites. This is a consensus standard and has been thoroughly peer reviewed. E-1739 presents a three-tiered process for determining appropriate corrective action. The tiered approach was designed to address the variation in complexity of petroleum release sites. For a given site, increasingly sophisticated levels of data collection and analysis are employed as the decision process moves to higher levels of complexity. The three tiers are fundamentally different from the three tiers presented in the commissions report. In E-1739, regardless of the tier, corrective action can include remediation (either active or natural) engineering controls, and or institutional controls. In E-1739, decisions regarding mass reduction and or exposure pathway elimination to achieve a specified level of protection are based on risk reduction not permanence.

Specific Comments

- (page 20) - Utilization of ASTM E-1739 by DEP would insure the Commission's stated objective of establishing a consistent decision-making that is supported by sound, peer reviewed toxicological and exposure data.
- (page 32) - The Commission states that "the selection of the appropriate remedial action is, in effect a risk management decision. This is a critical policy point that needs more emphasis. For a risk based corrective action approach to be utilized, regulatory agencies need to redefine corrective action or remedial action as a risk reduction action. Unless this is done and accepted by the regulatory agencies, application of numerical cleanup criteria regardless of their impact on risk reduction will continue. The Commission needs to emphasize the importance of this concept and recommend acceptance of it.
- (page 35) - We question the intent and application of the statement that the "remediation criteria require an order-of-magnitude more stringent standard when exposure controls are employed". If the exposure route is eliminated, then the risk is eliminated. The statement implies that exposure elimination options would also require active contaminant mass removal. Is this the case? If the objective in remediation or corrective action is risk reduction why isn't exposure route elimination an equally valid option?

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- . (page 36 and 37) - The Commission is addressing liability issues but it is not clear how this is related to risk based corrective action decision making. It is certainly an issue in promoting remediation and development of contaminated sites in New Jersey but, we don't see that the liability issue is relevant in this context, based on the Commission's original directive from the Legislature.
- . (page 37) - The Commission also appears to be taking on the issue of the "slow pace of environmental remediation in New Jersey". We do not believe this was the role of the Commission. The Commission should restrict itself to risk based corrective action.
- . (page 37) - A remediation surcharge is suggested at perhaps 1-5% but it is not clear what the 1 to 5% is a part of. Is it 1-5% of the cost of the remediation? Isn't this a disincentive in itself to conduct remediation in New Jersey?
- . (page 38) - The three tiered approach is again focused on soil remediation standards. This is limiting and does not consider other exposure pathways besides soil. We recommend that the Commission consider air and water exposure pathways as well.
- . (page 38) - It is stated that Tier I is a "restatement of the current NJDEP Soil Cleanup Criteria". This statement in effect validates a set of numbers that have not yet been promulgated by DEP. The cleanup numbers are based on a set of generic inputs that are not site specific but are applied across the entire State of New Jersey. The Commission should not be accepting the soil cleanup criteria. Instead the DEP should be reevaluating the proposed Cleanup Standards that have yet to be promulgated as regulation in light of the recommendations of the risk Management Commission. It should be made clear that Tier I values use default assumptions that are not site specific and therefore do not represent site specific risks. If Tier I were used as a screening tool only, and responsible parties were allowed to move to a Tier II site specific analysis, many of these problems could be eliminated. The term "Cleanup Criteria" should be replaced with "Screening Criteria".
- . (page 42) - There are many other impediments to remediation in New Jersey that were not listed here. We do not believe the role of the Commission was to identify impediments to remediation but to clearly define the role that risk assessment should play in remedial decision making.

Permanent vs Non-Permanent Remedies

- . (page 32) - The Commission states that remedial decisions are risk management decisions. Exposure pathway elimination is a

valid means of risk reduction however the Commission implies that a penalty of some sort is imposed for achieving the goal that they state they want to obtain. The implication here is also that contaminant mass removal or transformation may be the only viable "permanent" remedy. Use of contaminant removal mechanisms in place of exposure pathway elimination for the sake of achieving a "permanent" remediation may impose higher risks on the community. Again, the interjection of the "permanent" issue is clouding the risk management decision making process.

- . (page 33 and 35) - We question the distinction between a "permanent" versus an "exposure control remedy." The implication is that exposure elimination is not permanent. We disagree with this contention. If the receptor is a water supply well and the corrective action decision (risk management decision) is to seal the well and connect the facility to a public water supply this would be an example of a "permanent" exposure elimination option that also eliminates the risk (no exposure = no risk). We urge the Commission to reconsider this distinction.
- . The Commission states that when compared to exposure control remedies, permanent remedies are the most desirable. This may not always be the case from a risk perspective. Permanent remedies (which include excavation, soil vapor extraction etc.) may result in health and safety risks that exceed the risks posed by an exposure control mechanism. For example, some remediation systems cause contaminant transfer from one media to another. Contaminants could be transferred from a media with no exposure pathway (soil) to a media with an exposure pathway (air) thereby increasing the risk by seeking a "permanent remedy."
- . (page 39) - The Commission should not set arbitrary criteria that must be satisfied prior to the application of Tier 3. For example, the "costs for permanent remediation (Tiers 1 or 2) must exceed 110% of the costs for the Tier 3 options".
- . (page 38) - The difference between Tier II and Tier III appears to be the level of effort placed into incorporating site specific factors. Is this the case? It appears that the Commission's Tier III is intended as additional refinement or continuous improvement of the risk assessment. Is this the case? Using permanent and non-permanent remedies in the discussion of the three tiers clouds the entire risk reduction objective.
- . (page 40) - The statement is made that "calculation of site specific cleanup standards should be encouraged." However, the implication is that as you improve the quality of the risk assessment you get further away from a "permanent" remedy which is supposedly desirable. There appears to be a conflict here that could be eliminated by taking the permanent vs non-

permanent issue out of the risk based decision making process. If the risk is eliminated it should not matter whether the remedy is "permanent" vs "non-permanent". Non-permanent options would require ongoing maintenance costs that would be considered as part of a risk management decision.

We concur with the Commission that a Work Group be established to implement risk based corrective action decision making in all appropriate DEP programs. However, there must first be a commitment by the legislature and DEP to develop and implement a risk based corrective action decision making system for all DEP programs. Without this commitment, the impact of the work group will be minimal. This group should be multidisciplinary and composed of the regulated community, EPA and DEP personnel, consultants, hydrogeologists and public health representatives. ASTM E-1739 should form the framework for a risk based corrective action decision making system for New Jersey. The Work Group should be charged with implementing E-1739 within the regulatory structure of New Jersey.

The New Jersey Petroleum Council and our member companies offer to assist the Commission, the Legislature and DEP in developing a risk based corrective action program for New Jersey. Please do not hesitate to contact us if you have any questions or need additional information.

Sincerely,

A handwritten signature in cursive script, appearing to read "John i. Maxwell", followed by a horizontal flourish line.

John Maxwell,
Associate Director

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4 December 1995

Michael A. Gallo, Ph.D.
Chairman
Environmental Risk Assessment and
Risk Management Study Commission
State House Annex
CN-068
Trenton, New Jersey 08625



Re: Comments on the *Draft Report of the Environmental Risk Assessment
and Risk Management Study Commission*

Dear Dr. Gallo:

I am writing to provide comments from Environmental Resources
Management, Inc. (ERM) on the *Draft Report of the Environmental Risk
Assessment and Risk Management Study Commission* dated November 1995.
ERM's comments on this draft document are as follows:

- 1.) General Comment: As is presented on page 7 of the draft report,
the Environmental Risk Assessment and Risk
Management Study Commission was
established, as required by ISRA, and given
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." While the draft report dated
November 1995 does address the fact that "the
use of one in a million excess cancer risk (10^{-6})
is an issue of public policy, not of science," the
draft report falls short of the ISRA mandate in
that absolutely no documentation is presented
to support the Committee's position that 10^{-5}
is a better standard.

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- 2.) Table 1: It might be helpful to identify which columns in the table correspond to the Commission's Tiers 1, 2 & 3 of the three-tiered approach to site remediation.
- The last row of column VI should not have a "1" in it because noncancer endpoints are not averaged over the 70 year lifetime as is indicated in the column heading. As the table is currently formatted, this cell should be blank.
- 3.) First Cited Page 12: The use of the terms "universe" and "constellation" seem out of place in an opinion piece on risk assessment methodology and risk management. Perhaps these terms could be replaced with less-"astrological" terms.
- 4.) Page 24: HEAST is not a database; it is a report. Therefore, the word "database" should be moved from its position following "(HEAST)" to follow "(IRIS)."
- 5.) Page 25: Noncarcinogenic substances are assigned reference doses (RfDs) for the oral exposure pathway AND reference concentrations (RfCs) for the inhalation pathway, if appropriate. The discussion of noncarcinogenic toxicity values should be expanded to include the RfC.
- 6.) Page 27: The last sentence of the 2nd full paragraph states that "this risk level was established by the USFDA for food additives and adopted by USEPA and NJDEP for certain other uses." It is assumed by the reader that the risk level being discussed in this statement is 1×10^{-6} , but the sentence should be reworded to clarify this, especially in light of the fact that the previous sentence discusses the NCP's 10^{-6} to 10^{-4} risk range.



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7.) Pages 29-31:

A great amount of effort has been devoted to the discussion of Monte Carlo analysis in the risk assessment process. Is it the Commission's position that NJDEP should endorse techniques such as Monte Carlo in developing the target risk levels or has the Commission included this discussion to support the use of Monte Carlo or other techniques for quantifying uncertainty in risk assessments performed in general for contaminated sites in New Jersey?



8.) Page 34:

No data is presented in the draft report which supports the use of 10^{-5} over 10^{-6} as the cancer benchmark. One place where supporting information should be placed is on page 34 following the 2nd full paragraph which discusses New Jersey's having adopted 10^{-5} for risk management for selected environmental exposures.

In support of the 10^{-5} cancer benchmark, ERM offers the following examples of various agencies supporting cancer risk levels higher than 10^{-6} :

Federal programs have often used target risk levels higher than 10^{-6} :

"OSHA's 'acceptable risk' range is far less stringent than EPA's. Based on a 1980 Supreme Court ruling for a benzene standard that found 1-in-1000 (10^{-3}) risk to be clearly significant and a 1-in-a-billion risk to be clearly insignificant, OSHA has often regulated to limit risk at 10^{-3} , which is the risk level EPA usually considers the starting point for greater controls on exposure. OSHA also faces a statutory requirement that its rules be economically feasible." (*Inside EPA's Risk Policy Report*, 2(6):24-25, 16 June 1995)

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"To be 'protective' of human health, EPA believes that cleanup levels for carcinogens must be equal to or below an upperbound excess lifetime cancer risk level of 1 in 10,000 (1×10^{-4}). As proposed today, cleanup levels would be selected within the upperbound 1×10^{-4} to 1×10^{-6} risk range during the selection of the remedy process." (FR 55(145):30804, 27 July 1990)



"For soils, the starting point action level (preliminary remediation goal) is 1 ppm for sites where unlimited exposure under residential land use is assumed. Higher starting point values (10 to 25 ppm) are suggested for sites where the exposure scenario is industrial. Remediation goals for ground water that is potentially drinkable should be the proposed MCL of 0.5 ppb." Referring to the preliminary remediation for PCBs in residential soils, the "concentration of 1 ppm PCBs equates to approximately a 10^{-5} excess lifetime cancer risk assuming no soil cover or management controls. The 1 ppm starting point for residential scenarios reflects a protective, quantifiable concentration for soil." Referring to the preliminary remediation goal for PCBs in industrial soils, "a more appropriate concentration at which to start analysis may be 10 to 25 ppm, since direct exposure is less frequent than for residential land use and higher concentrations will be protective.... Even assuming exposure equivalent to that in residential areas, these levels (10 to 25 ppm) are still within the acceptable risk range (approximately 10^{-4}) based on the direct contact exposure pathways, and in fact will reflect a lower risk due to the reduced frequency of exposure expected at the site." Regarding ground water exposure, the "proposed MCL for PCBs is 0.5 ppb reflecting a 10^{-4} excess cancer risk."

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(USEPA; *Guidance on Remedial Actions for Superfund Sites with PCB Contamination*; pp26-34; August 1990)

Other State cleanup programs use a 10^{-5} risk target:



Recently enacted (5 June 1995) amendments to Part 201 of the Natural Resources and Environmental Protection Act (1994 PA 451) established Michigan's acceptable level of risk resulting from exposure to carcinogens at 10^{-5} for residential, industrial and commercial sites. Previously, Michigan's cancer risk target was 10^{-6} . (Interoffice memoranda from A.J. Howard, Chief, Environmental Response Division, Michigan Department of Natural Resources regarding generic residential cleanup criteria (5 June 1995) and remedial action plans using generic industrial or generic commercial cleanup criteria and other requirements (6 June 1995))

Using 10^{-6} for the most exposed individual at a site is too restrictive:

Travis et al. examined risks from an extensive number of regulatory decisions reached by various Federal agencies and concluded that: 1) every chemical with an individual lifetime risk above 4 in ten thousand received regulation, whereas those with values less than one in a million remain unregulated and 2) for small populations, regulatory action never ensued if individual risks were less than one in ten thousand. (Travis, C.C., S.A. Richter, C.E. Crouch, R. Wilson and E.D. Klema. 1987. Cancer risk management. *Environ. Sci. Technol.* 21:415-420.)

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10⁻⁵ is within the realm of or orders of magnitude below everyday risks:

ERM participated in a risk assessment performed to evaluate the human health impacts of future developments planned to occur at a power plant site in Maryland. Part of the *Discussion* section of that risk assessment addressed commonplace risks. "It is recognized that voluntary and involuntary risks are not comparable. However, Rodericks et al. (1987) have reviewed the issue of comparing estimated risks to everyday risks in a general sense: Examination of risks of common human activities demonstrates a lifetime risk of one in 100,000 is within the realm, or orders of magnitude below, everyday risks that generally do not cause undue concern. These are risks that people, while they are aware of them and may have some concern or fear over them, do not in general alter their behavior to avoid. The risks of many activities greatly exceed the level of one in 100,000. In comparison to these background risks of 'everyday activities', a lifetime risk of 1 in 100,000 is relatively small. (Rodericks, J.V., S.N. Brent and G.C. Wrenn. 1987. Risk decisions in federal regulatory agencies. *Reg. Toxicol. Pharmacol.* 7:307-320)



9.) Page 35:

The discussion in the first full paragraph regarding the 10 cancers in 70 years versus 0.1 cancers in 70 years is unclear. Where have these numbers come from? Additionally, 0.1 excess cancer cases per 70 years could be very "important from a public health perspective" to an individual living downgradient of a site with known ground water contamination.

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10.) Page 38:

In the Tier 1 approach, the Commission indicates that 10^{-5} should be used for both residential and industrial settings. It has been ERM's experience that USEPA will allow 10^{-4} for industrial sites. Thus, the Commission's recommendation would, in actuality, propose a more stringent target risk level than is enforced by USEPA in some situations.



11.) References:

Current citations were not provided for at least two of the references. Specifically, the following references should be inserted for reference numbers 2 and 88, respectively:

American Cancer Society (1995). *Cancer Facts and Figures-1995*.

USEPA (1995). *Health Effects Assessment Summary Tables, FY-1995 Annual*.

EPA/540/R-95/036. Washington, D.C. May.

ERM appreciates the opportunity to provide comments on the *Draft Report of the Environmental Risk Assessment and Risk Management Study Commission*. Please feel free to contact me at (609) 895-0050 with any comments and/or points of clarification.

Sincerely,

Randy L. Shuler, Ph.D.
Project Scientist

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Risk Assessment: A Tool for Increasing Pollution, not Minimizing Risk

From Lois Gibbs "Risk Assessment: A Community Perspective"

- who is being asked to take the risk and who is getting the benefit?
- risk assessments are "the risks that someone else has chosen for you to take"
- risk assessments are used to justify victimizing poor communities or communities of color
- they are almost always cancer risk assessments, when other problems are of equal concern
- don't take into account exposure of people who are already sensitive for other reasons
- exposure in real-life situations is to a complex mixture of chemicals, risk assessments based on exposure to a single compound

Not based on science, if it were based on science (see above) the risks would be much greater than normally calculated

- we should not forget that the end result of a risk assessment is an opinion, not a fact, and that these opinions may be wrong
- often risk assessments are used by polluters and government agencies to justify bad decisions that protect special interests
- risk assessments are used to justify dumping huge quantities of toxic chemicals into rivers and lakes and to justify leaving families in communities that are heavily polluted despite having statistically significant adverse health outcomes

Other points about New Jersey's work on this issue:

The trend in risk assessment is **always** in the wrong direction -- always in the direction of saving industry money and never in the direction of being more protective of public health.

Industrial vs. Residential: Under Superfund, an industrial site located adjacent to residential sites may be classified as residential. It is a very dangerous precedent to make a distinction between the two in many situations throughout New Jersey.

One kind of chemical (known carcinogen) vs. Another kind of chemical (suspected carcinogen): Run the risk of underestimating the risk of one or both chemicals, ignores the fact that exposure to more than one chemical may increase risk of negative health effects, synergistic effects

Pathways of Exposure: Can ignore evidence that certain chemicals are dangerous no matter what the pathway of exposure is

Temporary vs. Permanent Remedies: Sometimes, it is impossible to tell the difference. Even those so-called "permanent" remedies are really nothing more than temporary containment, or removal of contamination from one site only to move it to another, creating a new problem at the second location. This creates still one more level of distinction, which once again introduces the possibility of overlooking real risks and adopting a "solution" that is less than adequate to protect the public health.

Cleaning up based on the proposed future use of the land: Another risky operation, which may result in unnecessary and unhealthy exposures to workers, consumers and others who utilize the premises of buildings constructed on contaminated land. Once we start allowing more and more contamination to remain at a location because we don't anticipate it being used as residential property, we are relagating ourselves to a legacy of increased community-wide contamination. The contamination won't stay on the piece of property we have developed. It will still be in the environment.

Examples:

Westinghouse in Bloomfield: Opted to allow Westinghouse to clean up to "industrial standards" rather than residential standards, despite the many homes within 1 mile of the site, despite the observed evidence of cancers, despite the desire of local community for stricter standard to be achieved

Chromium Waste in Jersey City: 150 total sites, many residential which are adjacent to industrial, splitting chromium into chromium 6 and chromium 3 despite the fact that there is no reliable way of finding out which is which and how much of each chemical exists, ignoring evidence of the dangers of both kinds of chromium and all of the points made above

More Arguments Against the Kind of Risk Assessment Being Employed, Particularly in Jersey City

Special Status for Chromium:

1. NJ Legislature gave Hudson County chrome site special status and indicated on several occasions that the chromium would have to be TREATED OR REMOVED. The risk assessment process being conducted by DEP will allow the chromium to remain where it is, with no treatment. The alternatives stated by the legislature **did not** include leaving it in place, covering it with soil, or walking away from it, all alternatives supported by the current risk assessment process.

2. January 1993, Senator McNamara, sponsor of S-1070 stated, "Because of chromium being as toxic a chemical as it is, the only way you can treat it is by removing it."

3. C.58: 10B-12 35(h)(1): Historic fill (old waste) material shall not include any material which is substantially chromate chemical production waste or any other chemical production waste or waste from processing of metal or mineral ores, residues, slags or tailings. (From ISRA)

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DEP Not Recognizing the Problem:

... the fact that effects have been found to both chromium 6 and chromium 3:

- a. The International Agency for Research on Cancer in France considers chromium 6 a carcinogen by all routes: inhalation causes lung cancer, ingestion causes stomach cancer
- b. According to a 1979 study on contact dermatitis, exposure to trivalent chromium on industrial leather gloves, at levels of 1200ppm to 36,000ppm can cause allergic contact dermatitis. The DEP is considering to change standard to 78,000ppm. This would render all previously contaminated sites magically clean.

Dangers in Site-Specific Risk Assessments

All of the above mentioned problems created by the misapplication of the principles of risk assessment and the very real need, when dealing with the quantities and toxic qualities of so many of the contaminants present in our environment, to err on the side of safety, as opposed to making more and more concessions to the polluting industry.

Submitted by:

*Madelyn Hoffman
Director, Grass Roots Environmental Organization (GREO)
P.O. Box 146
Flanders, New Jersey 07836*

(201)252-0797

December 19, 1995

Comment to the Environmental Risk Assessment and Risk Management Study Commission Draft Report

Michael A. Gallo, Ph.D., Chair

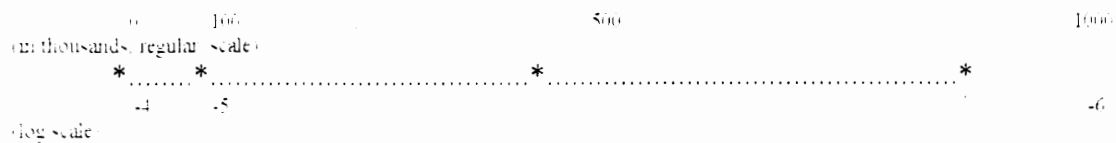
Reviewing the Use of 10^{-6} as the New Jersey Cleanup Criteria and Advise for Caution Concerning Movement to a 10^{-5} Risk Based Cleanup Criteria

Comments by

Arnold L. Gray, Ph.D., Kristin Alexandersen, Chris Bullock, Anthony Galasso,
Michael Gazaleh, Jennifer B. Gifford, Amy Godfrey, Matthew Kreiger,
Marc Kurhansade, Renee McLaughlin, Kathleen Nolan, David D. Podobel,
Christopher Roth, and James Shaflucas

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The cleanup criteria in New Jersey for carcinogens in the soil is presently 1×10^7 or 1:1,000,000. While this criteria--devised for food additives--is inappropriate when applied to industrial soil contamination, the Commission recommendation to move to 1×10^5 or 1:100,000 seems an extreme over reaction. There are smaller steps that can be taken. The problem seems to be tied to the notion of using whole number exponents. Put in order, 10^{-4} , 10^{-5} , 10^{-6} seem to be in much the same ballpark in terms of protection to the public. The use of scientific notation in this case is misleading. Below is a number line that shows the jump from 10^{-6} to 10^{-5} with each dot representing 10,000.



Viewed in a normal scale, the impact of moving one exponent is more clearly defined. It is interesting to note that at 10^{-4} proposed for industrial contamination, protection is virtually zero.

It has been noted in testimony that there is no scientific basis for 10^{-6} . This is correct. There is, however, no scientific basis for any cleanup criteria--this is purely a public policy decision, and nothing more. Despite all testimony about the inappropriateness of 10^{-6} , adequate toxicology exists for only 2-3% of the more than 70,000 substances used to make five million products (Mukerjee, 1995). In issues where doubts far exceed knowledge, we must move cautiously. The committee should not fall into the trap of thinking that its only recommendations has to be with whole number exponents. Instead of jumping 10X, it is possible to cut the clean up levels in half, i.e., 1:500,000, or any other number the committee deems appropriate. It may then express that figure in scientific notation if it chooses. If the

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clean up criteria was eased by one half, for example, then the exponent would be -5.69897 for a scientific notation value of $1 \times 10^{5.69897}$.

When determining soil cleanup levels and criteria, a factor that must be considered is the possibility of having more than one contaminant present in the soil. There are a variety of consequences that may occur in this situation. One is that the interaction of the two contaminants will have no effect at all, either positive or negative. The best possibility would be that the two contaminants would "cancel" each other out, but this is unlikely. Another consequence that may occur as a result of combining two contaminants is one harmful element may "infect" a harmless element, causing the harmless one also to become toxic. For example, chlorine gas can be dangerous at certain levels and is used in small amounts to purify water. When it reacts with harmless, organic substances found in water, it forms chloramines, substances that may be toxic or carcinogenic.

The worst-case scenario that could occur is the combination of two chemicals that could be synergistic. That is, the effects of a pollutant are sometimes the result of interactions with other substances, causing them to be more harmful than the separate components combined. The presence of two contaminants may also have a lag-time effect. When a soil contaminant is first tested, the toxicity may be relatively low, allowing the soil to meet the criteria. However, when a lag-time effect occurs, the contaminants will have a more toxic or carcinogenic effect over time.

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There are currently no studies that examine the impact of having two or more contaminants in a medium in terms of increased carcinogenicity. At very least, we should expect the substances to have an additive effect. Currently in New Jersey, at the 10^{-6} criteria, this is not done. Benzo(a)pyrene and Dibenzo(a,h)anthracene--together with many other known carcinogens-- may be present at their cleanup criteria without triggering a cleanup. While this uncertainty was acceptable at 10^{-6} , it would certainly not be at 10^{-5} . Since it is the duty of the State to protect human health and safety, the safety of mixed contaminants must be demonstrated to be below the new total criteria. This will prove exceedingly costly to industry.

In addition to the problems outlined above, industry has also testified that where the carcinogenicity of a substance has not been proved for B and C levels as defined by the draft report, 10^{-4} should be employed. Unlike citizens, chemicals are not presumed innocent until proven guilty. It is the responsibility of the producer of the chemical to demonstrate and assure its safety.

It has been proposed that New Jersey "*join other states*" in adopting a contamination limit of 10^{-5} . It should first be noted that adopting a level because another state has done so fails to demonstrate the scientific basis for decision making for which industry calls. Second, direct comparison of states is inappropriate. New Jersey has the second highest population per square mile in the United States (1,062.0), with industrial and residential sites in close proximity. New Jersey also has a cancer rate that is 50% higher than the national average (Najem, 1988). The types of industry also varies from state to state. The petrochemical industry is the major business in New Jersey, which

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poses a high risk for soil and groundwater contamination. What has to be stressed is the particular threat of contact. In New Jersey, because we are densely populated, there is a higher risk of contamination from releases.

The cleanup criteria that has been proposed will prove to be detrimental to industry itself. The current criteria may, indeed, be too severe; however, the proposed revisions are not strict enough. The establishment of criteria that is somewhere *between* the current and proposed figures (10^{-4} and 10^{-5} , respectively) will not only secure human health and safety and the integrity of our natural environment, it will also protect industry.

While it may be that industry can escape regulation, it will never be able to successfully avoid the liability associated with contaminated sites. This is due, in part, to various environmental statutes that have been enacted by Congress. In particular, the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) has provided the government with an explicit protocol for dealing with hazardous contamination. CERCLA establishes a level of liability to tie concerned parties to contaminated sites. Liability, in this case, refers to financial responsibility. Potentially responsible parties may be legally identified as responsible for cleanup even if they had relatively little involvement with the site difficulties. Potentially responsible parties can include present and past owners and operators of the site, transporters of the substances to the site, and generators who produced the substances. Joint and several liability may be assigned, meaning that the responsible party may be appointed all, or any part, of the liability. Therefore, although a company may have been involved with only a small aspect

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of the contamination of a site, it can be held responsible for all associated cleanup costs.

Liability is also retroactive, whereby companies are responsible for their contamination regardless of when it occurred and whether or not they were in compliance with existing laws. Strict liability applies as well; this means that even if a company met all requirements existing at the time of contamination, problems occurring today still put them under the purview of CERCLA (Kubasek and Silverman 1994).

The general public will also hold industry liable for its contamination. In fact, the public is often times more aggressive in pursuing such cases than is a government regulatory agency. The public can hold industry responsible through statutes such as CERCLA, or through personal tort lawsuits for damages to person and property. If the proposed criteria revisions are instituted, the public is likely to view the changes as industry's way of selecting cost-effectiveness over the desire to achieve truly safe, clean conditions for humans and the environment. Such a decision will not settle very well with most citizens, especially those who may be directly affected by it (either presently or in the future). The public has worked on many occasions, both alone and in conjunction with the government, to hold industry responsible for their contamination to the fullest possible extent. While New Jersey may offer regulatory relief, it is simultaneously setting corporations up for future lawsuits. It can now always be argued that the company chose a lesser standard of protection despite knowledge of the risk.

What is particularly disturbing is that there are far better ways to combat high remediation costs without increasing risk to the public. New Geographic Information

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System (GIS) technology now offers opportunities for cost savings in remedial activities never before possible. In the past, the government needed to remediate any contaminated sites immediately, due to the fact that any data collected pertaining to these sites could not be reliably stored or retrieved as needed. Therefore, remediation occurs in numerous hazardous sites and millions of dollars are spent because no one can afford the possibility of allowing the waste to reach a receptor. Some sites may not need be remediated immediately but economics and the human risk factor necessitates action to be taken. GIS is an integration of hardware, software, geographic data, and personnel.

GIS can overlay different graphs and features in order to integrate many different aspects of the ever changing environment pertaining to the location, weather condition, trends, or any other features. GIS can also store non-spatial data and is also capable to be used in conjunction with other programs. Because of this, the GIS enables the government or any company to monitor the contaminated sites of interest. GIS can detect any pathways and receptors within the regulated vicinity of the contaminated site. Sometimes inorganics can be remediated in the future as long as it poses no threat to the surrounding environment and groundwater table. Then the site can be remediated when it is economically feasible. Organics tend to break down naturally over a period of time and can sometimes be left alone and nature will accomplish the biodegradation of the chemicals. This offers much greater savings to New Jersey corporations than lowering the cleanup criteria without any of the ancillary liability risks.

209X

We still attack pollution from the wrong end, however. *Generous* tax credits

~~should be provided to industry to develop methods of pollution prevention. It is cheaper~~

and safer to avoid contamination than it is to remediate contamination. Simple engineering structures like diked, impervious structures in loading zones, waste reduction, and recycling offer significant benefits in terms of cost savings in production activity.

In closing, industry can achieve far greater cost savings through the implementation of new technologies that are now making their way to market than by moving to risky contaminant policies. The savings today may be the seeds of tomorrow's financial tort disaster. In view of these facts, the committee should consider modification of its recommendations from 10-5 to 10-5.69897 (one in 500,000) or even 10-5.39794 (one in 250,000). Better yet, the committee should recommend creation of a task-force to investigate and propose more wide-ranging proposals to provide significant cost savings to industry while maintaining a high level of protection for the citizens of the State of New Jersey.

BIBLIOGRAPHY

Frank-Stromborg, Marilyn, Krafka, Barbara, Gale, Danielle, "Carcinogens: Are Some Risks Acceptable?", American Journal of Nursing, V 86, July 1986, P 814-817.

Kubasek, Nancy K. and Gary S. Silverman, *Environmental Law*, Englewood Cliffs, New Jersey: Prentice Hall, 1994.

Spirtas, Robert, Steinberg, Marsh, Wands, Ralph C, Weisburger, Elizabeth K, "Identification and Classification of Carcinogens", American Journal of Public Health, V 76, October 1986, P 1232-1235

210X

**Fuel Merchants
Association
of
New
Jersey**

STATEMENT OF

ERIC DEGESERO, ASSOCIATE DIRECTOR

FUEL MERCHANTS ASSOCIATION OF NEW JERSEY

BEFORE THE

ENVIRONMENTAL RISK ASSESSMENT AND MANAGEMENT COMMISSION

DECEMBER 5, 1995

211X

GOOD AFTERNOON. MY NAME IS ERIC DEGESERO AND I AM AN ASSOCIATE DIRECTOR OF THE FUEL MERCHANTS ASSOCIATION OF NEW JERSEY (FMA). FMA REPRESENTS APPROXIMATELY 300 INDEPENDENT PETROLEUM MARKETERS IN THIS STATE.

FMA ENDORSES THE BASIC PREMISE OF THE ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION. NAMELY, THAT CLEAN-UPS SHOULD BE BASED ON SOUND SCIENTIFIC STANDARDS WHICH ANALYZE ACTUAL RISKS TO HUMAN HEALTH.

WHILE THE REPORT IS FOCUSED ON CLEAN UP STANDARDS FOR INDUSTRIAL SITES, AS OUTLINED IN THE INDUSTRIAL SITE RECOVERY ACT (ISRA), FMA URGES THE COMMISSION TO TAKE INTO ACCOUNT A SPECIFIC CIRCUMSTANCE WHEN RISK BASED CLEAN UP CRITERIA SHOULD BE APPLIED TO RESIDENTIAL PROPERTIES, NAMELY INCIDENTS WHERE THERE HAS BEEN A DISCHARGE FROM AN UNDERGROUND FUEL OIL TANK.

FMA HAS BEEN EXTREMELY PROACTIVE IN ITS EFFORTS TO AFFORD HOMEOWNERS THE MOST PROTECTION POSSIBLE IN THE RARE INSTANCE THAT A FUEL OIL TANK SHOULD HAVE A DISCHARGE. I SAY RARE BECAUSE A 1995

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STUDY BY THE ENVIRON CORPORATION STATES THAT THE FREQUENCY OF RELEASES FROM EXEMPT USTs (i.e., FUEL OIL TANKS SINCE EPA DOES NOT REGULATE THEM, ALTHOUGH NJ DOES WHEN THEY ARE ABOVE 2,000g AND USED FOR COMMERCIAL PURPOSES.) IS LESS THAN 1%.

FMA HAS DESIGNED THE HOMEOWNERS ENVIRONMENTAL LOSS PROTECTION (H.E.L.P.) PROGRAM WHICH AFFORDS HOMEOWNERS UP TO \$ 100,000 TO CLEAN UP A DISCHARGE. HOWEVER, FOR THIS PROGRAM TO BE ULTIMATELY SUCCESSFUL RISK BASED CLEAN UP STANDARDS FOR #2 FUEL OIL MUST BE PROMULGATED. UNFORTUNATELY, THE CURRENT CRITERIA IS NOT BASED UPON RISK BASED STANDARDS.

THESE STANDARDS MUST TAKE INTO ACCOUNT THE FACT THAT THE BENZENE PRESENT IN THE TOTAL PETROLEUM HYDROCARBON (TPHC) CONTENT OF #2 FUEL IS IN DE MINIMIS QUANTITIES. ASIDE FROM THE REDUCED LEVELS OF BENZENE #2 FUEL OIL IS RETAINED IN SOIL TO A DEGREE FOUR TO FIVE TIMES THAT OF GASOLINE.

FMA BELIEVES THAT RECOMMENDATION #5 IN WHICH THE COMMISSION ENDORSES THE NJDEP POLICY OF DIFFERENTIAL REMEDIATION CRITERIA FOR RESIDENTIAL AND NON-RESIDENTIAL SITES SHOULD BE AMENDED TO THE EXTENT THAT IT INCORPORATES THE THOUGHTS REFLECTED ON PAGE 20 AND

IN RECOMMENDATION #1. SPECIFICALLY, THAT SCIENTIFIC INFORMATION BE USED TO DETERMINE RISK AND THAT SPECIFIC DATA, WHICH INCORPORATE THE PROPERTIES OF #2 FUEL OIL BE USED IN DETERMINING A CLEAN UP STANDARD AND NOT AN DEFAULT ASSUMPTION.

FMA WILL PROVIDE FURTHER COMMENTS TO THE COMMISSION AND LOOKS FORWARD TO WORKING WITH ITS MEMBERS AS THIS PROCESS ADVANCES.

THANK YOU MR. CHAIRMAN.

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ENVIRON

December 18, 1995

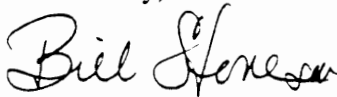
Federal Express

Judith Horowitz
Office of Legislative Services
State House Annex
Room 381
CN068
Trenton, NJ 08625

Dear Ms. Horowitz:

Enclosed are comments on the November 1995 *Environmental Risk Assessment and Risk Management Study Commission Report*. These comments were prepared by ENVIRON Corporation on behalf of the Fuel Merchants Association. Please call either one of us at (609) 452-9000, if you have any questions.

Sincerely,



William A. Stone, Jr.
Principal



Stephen T. Washburn
Principal

WAS/STW:jlm
bpstw:horowitz

Enclosure

cc: E. Degesero, FMA

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**COMMENTS BY THE FUEL MERCHANTS ASSOCIATION ON THE
ENVIRONMENTAL RISK ASSESSMENT AND
RISK MANAGEMENT STUDY COMMISSION REPORT**

The Fuel Merchants Association (FMA) would like to commend the Environmental Risk Assessment and Risk Management Study Commission ("Commission") for its efforts in evaluating the role of risk assessment in establishing remediation standards in New Jersey. We strongly advocate the use of risk-based standards in New Jersey, and concur with the Commission's recommendation that the best available scientific information and judgement be used to predict human health risk.

One critical issue not directly addressed by the Commission Report is New Jersey's current guidance for total organic constituents in soil. NJDEP has set an upper limit of 10,000 ppm for total organic constituents in soil using an approach which is not risk-based, and does not take into account critical differences between organic mixtures. The FMA believes that the same risk assessment principles endorsed by the Commission for other types of contaminants should also be applied to in developing standards for total organic constituents, including those associated with fuel oil spills.

According to the Technical Basis and Background for Cleanup Standards for Contaminated Sites, N.J.A.C. &:26D, issued by NJDEP in January of 1992, the upper limit of 10,000 ppm for total organic constituents in soil is:

"...is set at approximately 10% of the lower end of average field capacities (8-30%, Brady 1974) a point beyond which movement of free product in the soil could occur."

In other words, a 10-fold safety factor was used to develop the total organic constituent guideline of 10,000 ppm, based on the lower end of the average field capacity of soil of

approximately 10% (or 100,000 ppm). Thus, the guidance is clearly generic (i.e. not specific to the organic constituents or the conditions at a site), and clearly conservative (i.e. applies a 10-fold safety factor to the low end of the range of data).

Despite the fact that the field capacity of soil is dependent upon both soil type and contaminant composition, the 10,000 ppm guidance is uniformly applied to all sites within the State of New Jersey. By way of example, based on a comparison of kinematic viscosity, No. 2 fuel oil is retained in soil to a degree four to five times greater than gasoline. Therefore, if an equivalent volume (e.g., 100 gallons) of No. 2 fuel oil and gasoline were released on the ground, the gasoline would penetrate approximately four to five times deeper into a uniform soil than the No. 2 fuel oil. This is a direct result of the lower retention of gasoline in soil, which is a result of its less viscous nature. Thus, a less stringent total organic constituent standard based on leaching to ground water would be appropriate for No. 2 fuel compared to gasoline.

For direct exposures to total organic constituents in soil, a risk-based, mixture-specific approach could also be used in addition to the field capacity criteria. Cleanup standards for complex mixtures, such as No. 2 fuel oil, could be developed based on a consideration of toxicity/carcinogenicity and concentration of selected components within the mixture. The most stringent cleanup level for any constituent in the mixture could be used to develop the standard for the entire mixture. The following example is provided for No. 2 fuel oil.

A review of the literature indicated that the principal constituents of No. 2 fuel oil are C_{10} to C_{25} alkanes. Fuel oil has also been shown to contain aromatics, a small fraction of which includes benzene, toluene, ethylbenzene, and xylene. The following polycyclic aromatic hydrocarbons (PAHs) have also been detected in No. 2 fuel oil: naphthalene, fluoranthene, pyrene, chrysene, phenanthrene, benzo(a)pyrene, and benzo(a)anthracene.

In order to demonstrate how a risk-based level for No. 2 fuel oil could be developed based on its chemical composition, an example calculation based on benzene is discussed below.

Based on review of the technical literature, the concentration of benzene in No. 2 fuel oil contains less than 100 ppm (Stone 1991). If it is conservatively assumed that No. 2 fuel oil has 100 ppm benzene, the calculated fuel oil concentration in soil necessary to achieve the current NJDEP direct contact residential soil cleanup standard of 3 ppm for benzene (based

on a target risk of 10^{-6}) would be 30,000 ppm. This is 3-fold higher than the current total organic constituent guideline used by NJDEP. Using the Commission recommended 10^{-5} target, the allowable fuel oil concentration in soil would be at least 10-fold higher than the current NJDEP guideline.

In conclusion, NJDEP's current total organic constituent guideline of 10,000 ppm is an arbitrary standard for No. 2 fuel oil and that has no relationship to the protection of human health. If a default cleanup standard for total organic constituents in soil is to be established, FMA strongly believes that a level significantly greater than 10,000 ppm would be appropriate for No. 2 fuel oil. Furthermore, consistent with the findings of the Commission Report, FMA believes that site-specific cleanup standards should be allowed to be developed considering the physical characteristics (i.e., soil retention capacity) of the soil and petroleum product released, and the risk posed by the constituents of the petroleum product following an analysis of relevant exposure factors.

REFERENCES

- Brady, N.C.. 1974. The Nature and Properties of Soil. The Milton Publishing Company, Inc. 8th Edition.
- Stone, W.A. 1991. Assessing Health Risks Associated with Diesel Contaminated Soils and Groundwater. In Hydrocarbon Contaminated Soils, Vol. I, eds. E.J. Calabrese and P.T. Kostecki, 167-179. Chelsea, Mich.: Lewis Publishers.

BPSTW95:PCC00DAC.W51

**Comments on the Draft Report of the Environmental Risk Assessment and
Risk Management Study Commission**
December 5, 1995

The New Jersey Environmental Federation (NJEF) is a state-wide non-profit environmental organization comprised of 94,000 members and an adjunct coalition of 74 member groups. NJEF has historically been involved with issues of contaminated site clean-ups, Superfund, and liability of responsible parties.

NJEF wishes to thank the committee for its efforts in attempting to answer the questions of risk assessment standards and methodology raised by ISRA, but we take issue with the recommendations and ask the commission to re-consider and amend the report. If not, we ask that Governor and Legislature refute this report and maintain a "one in a million risk standard" for contaminated site clean-ups.

Specifically:

- **The recommendations of the report exceed legislative intention and mandate and enter into areas of controversy that should be resolved through public debate due any change in public policy.** ISRA (PL 1993 c 139) required the commission to examine and assess the scientific basis for selecting the risk management standard of one in a million, and to examine risk assessment methodologies. The recommendations of the report exceed the goal of the legislation. ISRA specifically requests a review of risk assessment while the recommendations develop an entire clean-up strategy based on a tiered approach and severing joint and several liability. These deliberations were outside of the scope of the ISRA mandate to the commission.
- **The questions that have evolved over risk assessment methodology and standards remain unanswered.** Treatment, removal, technology, and liability are recommended by the Commission, but questions concerning public health risk assessment are not addressed.
- **Weakening the "one in a million" risk standard is unacceptable public policy and establishes a precedent for lowering of other similar standards established for other media.** While the commission acknowledges that "one a million" risk standard is utilized by both the FDA and EPA for food safety and water safety, it does not make an adequate case for the weakening of the standard by an order of magnitude (one in a hundred thousand) for

New Jersey Chapter of Clean Water Action, Washington, DC

State Office ☐

94 Church Street, Suite 201
New Brunswick, NJ 08901
(908) 846-4224
Fax: (908) 846-4320

Legislative Office ☒

1 Lower Ferry Road
Trenton, NJ 08628
(609) 530-1515
Fax: (609) 530-1508

Jersey Shore Office ☐

902 Main Street, Suite 104
Belmar, NJ 07719
(908) 280-8988
Fax: (908) 280-0371

South Jersey Office ☐

223 Park Avenue
Atco, NJ 08004
(609) 767-1110
Fax: (609) 768-6662

National Office ☐

1320 18th St. NW, Ste. 300
Washington, DC 20036
(202) 457-1286
Fax: (202) 457-0287

contaminated soil. Risk standards are not scientifically based, but public policy based and should be treated as such. The attempts by responsible parties to justify the weakening of standards by challenging the scientific justification of a one in a million standard is driven by their desire to lower remediation costs within. The debate over the scientific validity of a public policy risk standard has no grounds and is a contradiction in terms. A one in a million risk standard has been utilized historically to reduce risk to human health. As concern over the cumulative and concurrent effects of increases in scientific literature, it is imprudent to weaken a standard that will allow more risk of exposure.

Additionally, weakening the standard on the basis of population size is flawed because of the concerns surrounding cumulative and concurrent interactions of substances in addition to a challenge that is necessary to the assumption that if only 500,000 people are exposed the risk standard be increased because of the smaller population. All persons, regardless of population size in the vicinity of the site, should be protected from exposure via the most stringent standard.

As a consequence, it is NJEF's assertion that weakening the risk standard contravenes the public health protection mandate of the charge of ISRA.

- **Eliminating liability to theoretically enhance clean-ups is not justifiable and will result in shifting the burden of funding clean-ups to the public. Liability responsibility should be debated in the legislature, and exceeds the mandate of this committee.** Liability of contaminated sites is a public policy question that evolves around the public's support of making polluters pay. Furthermore, the recommendations of the commission on liability are not justified with any data to support the claim that the severance of liability will result in the completion, expedition, or thoroughness of clean-ups. Trade-off of a standard for permanent clean-up and elimination of liability is unacceptable when it cannot be quantified. Future liability of any sites that pollute after clean-up will eventually fall to the state and public, despite the creation of a fund. Incentive for clean-up by responsible parties should not need to go further than the moral and social responsibility incumbent upon those who are responsible for the pollution.
- **Differential standards for industrial and residential sites is not protective of public health.** Changes in land use of current contaminated sites leaves the possibility of development in the vicinity of the particular site, or of the site itself. Adverse effect on groundwater with differential standards has not been fully justified. Furthermore, ecosystem impact needs to be considered before differential standards can be assessed. The case for differential standards is inconclusive and poorly quantified.
- **Determination of a risk standard or recommendations for clean-up methodologies cannot adequately be made until an assessment has been made of ecosystem impact.** Although the commission acknowledged that this was not its charge, it made recommendations for over-hauling the site remediation program and clean-up process without considering the impact of

Page 3(NJEF)

ecological risk to society. The recommendation for the risk standard change did not include any consideration of ecological impact, although it could be substantial, even after “permanent clean-up”. Yet, the recommendations did include a severance of liability. We assert that the commission cannot conclude any recommendation on risk assessment without considering ecological impact. Ecological Risk Assessment and Human Health Risk Assessment must be integrated if risk assessment methodologies are to improve. For the commission to suggest a change in a risk standard without assessing the potential damage to the ecosystem is unacceptable.

- **We do support the inclusion of non-cancer endpoints to protect the most sensitive populations.** However, we urge that the reference dose of 1 be utilized throughout any suggested clean-up paradigm. The Rfd of 3 for Tier IV is not acceptable for adequate protection of public health. One of the major shortcomings of risk assessment has been the omission of non-cancer endpoints. To this end, the commission is commended for the inclusion of the endpoints, but guidance and emphasis on these endpoints is missing. We urge the specific selection of the endpoints that demonstrate adverse effects to the most sensitive populations from the specific xenobiotic.
- **We commend the commission for inclusion of a recommendation that risk standards apply to all clean-ups, even those to be capped or paved.**
- **NJEF does not support the creation of a Risk Assessment and Risk Management Science Advisory Board.** It is superfluous and unnecessary. NJDEP already has sufficient expertise within the Division of Science and Research whose role it is to provide objective risk assessment. To create a board which will influence NJDEP’s risk assessment policy and procedure undermines the role of these professionals and could unduly influence them to manipulate procedures that favor responsible parties.

In conclusion, we urge the Commission, Governor, and Legislature to maintain a “one in a million risk standard” and to reject the elimination of liability.

Thank you for the opportunity to comment

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STATEMENT BY ASSEMBLYMAN PAUL DIGAETANO
on the Report of the
ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT COMMISSION

December 5, 1995

As the sponsor of the amendment that created this distinguished group, let me first congratulate the commission on a job well done. The report was well worth the wait.

I cannot recall a group of experts like this one ever being convened before. While some people may disagree with aspects of this report, no one can attack the integrity, credibility or motivations of this commission.

The commission was charged with determining the scientific basis for the one-in-a-million risk standard and to examine and assess methodologies of risk assessment and their applicability in establishing site remediation standards. On both issues, I hail the commission on meeting its charge head on. With this report, we can now debate these issues with science rather than by anecdote or fear-mongering.

The bottom line of this report is a simple one - that environmental protection and economic development are not mutually exclusive goals. We do not have to sacrifice one for the other. We can enjoy the dual benefits of cleaning up our brownfields and returning these sites to commercial use more economically without jeopardizing public health and the environment. This report gives us hope that our cities, where the nation's industrial might was born, can enjoy a renaissance, put our people back to work and recapture past glory.

On behalf of the Legislature, I want to thank each member of the commission for volunteering so much of their valuable time on this project. It is your expertise and outstanding reputations that gives this report stature and value.

I look forward to working with the commission as we reopen examination of these issues.



New Jersey State Chamber of Commerce

**Statement on the the Environmental Risk Assessment and Risk
Management Study Commission's Proposed Report Concerning
Risk Assessment Methodologies**

Tuesday, December 5, 1995

Committee Room 11 (4th Floor, Room 438)

**Presented by: Michael Egenton, Manager, Government Relations
New Jersey Chamber of Commerce**

224X

**THE NEW JERSEY CHAMBER OF COMMERCE • 50 WEST STATE STREET • SUITE 1310
TRENTON, NJ 08608 • PHONE: 609-989-7888 • FAX: 609-989-9696**

I would like to thank the members of the Environmental Risk Assessment and Risk Management Study Commission for their efforts in addressing the very complex issue of risk assessment as it relates to the remediation of contaminated sites in New Jersey.

The New Jersey State Chamber of Commerce endorses the recommendations of the Environmental Risk Assessment and Risk Management Study Commission on its proposed report and recommendations concerning risk assessment methodologies and their efficiency and applicability for establishing remediation standards and the scientific basis for the selection of a risk management standard as required by section 47 of P.L.1993,c.139. In particular, we concur with the Risk Commission's characterization of the one-in-a million cancer risk (i.e., 10^{-6}) guideline as matter of public policy, rather than a scientifically derived figure. It is widely known that the one-in-a million cancer risk guideline was originally meant for application in regulating the food industry. It is our position that the Risk Commission's recommendation of a risk guideline default value of one-in-a hundred-thousand cancer risk (i.e., 10^{-5}) should be adopted as it is a more appropriate site remediation goal and is consistent with federal policy.

It should be recognized that overly conservative cleanup standards can have the unintended consequence of being a deterrent to site remediation. This occurs because of the technical and/or financial impracticability of achieving a "clean" site using currently available remedial methods. Allowing the development of site specific cleanup standards that are consistent with the future use of a property will promote a greater number of site remediations without compromising the health and welfare of the residents of New Jersey.

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The New Jersey State Chamber of Commerce endorses the Risk Commission's recommendation to establish a "RISK ASSESSMENT AND RISK MANAGEMENT ADVISORY BOARD" that will advise the Commissioner of Environmental Protection and the Governor on human health related matters. By forming this Board, New Jersey regulators will have a powerful tool to affect the adoption of environmental legislation that is based on the best available scientific information and judgement. This Board will be in a position to engender the public's trust and support on environmental policies, and assure that the State's limited resources are applied in the most effective manner. The Board should have a diverse make-up that includes qualified representatives from government, the scientific community, business, and environmental organizations.

We request that the State Legislature consider the Risk Commission's report and adopt their recommended approach to developing site cleanup standards. Doing so will enhance New Jersey's position as a business and environmental leader.

Thank you for allowing the New Jersey State Chamber the opportunity to offer our views.

Via Overnight Carrier (609-292-7676)

18 December 1995

Judith L. Horowitz
Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, New Jersey 08625

Dear Ms. Hunter:

**RE: New Jersey Risk Assessment And Risk Management Study Commission
Draft Report**

Air Products and Chemicals, Inc. (Air Products) has substantial operations in New Jersey. The recommendations articulated in the *New Jersey Risk Assessment And Risk Management Study Commission Draft Report* could have potentially significant impacts on our operations. Air Products encourages the New Jersey Department of Environmental Protection's efforts to utilize a risk based approach to site remediation. Many of the goals and approaches identified in the draft report should lead to more appropriate remediation of contaminated sites. However some of the risk assessment concepts and risk management proposals need to be revised to reflect current knowledge and experience in effective contaminated site remediation. It is suggested that the Study Commission:

- revise the draft report to more forcefully promote the use of good science in risk assessment,
- promote the study of the efficacy of engineering controls,
- rethink the penalty proposed for use of engineering controls - the current 1 to 5% surcharge proposal is not supportable, and
- include personnel from significant manufacturers and commercial users of the materials being regulated on the proposed Advisory Board.

It may also be useful to re-edit the report to rectify what appear to be section to section inconsistencies in content and conclusions on a given topic.

Specific comments based on the November 1995 draft report are as follows:

page 9: The concept of reopening remediation at a site if the federal or State health standards are decreased by a factor of 10 is inappropriate given the high level of conservatism in these numbers. As noted in the Study Commission report, existing health based values may be overstated by 15 to 10,800 fold. Given this range, reopening action at a site for only a 10 fold change seems to be imprudent and highly questionable. This reopening concept needs to be refined or deleted.

page 9: The proposed Tiered approach does not appear to recognize the efficacy of engineering and administrative controls. The proposed tiered risk levels are punitive. The approach may not be workable. Significant revision to this proposal is needed.

page 12: The assertion that "Since these capped sites have not been permanently remediated the *underlying environmental quality has not markedly improved.* (*emphasis added*)..." ignores the demonstrated performance of properly designed and maintained cap systems to reduce precipitation infiltration and reduce or eliminate contaminant migration to groundwater.

page 21: The Study Commission is to be applauded for their recognition that "...engineering or institutional controls can reduce or eliminate exposure..." thereby reducing or eliminating risk.

page 24: It may be appropriate to clarify and strengthen the concept of appropriate peer review.

page 27: "food" should not be designated as an environmental medium.

page 27: The exact definition of de minimis from the National Contingency Plan should be quoted.

page 29: Calculation of a Hazard Index should only include chemicals that target the same organ. In risk management decisions, use of an allowable range of 1 to 10 for a Hazard Index or Quotient should be recognized as appropriate for some sites.

page 30: EPA's commitment to new methodologies as articulated by Administrator Browner (March, 1995) should be referenced.

page 32: The Study Commission's recognition of the impact of bioavailability is to be commended. Further commentary on the incorporation of this concept in risk assessment is warranted.

page 34: The concept of "exposed population impact" needs further development to clarify its relevance to typical contaminated sites which have limited areal extent.

page 35: The espoused "preference for permanence" concept should be discarded based on Superfund experience.

page 35: The concept of requiring "... an order-of-magnitude more stringent standard when exposure controls are employed..." is inappropriate given statutory or other legal requirements for post closure care or monitoring and on-going maintenance.

page 36, Section VIII. LONG-TERM LIABILITY: The Commission's willingness to address the issue is refreshing. The proposed surcharge and target risk penalties are

Judith L. Horowitz
ATTN: DEP Docket No. 45-95-10/36
18 December 1995
Page 3

inappropriate. The overall concept of when to sever on-going liability needs to be re-addressed or this section deleted.

page 44, Recommendation 4: The application of a cumulative risk concept for carcinogens may not be appropriate. In some cases effects may not be synergistic and may be antagonistic. It is suggested that the Commission advocate further work on the concept of additivity of effects. At a minimum, the concept of additivity must be confined to those materials whose effects target the same organ and exhibit the same mode of action.

page 44, Recommendation 7: The surcharge concept appears to be inappropriate and should be removed from consideration. It appears to be a new tax.

Thank you for the opportunity to comment on the draft of the New Jersey Risk Assessment And Risk Management Study Commission Draft Report. Please contact me at 610-481-6148 if I can be of further assistance.

Sincerely,
Edward W. Pitera
Edward W. Pitera

Enclosure:
15 copies of comments as requested.

December 18, 1995

Michael G. Gallo, Ph.D., Chairman
Environmental Risk Assessment and Risk
Management Study Commission
State House Annex
CN-068
Trenton, NJ 08625

Dear Dr. Gallo:

AlliedSignal would like to convey its views regarding the recently released report from the Environmental Risk Assessment and Risk Management Study Commission ("the Commission"). We appreciate being given the opportunity to comment on the Commission's findings and recommendations. After extensive deliberation and substantial input from the public, the Commission has reached several important conclusions, which include:

- The use of a one-in-a-million (10^{-6}) excess cancer risk goal is not an issue of science.
- There are exceptions to the 10^{-6} cancer risk management goal in state and federal environmental programs, including the 10^{-5} risk management standard for air pollution used by the New Jersey Department of Environmental Protection ("NJDEP").
- Generic remediation standards are problematic for the soil-to-ground water pathway.
- Providing for the severing of liability at contaminated sites is important for promoting site remediation and redevelopment in New Jersey.

The Commission also made a number of recommendations. In a few cases, these recommendations endorsed certain facets of current NJDEP policy, most notably the following:

- Remediation goals should be set as a function of anticipated future land use.
- Site remediation goals can be achieved by treatment and removal or by exposure controls (such as capping).

In other cases, the Commission's recommendations would entail departures from current state policies. Key examples include the following:

- Generic soil cleanup criteria should be based upon a cancer risk management standard of ten in a million (10^{-5}).
- A flexible, tiered approach to site remediation should be adopted.
- Standard probabilistic risk assessment approaches should be developed, validated, and incorporated into the NJDEP's site remediation process.
- Acceptable environmental fate and transport methods should be developed by the NJDEP. At regular intervals they should be re-evaluated and, if appropriate, revised to incorporate the best scientific information.

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AlliedSignal has reviewed the relevant evidence and concurs with each of the conclusions and recommendations noted above. AlliedSignal agrees that risk assessments should use the "best available scientific information and judgment" and that remediation standards should be "supported by sound, peer-reviewed toxicological and exposure data." AlliedSignal further agrees that the preference for site-specific data over generic default assumptions and the incorporation of probabilistic analysis, bioavailability, environmental fate and transport (e.g., natural attenuation) models, and other techniques to more accurately predict risk are consistent with the use of "best available scientific information."

It would be useful if the Commission could clarify whether its recommendation of risk management standards greater than 10^{-6} pertain to ground water and other media or only to soil. The Commission may wish to note in its final report that remediation standards that meet a 10^{-5} cancer risk goal for individuals with "high end" exposures will generally meet a 10^{-6} cancer risk goal for a substantial portion of the exposed population.

The recommendation to establish a Risk Assessment and Risk Management Science Advisory Board ("the Advisory Board") has merit. A similar rationale was behind the Science Advisory Board to the U.S. Environmental Protection Agency. Two important ideas that could be addressed by such an advisory board would be: (1) the identification and evaluation of acceptable methods, data, and assumptions and realistic exposed populations for assessing the "residual risks" and "maximum risks" posed by exposure control remedies; and (2) the development and validation of standardized probabilistic approaches to better define risk. The Advisory Board may also wish to consider identifying how probabilistic analyses provide a scientifically defensible alternative to the "broad-based application of redundant conservative default assumptions" and that their usefulness is not limited to characterizing exposures to "high end" individuals. Probabilistic analyses can be used to characterize the full distribution of dose in exposed populations, as well as the uncertainty in estimates of dose for individuals, and can be used to establish and evaluate remediation standards based upon both typical (e.g., median) and "high end" exposures.

The Commission identified certain requirements under which liability for responsible parties could be severed. AlliedSignal agrees that the potential for liability into the indeterminate future is an impediment to the remediation and redevelopment of sites generally. We welcome the Commission's efforts to reduce this impediment by clarifying requirements and identifying potential incentives for all stakeholders.

AlliedSignal also welcomes the Commission's acknowledgment that "[p]ractical considerations should also be considered in developing final remediation standards." In addition to limitations of analytical methodology, consideration should be given to "limitations in remediation technologies" as a factor that should be considered in the development of "workable standards."

The Commission may wish to elaborate upon the rationale for its recommended risk management goals (i.e., values of Hazard Quotient in Table 1 of the Commission's draft report), which are less flexible than those recommended by the Commission for carcinogens. AlliedSignal believes that

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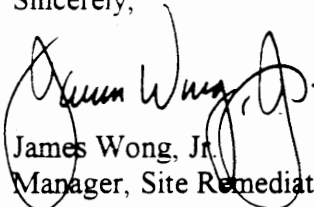
the risk management goals for non-cancer endpoints should be flexible. Consistent with the recommended use of "best available science and judgment," the Commission should consider proposing risk management goals for non-cancer endpoints that reflect technical uncertainty in the underlying dose-response relationships (i.e., uncertainty in the Reference Dose values).

The Commission recommended risk management goals for cancer endpoints that reflect the uncertainty of the underlying assessment of carcinogenicity (i.e., Class A versus Class C carcinogens). The Commission's report provides documentation that there is substantial technical uncertainty in the underlying dose-response relationships also (i.e., uncertainty in the cancer slope factor values). AlliedSignal believes that the risk management goals for cancer endpoints should reflect both sources of uncertainty.

Finally, the Commission recommended adoption of a three-tiered approach to site remediation, which incorporates a different risk management goal for remediation based upon removal and/or treatment versus remediation based upon exposure controls. AlliedSignal agrees that a flexible approach to site remediation is needed and appropriate. The use of site-specific information to replace generic default assumptions is a particularly important concept. AlliedSignal believes that estimates of "population risk" (e.g., number of adverse health events per 70 years) should be based upon median or average exposures, which can be estimated using probabilistic analyses, and realistic exposure scenarios.

We hope that the Commission finds AlliedSignal's comments and suggestions to be helpful. Again, AlliedSignal appreciates having this opportunity to comment on the Commission's findings/recommendations and thanks the Commission members for their important service.

Sincerely,



James Wong, Jr.
Manager, Site Remediation

JW/sp

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Amoco Corporation
Environment, Health and Safety Department

December 14, 1995

Northeast Region
Morris Corporate Center One
300 Interpace Parkway
Parsippany, New Jersey 07054-1100
(201) 331-7000 (201) 334-0227 fax

Judith L. Horowitz
Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, NJ 08625

Dear Ms. Horowitz:

AMOCO Corporation is pleased to provide written comments on the report of the Environmental Risk Assessment and Risk Management Study Commission.

AMOCO Corporation compliments the Commission on their efforts at incorporating site specific risk based corrective action decision making into corrective action programs in New Jersey.

General Discussion

- It appears to us that the report is focused on soil remediation standards as a result of the history of the ECRA/ISRA program and their emphasis on soil sampling and remediation. The Commission should emphasize that the risk management principals discussed apply to all media and all DEP remedial programs. Standards in Tier 1 should be expanded to include groundwater, air and soil exposure pathways. All relevant exposure pathways should be identified in Tier 1.
- It appears that the Commission's mission was clouded by several issues that are not related to risk based corrective action decision making, namely liability, and a preference for "permanent" as opposed to "non-permanent remedies".
- Current NJDEP philosophy is resistant to moving beyond numerical cleanup criteria that are comparable to Tier 1 default cleanup values. Often there is no site specific risk at Tier 1 because the exposure or potential for exposure is absent. Tier I should be a screening criteria, not necessarily a remediation trigger.
- The Commission should review and recommend that ASTM E-1739 Risk Based Corrective Action Applied at Petroleum Release Sites be utilized as the basis for implementation of the Commissions recommendations. Although E-1739 is focused on petroleum release sites, the decision making principles and processes can be

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applied to other corrective action programs. An ASTM Committee is currently working on a modified risk based corrective action guide for application at non-petroleum sites.

- The ASTM E-1739 RBCA standard provides an effective approach for dealing with petroleum release sites. This is a consensus standard and has been thoroughly peer reviewed. E-1739 presents a three-tiered process for determining appropriate corrective action. The tiered approach was designed to address the variation in complexity of petroleum release sites. For a given site, increasingly sophisticated levels of data collection and analysis are employed as the decision process moves to higher levels of complexity. The three tiers are fundamentally different from the three tiers presented in the Commissions report. In E-1739, regardless of the tier, corrective action can include remediation (either active or natural) engineering controls, and or institutional controls. In E-1739, decisions regarding mass reduction and or exposure pathway elimination to achieve a specified level of protection are based on risk reduction not permanence.

Specific Comments

- (page 20) - Utilization of ASTM E-1739 by DEP would insure the Commission's stated objective of establishing a consistent decision-making that is supported by sound, peer reviewed toxicological and exposure data.
- (page 32) - The Commission states that "the selection of the appropriate remedial action is, in effect a risk management decision. This is a critical policy point that needs more emphasis. For a risk based corrective action approach to be utilized, regulatory agencies need to redefine corrective action or remedial action as a risk reduction action. Unless this is done and accepted by the regulatory agencies, application of numerical cleanup criteria regardless of their impact on risk reduction will continue. The Commission needs to emphasize the importance of this concept and recommend acceptance of it.
- (page 35) We question the intent and application of the statement that the "remediation criteria require an order-of-magnitude more stringent standard when exposure controls are employed". If the exposure route is eliminated, then the risk is eliminated. The statement implies that exposure elimination options would also require active contaminant mass removal. Is this the case? If the objective in remediation or corrective action is risk reduction why isn't exposure route elimination an equally valid option?
- (page 36 and 37) - The Commission is addressing liability issues but it is not clear how this is related to risk based corrective action decision making. It is certainly an issue in promoting remediation and development of contaminated sites in New Jersey but, we don't see that the liability issue is relevant in this context, based on the Commissions original directive from the Legislature.

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- (page 37) The Commission also appears to be taking on the issue of the "slow pace of environmental remediation in New Jersey". We do not believe this was the role of the Commission. The Commission should restrict itself to risk based corrective action.
- (page 37) - A remediation surcharge is suggested at perhaps 1-5% but it is not clear what the 1 to 5 % is a part of. Is it 1-5% of the cost of the remediation? Isn't this a disincentive in itself to conduct remediation in New Jersey?
- (page 38) - The three tiered approach is again focused on soil remediation standards. This is limiting and does not consider other exposure pathways besides soil. We recommend that the Commission consider air and water exposure pathways as well.
- (page 38) - It is stated that Tier 1 is a "restatement of the current NJDEP soil Cleanup Criteria". This statement in effect validates a set of numbers that have not yet been promulgated by DEP. The cleanup numbers are based on a set of generic inputs that are not site specific but are applied across the entire State of New Jersey. The Commission should not be accepting the soil cleanup criteria. Instead the DEP should be reevaluating the proposed Cleanup Standards that have yet to be promulgated as regulation in light of the recommendations of the Risk Management Commission. It should be made clear that Tier I values use default assumptions that are not site specific and therefore do not represent site specific risks. If Tier 1 were used as a screening tool only, and responsible parties were allowed to move to a Tier II site specific analysis, many of these problems could be eliminated. The term "Cleanup Criteria" should be replaced with "Screening Criteria".
- (page 42) - There are many other impediments to remediation in New Jersey that were not listed here. We do not believe the role of the Commission was to identify impediments to remediation but to clearly define the role that risk assessment should play in remedial decision making.

Permanent vs Non-Permanent Remedies

- (page 32) - The Commission states that remedial decisions are risk management decisions. Exposure pathway elimination is a valid means of risk reduction however the Commission implies that a penalty of some sort is imposed for achieving the goal that they state they want to obtain. The implication here is also that contaminant mass removal or transformation may be the only viable "permanent" remedy. Use of contaminant removal mechanisms in place of exposure pathway elimination for the sake of achieving a "permanent" remediation may impose higher risks on the community. Again, the interjection of the "permanent" issue is clouding the risk management decision making process.

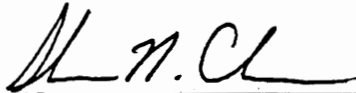
- (page 33 and 35) - We question the distinction between a "permanent" versus an "exposure control remedy." The implication is that exposure elimination is not permanent. We disagree with this contention. If the receptor is a water supply well and the corrective action decision (risk management decision) is to seal the well and connect the facility to a public water supply this would be an example of a "permanent" exposure elimination option that also eliminates the risk (no exposure = no risk). We urge the Commission to reconsider this distinction.
- (page 38) - The statement is made that in Tier II site specific characteristics and exposure scenarios are used to develop remediation criteria. Remediation under these criteria are considered permanent. If you consider exposure pathways on a site specific basis, in many cases there is no exposure and consequently no risk. In this case risk reduction is achievable without contaminant mass reduction. Previously it was stated that exposure reduction was not permanent. This statement seems to contradict this. Again, the notion that exposure pathway elimination is not permanent needs to be reevaluated.
- The Commission states that when compared to exposure control remedies, permanent remedies are the most desirable. This may not always be the case from a risk perspective. Permanent remedies (which include excavation, soil vapor extraction etc) may result in health and safety risks that exceed the risks posed by an exposure control mechanism. For example, some remediation systems cause contaminant transfer from one media to another. Contaminants could be transferred from a media with no exposure pathway (soil) to a media with a exposure pathway (air) thereby increasing the risk by seeking a "permanent remedy".
- (page 39) - The Commission should not set arbitrary criteria that must be satisfied prior to the application of Tier 3. For example, the "costs for permanent remediation (Tiers 1 or 2) must exceed 110% of the costs for the Tier 3 option".
- (page 38) - The difference between Tier II and Tier III appears to be the level of effort placed into incorporating site specific factors. Is this the case? It appears that the Commissions Tier III is intended as additional refinement or continuous improvement of the risk assessment. Is this the case? Using permanent and non-permanent remedies in the discussion of the three tiers clouds the entire risk reduction objective.
- (page 40) - The statement is made that "calculation of site specific cleanup standards should be encouraged." However, the implication is that as you improve the quality of the risk assessment you get further away from a "permanent" remedy which is supposedly desirable. There appears to be a conflict here that could be eliminated by taking the permanent vs non-permanent issue out of the risk based decision making process. If the risk is eliminated it should not matter whether the remedy is "permanent" vs "non-permanent". Non-permanent options would require ongoing maintenance costs that would be considered as part of a risk management decision.

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We concur with the Commission that a Work Group be established to implement risk based corrective action decision making in all DEP programs. However, there must first be a commitment by the legislature and DEP to develop and implement a risk based corrective action decision making system for all DEP programs. Without this commitment, the impact of the work group will be minimal. This group should be multidisciplinary and composed of the regulated community, EPA and DEP personnel, consultants, hydrogeologists and public health representatives. ASTM E-1739 should form the framework for a risk based corrective action decision making system for New Jersey. The Work Group should be charged with implementing E-1739 within the regulatory structure of New Jersey.

AMOCO Corporation is prepared to assist the Commission, the Legislature and DEP in developing a risk based corrective action program for New Jersey. If we can be of further assistance please call us at 201-331-7018.

Very truly yours,

A handwritten signature in dark ink, appearing to read 'S. N. C.', is written over a horizontal line.

Shawn Croucher
AMOCO Corporation

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**APPLIED
ENVIRONMENTAL
MANAGEMENT, INC.**

December 18, 1995

16 Chester County Commons
Malvern, PA 19355
610-251-0450

Ms. Judith L. Horowitz
Office of Legal Services
State House Annex
Room 381
CN 068
Trenton, NJ 08065

Received By: _____

Date: _____

Re: Docket No. 4445 (b)
Comments on "Draft Report of the Environmental Risk Assessment and Risk Management
Study Commission" dated November 1995

Dear Ms. Horowitz:

These comments are submitted by Applied Environmental Management, Inc. on behalf of Maxus Corporate Company, which is performing certain environmental projects in New Jersey on behalf of Occidental Chemical Corporation.

From an overall perspective, the approach embodied in the subject draft report is considered a positive development towards the ISRA mandate of using scientifically-defensible risk information to determine the necessity and degree of remediation required in order to restore contaminated property in New Jersey to productive use. Additionally, the Commission is to be applauded for its objective evaluation of the 1 in 1,000,000 risk basis which has been the cornerstone of the New Jersey Department of Environmental Protection (NJDEP) policy in setting State clean-up standards and concluding that 1 in 100,000 is more appropriate cancer risk level for New Jersey.

We also endorse the hierarchal approach for setting risk management standards as embodied in Table 1 of the report. However, as the report only provides a framework for risk management strategy development by the regulated community and policy-making by the NJDEP, there are a number of technical and procedural concerns which need to be addressed before the Commission completes its work.

With regard to residual non-permanent remedies, there are three concerns which need to be addressed:

- The report seems to require the demolition of structures covering or immediately adjacent to soil with contamination that has been determined to represent a risk in excess of 1 in 10,000
- The report anticipates catastrophic failure of engineering controls, such that an order-of-magnitude greater risk is assigned compared to permanent remedies, apparently without considering their significantly different cost-benefit prospects for protecting human health and the environment.

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- It is unclear for non-permanent remedies whether a risk assessment must be done before implementing a non-permanent remedy.

On the first point, it is not believed that the Commission intended to promote demolition of buildings or other structures in the event that soil contamination is suspected or identified either beneath or immediately adjacent to a structure. For instance, an occupied building constructed in the early part of this century may be located upon residual materials from energy production or materials manufacturing or fill materials from construction debris which contain elevated concentrations of metals of concern. Should the concentrations of such metals be identified, and the human health cancer risk be considered to be greater than 1 in 10,000 based on the hypothetical scenario of a structural failure of the building, an owner should have the option of taking remedial measures to reduce the risk through engineering controls, without necessarily remediating the contaminated soil such that the owner can continue using the land in the same or similar manner as it has been most recently used. This assumes that the properties of the material beneath or immediately adjacent to the structure can be managed suitably with reliable engineering controls to protect human health and the nearby environment. Likewise, a change in property ownership under such circumstances should not be considered the basis for disturbing the structure to remediate underlying soils, unless the building were to be demolished by the new owner and the subsurface soils disturbed or otherwise managed such that the soils would become available for exposure to on-site workers or nearby residents.

With regard to the second item, the report indicates (p. 35) that when exposure controls are employed, such "controls may deteriorate", and thus, an order-of-magnitude more stringent standard has been stipulated compared to permanent remedies 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. Many engineering controls can achieve effective containment of contaminated soil, for example, and be maintained with minimal effort and resources for long periods of time, such as capping and encapsulation. Others such as perimeter fencing with locked gates to minimize site access by unauthorized individuals have limited effectiveness, i.e. a higher propensity for failure, in achieving their objective. In the case of a capped site, failure of the cap is likely to be limited and create minimal exposure risk compared to pre-capping conditions, whereas breach of access-restriction fencing, if solely relied upon to exclude exposure, could result in a high risk of exposure. Clearly, fencing as an engineering control is an example where catastrophic failure is relatively easily induced, whereas failure of a suitably designed and installed cap is likely to occur only gradually and can be inspected and repaired with minimal increased risk compared to the newly installed cap. Clearly, there needs to be distinction in the risks assigned to the use of different types of engineering controls proportionate to the degree of protection afforded, rather than presuming that all engineering controls will fail catastrophically.

Finally, for non-permanent remedies, Table 1 shows a maximum allowable risk of 1 in 10,000

Ms. Judith L. Horowitz
Comments on Draft Risk Commission Report
December 18, 1995

must be attained for all three tiers in Column V, Maximum Risk with Failure of Exposure Control Remedy. There is concern about how this risk standard is intended to be interpreted. If a non-permanent remedy is to be implemented at a site where contamination is known to have potential adverse health effects and/or migration potential, and engineering controls, such as capping or encapsulation, can achieve risk reduction to substantially less than 1 in 1,000,000, for example, would it be necessary to conduct a risk assessment prior to implementing the engineering controls? Also, would it be necessary to remediate to a risk of less than 1 in 10,000 before implementing the engineering controls? For the record, we would expect the answer to be "no" since, as discussed above, complete failure of engineering controls is not necessarily a reasonable assumption; residual risk should be evaluated site by site using reasonable assumptions as to possible remedy failure.

We appreciate the opportunity to submit these comments for consideration by the Risk Commission. Should there be any questions, please contact the undersigned at 610-251-0450.

Very truly yours,



John C. Petura, P.E., DEE
Principal

Transmitted Via Federal Express

December 19, 1995

Judith L. Horowitz
Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, New Jersey 08625

Re: Comments on Report and Recommendation of the Environmental Risk Assessment and Risk Management Study Commission

Dear Ms. Horowitz:

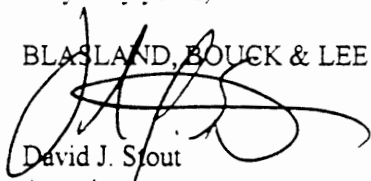
On behalf of Bristol-Myers Squibb Company (BMS), Blasland, Bouck & Lee, Inc. (BBL) transmits the enclosed comments on the draft report and recommendations of the Environmental Risk Assessment and Risk Management Study Commission (Commission).

Owing to the complexity of the information provided in the draft report, we respectfully note that the allowed comment period following the December 5, 1995 hearing before the Commission did not allow enough time to fully analyze the material in the Commission's draft report. With this qualification, we appreciate the opportunity to submit these comments on behalf of BMS.

If you have any questions, please call me at (609) 860-0590.

Very truly yours,

BLASLAND, BOUCK & LEE


David J. Stout
Associate
RISKCOMM.LTR

cc: Mary Beth Koza, Bristol-Myers Squibb Company
Sue Voigt, Bristol-Myers Squibb Company

Comments of Bristol-Myers Squibb Company

Draft Report of Environmental Risk Assessment
And Risk Management Commission

(November 1995)

Bristol-Myers Squibb Company
Prepared and submitted by Blasland, Bouck & Lee, Inc.
December 19, 1995

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INTRODUCTION

Bristol-Myers Squibb Company (BMS) operates multiple facilities in the State of New Jersey and actively participates in development of regulations and standards that impact their facilities. BMS has reviewed the November 1995 draft report (Report) prepared by the Environmental Risk Assessment and Risk Management Study Commission (Commission). However, due to the complexity of the information, we respectfully note that the allowed comment period following the December 5, 1995 hearing before the Commission did not allow enough time to fully analyze the Report. With this qualification, we appreciate the opportunity to submit comments on behalf of BMS. In reviewing this document, we can understand the considerable undertaking on the part of the Commission in developing the Report and we concur with the Commission's encouragement for calculation of site-specific cleanup standards. However, we believe that several substantial modifications are necessary if the Commission's recommendations are to help achieve the State's goal to protect public health, safety, and the environment, and expedite and reduce the cost of site remediation.

BMS appreciates and supports the Commission's efforts to 1) examine and assess the scientific basis for the one-in-one million (1×10^{-6}) risk management standard, and 2) examine and assess risk assessment methods and their efficacy and applicability for establishing remediation standards. However, many of the remediation standards and procedures recommended by the Commission are so structured that they would neither expedite remediation nor reduce costs.

Under New Jersey Department of Environmental Protection (NJDEP) oversight, BMS continues to progress remediation projects at several facilities and other sites in New Jersey. Many of the Commission's recommendations would compromise the significant progress that BMS has made to ensure protection of human health and the environment. For example, the Commission purports

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that remedies involving exposure (engineering) controls are less desirable than treatment or removal, and, therefore, recommends that these remedies require more stringent remediation standards than other remedies. Certainly, these additional constraints may adversely affect the timeliness of the remediation process and could discourage responsible parties from expediting remediation. In addition, we believe that the recommendation for a 1 to 5 percent surcharge on all remediations is not warranted. Therefore, it is important that certain elements of the Commission's report be revised.

The following comments to the Commission's Report address three main issues: 1) risk management standards, 2) protectiveness of engineering controls, and 3) role of fate and transport modeling in estimating realistic exposure. Each of these issues is discussed below.

I. NJDEP SHOULD ADOPT A TARGET CARCINOGENIC RISK MANAGEMENT RANGE OF 1×10^{-4} TO 1×10^{-6} IN DETERMINING REMEDIATION STANDARDS.

The recommended remediation standards are far more stringent than necessary to achieve NJDEP's goal of protecting public health, safety, and the environment. Rather than basing its recommended standards on best available science, the Commission has based its assessment of remediation standards on assumptions we believe inappropriate, including: 1) use of one-in-one-hundred thousand (1×10^{-5}) as a standard for carcinogenic risk management, and 2) use of NJDEP default assumptions to quantify exposure. While BMS supports the Commission's recommendations for integrating land use and population size into the development of remediation standards, we would be interested in additional guidance from the Commission on the site-specific role for each of these important factors.

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A. Use of 1×10^{-5} as a Standard for Carcinogenic Risk Management Is Inappropriate

The Commission reported that use of 1×10^{-6} as a standard for carcinogenic risk management represents a policy decision rather than a scientific decision. However, both a scientific and policy basis for recommending 1×10^{-5} as an acceptable carcinogenic risk management standard are absent from the Report. If the use of this value is simply a policy decision, it will suffer the same weaknesses as the use of the 1×10^{-6} value (which are discussed in the Report). Additionally, the use of a single carcinogenic risk management standard, be it 1×10^{-6} or 1×10^{-5} , assumes that all potential carcinogens should be evaluated according to the same standard even though their potencies vary.

The Commission appropriately suggests the use of a range of risk management standards (Report Table 1) for Class A, B, and C carcinogens, but the resultant remediation standards are dependent on the type of remedy selected, rather than the class of potential carcinogen. In most site remediations, the remedy is selected based on the results of a site-specific risk assessment. Risk management standards should be established to protect human health based on site-specific conditions, not on a predetermined matrix of remedies.

Currently, the USEPA uses a range of 1×10^{-4} to 1×10^{-6} as standards for carcinogenic risk management. Section 300.430 (e)(2)(i)(A)(2) of the National Contingency Plan (NCP) provides that for "known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 1×10^{-4} and 1×10^{-6} ." Fed. Reg. 8848. Similarly, OSWER Directive 9355.0-30 indicates that remedial action need not always be required when the

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cancer risk falls between 1×10^{-4} and 1×10^{-6} . Thus, USEPA has determined that the 1×10^{-6} criterion should not apply in all circumstances. Given the regulatory precedent and endorsement by the USEPA, use of a carcinogenic risk range of 1×10^{-4} to 1×10^{-6} for site-specific risk management would allow better use of finite resources to remediate sites in New Jersey.

B. Use of NJDEP Default Assumptions May Greatly Overestimate Exposure and Associated Risks

In the Commission's proposed three-tiered approach to remediation standards, Tier-2 remediation standards "combines site-specific physical characteristics and exposures information with the NJDEP default assumptions." There are several limitations associated with using the NJDEP default assumptions. First, the NJDEP default assumptions are point estimates, and therefore, cannot accurately represent the characteristics of a potentially exposed population. Second, the values of the default assumptions are upper-bound values (95th percentile), which generally produce an unrealistic estimates of exposure when the values are combined in the exposure equations. Third, the use of point estimates to quantify exposure leads to single upper-end, point estimate of individual risk to represent potential risks to an entire population rather than a probabilistic distribution (ranges) of potential risks for groups of individuals within the population with similar exposures.

We agree with the Commission that greater emphasis should be placed on using Monte Carlo simulations. As stated in the Report, the Monte Carlo approach is dependent upon the quality of input information. However, data sets are currently available for evaluation, and statistical distributions have been published for many of the exposure

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parameters (e.g., body weight, skin surface area, inhalation and ingestion rates) (see references list for publications). Therefore, the Commission should place more emphasis on collecting and evaluating additional data, as well as reviewing the data currently available to facilitate the development of NJDEP-endorsed "Default Distributions" that could be used in Monte Carlo simulations in the near future.

C. Incorporation of Land Use and Population Size in Risk Assessment Merits Additional Guidance

We agree with the Commission that land use and "the size of the total affected population, in addition to the individual risk level, is important from a public health perspective... (and that) risk level alone is not sufficient to established a cleanup standard." However, the Report neither indicates how land use or population size could be incorporated quantitatively into a risk assessment nor how a "population at risk" is identified for a site. Therefore, the important role of the land use and population size in risk assessment and development of site remediation merits additional guidance. USEPA's (1995) guidance "Land Use in the CERCLA Remedy Selection Process" should be considered to assist the Commission in further assessment of this critical factor.

II. **THE COMMISSION UNDERSTATES THE PROTECTIVENESS OF EXPOSURE CONTROLS IN REDUCING POTENTIAL ENVIRONMENTAL RISKS.**

The Commission is currently proposing a three-tiered site remediation approach. Under this approach, the use of exposure control remedies would be associated with the most stringent risk management standards, continuance of liability, and required deed restrictions (Report

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Table 1). This approach underestimates the protectiveness of engineering controls. Exposure controls have been proven effective solutions to protect public health, safety, and the environment, and should be recognized as such by the Commission.

A. Assuming Total Failure of Engineered Exposure Controls Is Unrealistic

Exposure control remedies are designed to effectively prevent exposure, and there is no technical reason to assume that all exposure control remedies will deteriorate and possibly fail. The Commission should remove the unwarranted claim about failure of engineered exposure controls. Furthermore, NJDEP (and USEPA) requires responsible parties to engage in long-term operations and maintenance of remedies to ensure protectiveness (and prevent failure).

B. Remediation Standards for Exposure Control Remedies Unfairly Penalize Responsible Parties

The penalties associated with exposure control remedies may direct research efforts away from developing better engineering controls and improving current exposure control technologies, and the tiered approach unfairly penalizes parties responsible for sites where other remedies may not be practical or feasible due to site-specific features or economic constraints (e.g., small businesses). Therefore, exposure control remedies should not be associated with the most stringent risk management standards.

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III. GREATER EMPHASIS SHOULD BE PLACED ON FATE AND TRANSPORT MODELING IN ESTIMATING EXPOSURE

Greater emphasis needs to be placed on the role of fate and transport and bioavailability in calculating exposure. Environmental fate and transport of a constituent can substantially affect the concentration available for uptake, and in some cases, may render a constituent unavailable, thus eliminating exposure. Therefore, if fate and transport are not accurately evaluated on a site-specific basis, exposure may be erroneously quantified using unlikely, worst-case assumptions, which will not represent realistic exposure conditions.

For example, because the Toxicity Characteristic Leaching Procedure (TCLP) is inaccurate in estimating constituent release concentrations in many cases, NJDEP needs to consider alternate USEPA-approved methods of evaluating leaching from soil to ground water, such as the Synthetic Precipitation Leaching Procedure (SPLP) and the Multiple Leaching Procedure (MLP), which more accurately reflect the environmental conditions encountered at most sites. The sequential extractions in the MLP may also be more representative of potential constituent migration over time than the TCLP, making the MLP useful in evaluating potential future constituent migration. It is worthy of note that both the SPLP and the MLP are currently used by other states (e.g., Connecticut, Ohio) as well as the USEPA to evaluate constituent fate and transport.

CONCLUSION

We commend the Commission, as shown by the effort that went into developing the Report, understands the importance of creating an atmosphere that would increase the ability and desire to expedite the cleanup of sites throughout the state. However, although it appears that many relevant

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issues have been addressed, the remediation standards, as recommended, require significant modification if they are to achieve the desired goals.

In conclusion, the major areas requiring modification can be summarized as follows:

- Proper consideration of both current and future land use
- Standards for carcinogenic risk management
- Equal remediation standards for remedies involving exposure controls, treatment, or removal
- Use of probabilistic techniques
- Assessment of fate and transport processes
- Deletion of 1 to 5 percent surcharge provision

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FEDERAL EXPRESS (609) 292-7676

December 18, 1995

Ms. Judith L. Horowitz
Room 381
State House Annex
Trenton, New Jersey 08625

RE: ENVIRONMENTAL RISK ASSESSMENT REPORT

Dear Ms. Horowitz:

Ciba-Geigy Corporation (Ciba) is submitting the following comments on the "**Draft Report of the Environmental Risk Assessment and Risk Management Study Commission**," November 14, 1995. A disc copy of these comments is included in Word 6 format, along with 15 additional copies, as requested.

Overall, Ciba finds the draft report to be well conceived and well based technically. We are pleased that the Commission found the 10^{-6} risk to have no scientific basis in fact. We specifically endorse Chapter VI of the Report "**Examination and Assessment of Risk Assessment Methodologies**," as providing a sound foundation and guidance for conducting site specific risk assessments. However, there are several concerns with the draft report.

Costs

The cost of remediation at contaminated sites in New Jersey will increase from 2-7 times, with no additional protection of public health if the Tier 3 10^{-6} risk is used for exposure controls because of the preference for permanence. A \$50 million capping project, a very expensive solution in itself, would become a \$100 million soil removal or a \$700 million incineration. The proposed "**softening**" that a permanent remediation can only cost 110% of an exposure control solution, as long as there are no offsite receptors, is unsupported and inconsistent. The risk pathways offsite would be applied to any site specific assessment prior to evaluating remedial alternatives. The 110 % factor, like the 10^{-6} , risk has no technical, statistical, or even policy basis. In essence, the Commission is penalizing an exposure control remediation by raising the risk from 10^{-5} to 10^{-6} and requiring permanent remedies to be at least 110% of exposure control remedies. How did

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the Commission arrive at such a percentage? Are there case studies to back this up or is this another “public policy” pronouncement?

Tier 2. Site Specific Risk Assessment

In the true spirit of site specific risk assessment and in keeping with the Commission’s recommendations, we request that maximum flexibility be provided in establishing default assumptions and in using acceptable methodologies/probabilistic approaches and that any guidance in this area be reviewed and approved by the proposed Risk Assessment and Risk Management Science Advisory Board, prior to issuance. In the interim, risk assessments, assumptions and methodologies/approaches should continue to be reviewed by the NJDEP on a case by case basis and accepted as long as they are supported by sound technical information.

Tier 3 Exposure Control Remedy

Ciba believes there is no technical justification for “preferring” a permanent remedy over any exposure control one. The risk assessment and the selected remediation should evaluate the value of exposure control versus permanence and the possibility of failure. If the Commission, and the NJDEP, are concerned with risks due to future or potential failures of exposure controls, these issues should be dealt with in the maintenance, operation, and monitoring for a site after remediation, not by artificially increasing risk to 10^{-6} . In addition, it is consistent and reasonable that an owner/applicant continue to be financially responsible for a site that has been remediated via exposure controls. If offsite receptors are not likely to be impacted with the implementation of an exposure control and the site is deed restricted for the appropriate land use, there appears to be no technical reason for mandating a 10^{-6} risk requirement.

Table 1

As noted above, Ciba objects to the use of Column IV and V in Table 1 as too restrictive for exposure control implementation because it is inappropriate to assume all exposure controls will fail. In addition, it appears, there are no differences for remediation based upon future land use. In Table 1, the type of carcinogen and the permanence of the remedy dictate the risk not the land use. We understand that site specific assessments may factor in future land use and population assumptions, but there should be a much clearer definition of risk for different land uses. We suggest that 10^{-5} is appropriate for residential uses and that 10^{-4} be used for non-residential (commercial/industrial) land. In that regard a population event of once in 70 years is reasonable for residential land but, once in 25 years, should be used for non-residential lands. This is one default assumption that can easily be established up front.

Groundwater Protection

The four criteria to suspend active remediation are welcome; however, criteria (2) only provides for natural attenuation in 30 years and does not consider the other side, that 50

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years or more of active remediation may be insufficient for aquifer restoration to groundwater standards. There are likely to be many groundwater remediations where no significant difference can be shown between natural attenuation and active cleanup over time. If this can be demonstrated, and the other criteria are met, we see no reason to continue active remediation.

Surcharge

If a remediation is permanent, there is no need to surcharge future remediation. The IRSA legislation clearly provides for additional cleanup, at the responsible party's expense, if soil or groundwater criteria drop an order of magnitude. With an exposure control remedy, the PRP continues to be financially responsible in to the future also negating the need for a surcharge. Ciba does not wish to create another source of funding for the NJDEP where no other controls exist.

Science Advisory Board

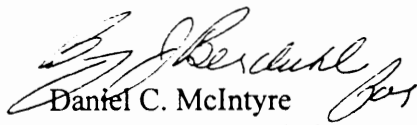
Ciba suggests that the proposed Science Advisory Board be given the final approval over risk guidance issued by the NJDEP and that, in fact, the Board be active, and not merely advisory.

Maximum Risk

The Commission has established a 10^{-4} risk floor for all remediations. We assume that this reflects the EPA policy of considering risks in the 10^{-4} to 10^{-6} range, depending on site specific conditions and population size. However, if we interpret Column V of Table 1 correctly, the potential failure of an exposure control requires permanent remediation of 10^{-4} risks up front. This infers a type of "hot spot," removal where 10^{-4} soil is removed from a large 10^{-6} source risk, which can then be left in place and capped or addressed by other types of source control. However, the cost of the exposure control has now been increased for a partial permanent remediation without any additional protection of the public health.

Ciba wishes to thank the commission for the opportunity to comment. If there are any questions regarding these comments, please call Dr. Barry J. Berdahl at (908) 914-2715.

Sincerely,


Daniel C. McIntyre
Director of Remediation

c: CIC/NJ
\\ENVRSKAR

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Department of Energy

Oak Ridge Operations
P.O. Box 2001
Oak Ridge, Tennessee 37831—

Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, NJ 08625

Dear Members of the Risk Management Study Commission:

COMMENTS ON REPORT OF THE ENVIRONMENTAL RISK ASSESSMENT AND RISK MANAGEMENT STUDY COMMISSION

Upon hearing of your commission and its goal of issuing recommendations for managing environmental risk in New Jersey, I and my colleagues at the Department of Energy's (DOE) Former Sites Restoration Division (FSRD) were encouraged and enthusiastic. The issues under consideration by the commission have a profound influence on the environmental cleanups for which our organization is responsible in your state.

While we agree with much of the general direction of the commission's draft report, a final report that would include more specific recommendations would be the most beneficial. Perhaps most helpful would be a final report in which your commission recommends *specific* guidance on how to implement reasonable risk management approaches, specifying risk assessment models and approaches that are appropriate and sufficiently validated for radioactively contaminated sites in New Jersey.

Please consider our attached comments to the "Report and Recommendations of the Environmental Risk Assessment and Risk Management Study Commission." But first, allow me to outline briefly our program and its activities in New Jersey.

FSRD, part of DOE's Oak Ridge Operations Office, is responsible for administering the Formerly Utilized Sites Remedial Action Program (FUSRAP), a program established in 1974 to identify, assess, and clean up radiologically contaminated sites associated with the nation's early years of atomic energy development. Five FUSRAP sites exist in New Jersey. For each, DOE is working closely with state and federal regulators to develop cleanup criteria and remedies that are protective and fiscally responsible. Because of the complexities and sensitivities associated with cleanups involving radioactive material, there tends to be a great divergence of opinion regarding the

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criteria that should be followed and in the models and approaches used to determine risk. Thus, your final report, when issued, could greatly impact our work and the affected communities.

As stated earlier regarding the commission's draft report, we agree with the general approach that risk management standards for contaminated sites should be developed differently than standards developed for other situations where large numbers of individuals are exposed involuntarily. We also concur that risk assessment considerations are but one principle to be applied in the selection of remedial goals for a site and that additional factors such as community acceptance, cost reasonableness, technical feasibility, land use and other regulatory constraints must be evaluated in the derivation of cleanup goals. Please consider these comments addressing more specific aspects of how the commission's final report might assist us in our cleanup work in New Jersey.

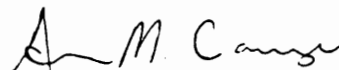
- The report does not mention risks associated with radiation. As there are significant differences in methods used for evaluating and managing radiation risks compared to chemical risks, the commission's specific recommendation for radiological risk assessment would greatly enhance the reports effectiveness and usefulness. For example, how does a cleanup program remediate radiation risks to 10^{-5} when background concentrations of radium, thorium, and uranium cause risks on the order of 10^{-4} ? This scenario, typical to many of our sites in New Jersey, presents obvious challenges that with the aid of specific recommendations by the commission could be more successfully and expeditiously overcome.
- The principles developed by the Commission are broad and general, with no discussion of how these principles will be put into practice. For example, how will second tier site specific risk and cleanup criteria be determined? What methodology and assumptions will be used and how will they be applied consistently from site to site?
- What is the basis, rationale, or justification for 10^{-5} ? Is that figure simply a split of the difference between the 10^{-4} to 10^{-6} acceptable risk range established by EPA? Although there is limited rationale for the acceptable risk range of 10^{-4} to 10^{-6} in federal CERCLA legislation, this range has been applied to hundreds of cleanups allowing flexibility in the application of reasonable risk based upon the chemicals present and the population exposed. It is desirable for New Jersey to adopt a risk range that mirrors the EPA range.

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- For our work, the exposure control remedy recommendations in the draft report present numerous problems. First, our reading of the draft report leaves us unsure as to why exposure controls require a 10^{-6} risk limit rather than the same 10^{-5} limit used for the permanent remedy or default alternatives. Why would a higher level of risk be allowed for an uncontrolled site? Also, the limit of 10^{-4} on risk in the event of failure of exposure controls, plus the Declaration of Environmental Restriction requirements, and no severance of liability, will effectively eliminate any engineering control as a viable remediation alternative.
- Clarification is needed on the Commission's recommendation that any remedy that still results in one or more adverse events every 70 years would not be acceptable. It is possible, by manipulation of certain calculations, to demonstrate that even extremely small doses of radiation could result in more than one cancer if received over 70 years by a large enough population. Our recommendation is that the Commission consider establishing a *de minimis* population exposure level in order to avoid the summation of minute radiation exposure over a larger population.
- The Commission may consider recognizing exceptions or exemptions of certain standards pertinent to unusual or difficult cleanup situations. Under DOE Order 5400.5, an exemption from radiation remediation standards can be requested for sites or portions of sites where it can be shown that basic dose limits are met but remediation would result in a clear and present risk of injury to workers or members of the public, excessive environmental harm, or excessive costs. An exemption can also be requested in situations where there is no technologically feasible remedial action.
- When determining the maximum risk for an exposure control cleanup failure, credit should be given for redundant controls. The complete failure of all control systems at a remediated and monitored site would be highly unlikely. The maximum risk exposure scenario due to control failure should reflect a probabilistic approach, not a catastrophic approach.

I and my division colleagues appreciate the opportunity to comment on your commission's draft report and applaud the commission for its efforts. Risk assessment, specifically as it pertains to radiologically contaminated sites, is a topic of great importance to the citizens and regulated community of New Jersey. We look forward to participating in state activities to accomplish these goals.

Sincerely,



Susan M. Cange, Site Manager
Former Sites Restoration Division

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REFINING DEPARTMENT
SITE REMEDIATION

December 18, 1995

Environmental Risk Assessment and Risk
Management Study Commission
State House Annex, CN-068
Trenton, NJ 08625-0068

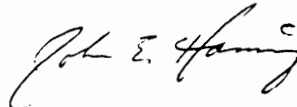
Attention: Ms. Judith L. Horowitz

Dear Ms. Horowitz:

Enclosed please find 15 copies of written comment prepared by Exxon Company, U.S.A. for the Environmental Risk Assessment and Risk Management Study Commission in response to its current public hearing process. This written comment builds upon the verbal testimony provided by Mr. Donald Esch, New Jersey Area Manager of Exxon Company, U.S.A. at the December 5, 1995 public hearing, and includes additional detail, examples and references.

We appreciate the opportunity to provide input to the Commission's efforts. If there are any questions, please contact me at (908) 474-6637.

Sincerely,



John E. Hannig
Site Remediation Project Administrator

JEH/kml
Enclosures

Via Courier

**EXXON COMMENTS ON THE
ENVIRONMENTAL RISK ASSESSMENT
AND
RISK MANAGEMENT STUDY
COMMISSION DRAFT REPORT**

December 15, 1995

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INTRODUCTION

The Governor's Environmental Risk Assessment and Risk Management Study Commission (the Commission) was established following adoption of the Industrial Site Recovery Act (ISRA). The Commission was charged with two tasks: 1) examine the scientific basis and applicability of a one-in-a-million (10^{-6}) incremental risk level for establishing remediations standards for carcinogens, and 2) examine methodologies of risk assessment and their efficacy and applicability for the purpose of establishing remediation standards under ISRA.

Exxon commends the Commission for their work on these key issues. We support the Commission's clear and strong statement that there is no scientific basis for 10^{-6} and for its appropriate movement away from it as a "bright line." In addition, we strongly support the Commission's recommendation to use the best available scientific information and judgment to predict hazard. This approach will both protect the public health and promote efficient and timely cleanups in the state of New Jersey.

Exxon is committed to responsibly addressing the environmental concerns which may exist from our historical operations. We are hopeful that the final implementation of Commission's recommendations and enlightened regulations will provide a sensible framework for fulfilling these responsibilities.

General Comments

- **Scientific Basis for Selecting the Risk Management Standards**

We commend the Commission for clearly stating that there is no scientific basis for 10^{-6} . We agree that the historical use of 10^{-6} in food safety issues, where there is exposure to the general population, should not form the basis for its use in environmental risk assessments, where the potentially exposed population is much smaller. We also commend the Commission for proposing an alternate acceptable risk scheme based on EPA weight-of-evidence classifications, rather than using 10^{-6} as a "bright line." However, to foster better public understanding, we believe the report should include more information on how actual risks resulting from contaminated and remediated sites compare to other risks.

- **Site Specific Risk Assessments**

We encourage the Commission to strongly recommend the acceptance of valid, new data and state-of-the-art methods, both for developing alternate remediation standards in site specific risk assessments, and for periodic updates of generic standards. Concerning site specific risk assessments, in the spirit of ISRA, we believe that responsible parties who develop alternate remediation standards using valid, new data and state-of-the-art methods should be able to gain approval to use such standards in advance of formal rule-making.

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The ability to use valid site specific data, including actual exposure information, natural biodegradation, fate and transport of the contaminant, and state-of-the-art-risk assessment methods, is the centerpiece of ISRA. These data and tools, which currently exist, but which are not currently accepted by NJDEP, would allow a responsible party to better define the true range of exposures and risks which may exist at a site.

It is not clear why the Commission is recommending to further delay the implementation of site specific risk assessments pending creation of a "decision tree" by NJDEP and an advisory committee. Site specific risk assessments are clearly provided for under ISRA. We are concerned that waiting for the development of a "decision tree" will substantially delay progress in remediating sites in New Jersey. Rather, we recommend that the "decision tree" be developed in parallel with approval of site specific site assessments. Also, we recommend that the advisory committee itself lead the effort and that other well developed concepts, such as the ASTM E-50 standard, be considered. It is critical that the final scheme allow for use of the best available scientific data and flexibility in performing site specific risk assessments as described under ISRA.

The Commission has not mentioned many factors affecting exposure which can and should be incorporated into site specific risk assessments according to ISRA. These include a variety of intake rates, time-activity patterns, physiological data, and chemical specific factors, including alternate toxicology data. Also, it is not clear why the discussion on site specific risk assessment is focused solely on protection of groundwater quality. Section 35f of ISRA, which describes alternate remediation standards, applies generally to all media for either residential or non-residential land uses.

- **Risk Assessment Methodologies**

The Commission recommends the use of sound, peer reviewed toxicological information, physiologically based pharmacokinetics (PBPK) and mechanistic toxicology. However, the Commission endorses the use of EPA Carcinogenicity Slope Factors and Reference Doses which are not subjected to review outside of EPA and which for many chemicals do not contain the best available PBPK and mechanistic toxicology data.

Non-Cancer Endpoints

While we strongly support the inclusion of non-cancer endpoints in establishing remediation targets, we recommend that an appropriate assessment and weighting of health concerns be incorporated into their determination. Accordingly, we ask that the Commission recommend that the selection of endpoints be heavily weighted towards long-term, irreversible health effects which have been accepted by the majority of the scientific community and exclude or give little weight to unsubstantiated anecdotal claims. For example, dose-related evidence of adverse histopathological effects in target organs are serious effects, whereas contact dermatitis is not.

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For EPA Class C carcinogens, we ask that the Commission recommend, as an option, the use of risk assessment procedures based on non-cancer effects (e.g., Reference Doses). This approach is consistent with EPA risk assessment guidance for Class C Carcinogens.

- **Uncertainty in Risk Assessments**

It is unclear why the Commission is endorsing the "validation of standard probabilistic approaches." The science of performing such analyses is still evolving. Therefore, it is premature to attempt to standardize these techniques or to arrive at a "default" methodology. Rather, we recommend that the Commission advocate that NJDEP should: 1) follow developments in this area at the national level (e.g., EPA, AIHC); 2) promote the incorporation of the current best, rather than the easily outdated default, methodologies into risk assessments performed by and for the department; and 3) provide training in probabilistic risk assessment for NJDEP staff involved in preparing and reviewing such assessments.

- **Table 1**

Clarification is needed on how to assess maximum risk with failure of exposure control remedy (Column V) and on population based events (Column VI).

Column V

We question the concept of using alternate risk goals for various remedies with more stringent risk goals for non-permanent remedies. As stated by the National Research Council, risk is a function of exposure to an agent and the inherent toxicity of the agent. If a remedy reduces or limits exposure, there should be no need to make a distinction for the type of remedy resulting in the reduced exposure and risk. Therefore, the risk goal of 10^{-5} for A, B, and C classified carcinogens, should also apply to exposure control remedies. Alternately, a risk goal of 10^{-4} should be considered for Class B and C carcinogens, which are not designated as human carcinogens.

In Column V, the Commission suggests that when exposure control remedies are applied, the site must also be remediated to meet a 10^{-4} risk goal before institution of the exposure control remedies. This requirement is based on the premise that the exposure controls someday will fail. Exposure control remedies are not designed to be temporary fixes to a contaminated site. Such remedies include slurry walls, liners, and caps, are all designed to meet performance standards that are protective of human health. In addition to these controls, Declarations of Environmental Restrictions are always applied. These restrictions define what and where concentrations are left at the site and requirements to maintain the controls. In the event of failure of the exposure control, such information can be used to define new or better controls. Therefore, we believe the additional requirements under Column V are not warranted.

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We do not understand the stated basis for differing risk goals for permanent versus exposure control technologies, namely "improvement of underlying environmental quality." The remediation standards described in ISRA are based on the protection of human health, safety, and the environment. A separate committee, the Environment Task Force, was created to address environmental risk assessment issues.

Column VI

Several questions arise concerning assessment of risk to a population at a specific site. How will the size of the "exposed" population be determined? Who will make this determination?

- **Risk Assessment Advisory Board**

We agree that the concept of creating a board to advise NJDEP on risk assessment issues has merits. However, we recommend the creation of a risk assessment advisory group that addresses all issues related to risk assessment, rather than a group targeting only site remediation. It should be clearly described in the mission statement for this board that their tasks do not include review of site specific risk assessments. This would likely result in additional delays in the remediation process. Rather, their activities should be limited to general risk assessment issues. Also, the criteria for panel selection should be open for public input.

- **Severance of Liability**

We support the Commission's recommendation that severance of liability be offered as an option to responsible parties, but feel that the surcharge should be assessed to only those parties electing the option. We strongly believe that the option to severe liabilities will, in itself, serve as a significant incentive to responsible parties to pursue permanent remedies. However, the imposition of more restrictive standards and controls for non-permanent remedies purely for incentive reasons is inconsistent with the concept of risk-based decision making.

In many cases, there exists no cost-effective permanent solution. A non-permanent remedy is the only choice. The process, as laid out in the reports, results in double jeopardy for a responsible party in such cases. First, a fee is charged, for which no benefit is received. Then, a more stringent risk level is applied. Such a result is highly unfair to the responsible party.

Specific Comments

- Introduction

While extensive information is provided on the number of sites in need of remediation in New Jersey, no information is provided concerning the actual public health concerns presented by these sites or the public health benefit which would result if all the sites were remediated. Given the level of effort needed to remediate these sites, some clear statement of public health benefits should be included in this section.

- Page 24, paragraph 2

It is stated in the report that ISRA suggests that the toxicity values used by the Safe Drinking Water Quality Institute, and by EPA IRIS and HEAST, be used to calculate risk. Since no such endorsement appears in ISRA, these statements should be deleted from the report. In the same paragraph, it is stated that the primary consideration for utilization of any toxicity reference or toxicity data base is peer review to assure reviewed scientific validity. It is not clear, then, why the Commission endorsed the use of EPA CSFs and RfDs, which receive no public review outside of EPA.

- Page 28, paragraph 2

The Commission endorses the use of CSFs "in the absence of other methodologies." In fact, many other better methodologies are available for assessing risks to carcinogenic agents than the worst case default procedures used by EPA. Some of these procedures, for example, the comprehensive health assessment methodology used by the American Industrial Health Council, use the full data base for the chemical of concern and result in risk assessments with much less uncertainty than those developed by EPA (estimated to be on the order of 15 to 10,800-fold as described by EPA and cited in the Commission's report). It should be noted that other investigators have estimated that CSFs may overestimate risks by more than the range described above. Given the above discussion and the fact that alternate methodologies are provided for in ISRA, it is surprising that the Commission has chosen to issue a blanket endorsement of the EPA default risk assessment procedures.

- Page 28, last paragraph

No mention is made concerning the Commission's endorsement of the use of EPA RfDs. However, given the discussion on page 28 and the Commission's blanket endorsement of the use of EPA CSFs, it is assumed that the Commission also endorses the use of RfDs. As for CSFs, RfDs are not subjected to peer review outside of the EPA. In addition, RfDs are derived using multiple factors of 10 (which combined may equal a factor of 10,000 for some chemicals) to account for various uncertainties. There has been a general recognition by the scientific community that for certain components of the uncertainty in risk assessments for chemicals exhibiting a biological threshold, factors less than 10 are needed.

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- **Page 35**

We question the concept that so-called "permanent remedies" are most desirable. In many cases, permanent remedy translates to contaminant removal (truck and haul). Movement of contaminated materials to another site is a process which itself carries certain risks often not considered by regulatory authorities and results in other sites which may require remediation at some further date.

- **Page 35, last paragraph**

The paragraph on individual versus population based assessments is confusing. It is not clear what is meant by "one or more adverse event." It is also not clear what the additional criterion of assessing risk for population at the site is expected to achieve and how the "size of the population at the site" will be determined. It is not clear, from a public health perspective, why one adverse event over, for example, a 70 year period, is deemed unacceptable, or how the occurrence of such an event could be predicted with any certainty.

- **Page 42, under impediments to remediation**

We disagree that inability to achieve permanence is an impediment to remediation. In many cases, there exists no cost-effective permanent solution. A non-permanent remedy is the only choice.

- **Page 44, no. 3**

The Commission has introduced the concept of cumulative risks. This concept is inconsistent with ISRA. As stated in section 35(d)(2) of ISRA, "the risk levels are for any particular contaminant and not for cumulative effects of more than one contaminant at a site." Therefore, unless ISRA is amended, the statements concerning cumulative risk should be deleted from the report.

Mobil Oil Corporation

3225 GALLOWAY ROAD
FAIRFAX, VIRGINIA 22031-0001

Judith L. Horowitz
Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, New Jersey 08625

Environmental Risk Assessment and Risk Management Study Commission Report

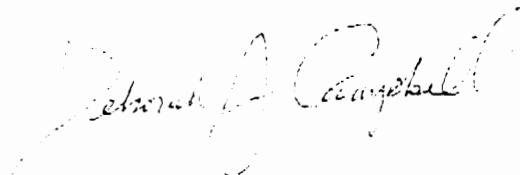
December 18, 1995

Dear Ms. Horowitz,

Mobil Americas Marketing and Refining, a division of Mobil Oil Corporation, appreciates the opportunity to submit comments on the Environmental Risk Assessment and Risk Management Study Commission's report. Within the State of New Jersey, Mobil owns and operates a refinery and other facilities integral to the petroleum industry operations - including three distribution terminals, a lubricant blending and packaging plant, a research facility and numerous service stations. Therefore, Mobil is vitally interested in this report. Mobil is also committed to ensuring the protection of human health and the environment.

Mobil would like to compliment the Commission on their efforts to address the difficult but important policy issues facing New Jersey's site remediation program. We do however have several concerns with the Commission's recommendations. The attached comments discuss our concerns in more detail. If you have any questions please contact me in person at (215) 862-3487 or at the following mailing address:
1 Glen Eagle Drive New Hope, Pa 18938.

Very truly yours,



Deborah Campbell
Regulatory Advisor
Mobil Oil Corporation

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MOBIL OIL CORPORATION COMMENTS ON RISK COMMISSION REPORT

Mobil Oil Corporation appreciates the opportunity to provide comments to the New Jersey Risk Assessment and Risk Management Commission on their recent draft report. Mobil operates retail gasoline stations, petroleum bulk storage tank facilities, a refinery, petroleum distribution pipelines and chemical plants in the State of New Jersey.

We would like to commend the Commission for their efforts on a number of important issues addressed by the Commission report. Most importantly, the Commission has clearly pointed out the lack of scientific basis for, and general misapplication of, the 10^{-6} risk level in the corrective action process. The Commission report points out that adoption of the 10^{-6} level for environmental cleanups was purely a policy decision and not one grounded in sound science. Clearly, the use of the 10^{-6} risk level, as originally put forth in the Delaney Clause for protection of the general food supply, may be reasonable when tens of millions of people will be exposed to contaminants in that food supply. However, the use of the same 10^{-6} risk level at contaminated sites, where relative handfuls of individuals may actually be exposed to contaminants, is not a reasonable approach and has no scientific basis. We also commend the Commission on their recommendation to use the best available scientific information in the risk/hazard assessment process. The use of such information, while ensuring full protection of human health and the environment, will lead away from the use of unnecessarily conservative assumptions and procedures, which ultimately misdirect resources to remedial actions that provide no incremental increase in health or environmental protection.

We also feel that the Commission has taken a step in the right direction in giving the responsible party an option for severance of liability from a site. Unfortunately, such a step will have limited benefits since it does not protect against third party suits and, in addition, we are concerned that taxes associated with the liability proposal will be unnecessarily burdensome and inhibit the corrective action process (as discussed below).

We do have a number of significant concerns with the recommendations of the Commission which are described under the headings given below.

Use of Permanent vs. Non-Permanent Solutions

The Commission's attempt to drive remedial efforts towards "permanent" solutions is well intentioned but is flawed because it does not recognize many of the limitations associated

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New Jersey State Library

with "permanent" solutions and many of the advantages associated with so-called "non-permanent" solutions. Some of these issues which must be considered are as follows:

- For numerous sites, technologies do not currently exist which can effectively address remedial needs in terms of achieving a "permanent solution".
- A "permanent solution" often means excavating huge volumes of marginally contaminated soils and directing those materials to landfills or incinerators. Both remedial alternatives effectively destroy a resource (the soils) and, in addition, the landfilling of marginally-contaminated materials unnecessarily uses very limited landfill space.
- Engineering and institutional controls are often intended to be, and can be, permanent solutions to environmental contamination, totally removing exposure pathways and allowing sites to be cost-effectively re-used for a full spectrum of purposes.
- As noted, engineering and institutional controls can completely remove exposure pathways, totally eliminating contact with contaminants, while with so-called permanent solutions, some contact with contaminants may remain.
- The cost differential between "permanent" and "non-permanent" solutions are enormous, with costs of permanent solutions often seven to fifteen times the cost of "non-permanent" solutions.

Thus, the goal of discouraging "non-permanent" solutions at sites, by applying a 10^{-6} rather than a 10^{-5} risk level when "non-permanent" solutions are implemented (and by demanding, in the total absence of controls, that a 10^{-4} risk level not be exceeded), will not be achieved. The end result will be that unnecessary resources will be directed towards attaining the 10^{-4} risk level, when, in-fact, the control measures can be fully protective of human health and the environment on an indefinite basis and allow the cost-effective re-use of sites for a wide spectrum of purposes.

We, therefore, encourage the elimination of Tier 3 as described in the Commission report and suggest that the use of "non-permanent" solutions be incorporated into Tier 2.

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Surcharge on Cleanups in New Jersey

With the present huge costs of environmental cleanups, we are concerned that further costs will impede the progress of cleanups in New Jersey and will lead to further misallocation of resources associated with environmental activities. Based on the presently proposed risk guidelines, it seems highly unlikely that there will be a significant need to further cleanup sites that have already been remediated under the Commission guidelines. The present recommendation for a 1 - 5% surcharge seems to be completely arbitrary and some economic analysis needs to be conducted on sites to understand if a fund is necessary and the appropriate size of such a fund. Certainly if any surcharge is imposed it should be kept as small as possible (<1%) to prevent an impediment to remediation activities and should only be levied on those sites where release from liability is attained.

Risk Level Associated with Group A, B and C Carcinogens

For Tier 1 assessments, the Commission report presently suggests that a 10^{-5} risk level be applied to chemicals placed in A, B and C groups by the U.S. EPA. In Tier 2, the Commission recommends that a 10^{-5} risk level be applied to Group A and B chemicals and a 10^{-4} risk level be applied to Group C compounds.

For Tier 1, we would suggest the use of a 10^{-5} risk level for EPA Group A and B chemicals, as an appropriately conservative approach for the establishment of statewide standards. We strongly disagree with evaluating Group C compounds as human carcinogens. The weight of evidence simply does not exist which would justify treating these chemicals in a risk assessment as carcinogens. There is certainly no evidence which demonstrates that these materials are human carcinogens. We strongly recommend the use of reference doses based on no observed adverse effect levels (NOAELs) or lowest observed adverse effect levels (LOAELs) for Group C materials. It should be noted that the huge safety factors incorporated in the generation of reference doses (typically 100 to 10,000) should ensure that calculated cleanup levels are fully protective.

In Tier 2, which is meant to incorporate site-specific factors into the risk assessment, we strongly suggest that a range of risk be used based on site-specific characteristics. This is fully in line with U.S. EPA recommendations for site-specific risk assessments. For example, a 10^{-5} risk level may be appropriate at sites where exposures to potentially contaminated media may be relatively frequent, while at isolated sites with no or infrequent potential

exposure to contaminants, a 10^{-4} risk level would be appropriate. Please note that as discussed above, we would strongly suggest that both permanent and "non-permanent" solutions be included as part of Tier 2 and the risk level would be decided based on site-specific conditions, independent of whether a permanent or non-permanent solution is implemented.

Use of Column VI (Risk Management Standards)

Column VI if the Risk Management Table is unnecessary and only invites misinterpretation and misapplication of the requirement specified under column VI. Looking at the size of populations that may contact contaminants on a site, it is virtually inconceivable that the upper limit of an event per 70 years could ever be exceeded.

Parameters Used in Site-Specific Risk Assessments

The Commission Report implies that Tier 2 will only allow the use of a limited number of site-specific factors. Specifically, only those factors associated with impacts to groundwater. In fact, a site-specific risk assessment should include as much site-specific information as possible. This will allow realistic estimations of risk/hazard that are fully protective of human health and the environment, while minimizing over estimations of risk which lead to the misapplication of resources. Site specific factors should be included for the direct-contact pathways and should include factors such as exposure frequencies based on soil depth. Overall, the use of site-specific information, rather than conservative default parameters, should depend on the availability and quality of that site-specific data and should not be restricted to impact to groundwater issues.

Delay in Use of Site-Specific Risk Assessments

The risk Commission has stated that there is a need to develop a "decision" tree prior to the use of site-specific risk assessments. It is unclear why such a decision tree now needs to be developed. ISRA legislation clearly permits the use of site-specific risk assessments and delineates the framework under which such assessments must be conducted (i.e., consistent with U.S. EPA RAGS and more current EPA guidance). Thus, appropriate procedures are

currently available for conducting site-specific assessments and the Commission and NJDEP should not delay the use of such assessments.

In addition, we would like to strongly recommend the framework set out in the ASTM Document (E 1739), *Guide to Risk-Based Corrective Action at Petroleum Release Sites*. This document is fully consistent with the ISRA requirements as given above and provides a clear framework under which generic and site-specific criteria are developed and risk management decisions are made. This approach has been strongly endorsed by the U.S. EPA and training is currently available to the States.

Closing Comments

Overall, we feel that the Commission should be commended for their efforts and feel that many of their recommendations will help to expedite cleanups in New Jersey and make them more cost effective, while being fully protective of human health and the environment. As outlined above, we do, though, have a number of concerns and believe that recommended modifications will further expedite successful cleanups in New Jersey.

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December 20, 1996

Michael A. Gallo, Ph.D.
Chairman
Environmental Risk Assessment and Risk
Management Study Commission
Legislative Office Building, CN-068
Trenton, NJ 08625-0068

Dear Dr. Gallo:

Draft Report of the Environmental Risk
Assessment and Risk Management Study Commission

The New Jersey Business & Industry Association, on behalf its 13,900 member companies, is pleased with the thrust of the draft report but concerned about some of the details. The most important finding in the report is the fact that an official Commission of New Jersey government, filled with highly qualified and knowledgeable scientific experts has finally declared that the one in a million excess cancer risk is an inappropriate standard for derivation of soil clean up standards.

"..the literature revealed no scientific basis for the selection of a one in a million as the criterion for developing remediation standards for environmental pollutants."

The Commission has accurately stated that the definition of acceptable risk in public standards is a political call, not a scientifically derivable factor. It is within the mandate of the Commission's charter to build an argument for an acceptable risk level to be utilized by elected representatives to fashion workable cleanup standards that meet the environmental, human health and economic goals of society. We support the Commission's concept of establishing a range of acceptable risk that starts at 10^{-5} and the need for differing cleanup requirements for different land uses (e.g., residential, commercial, industrial). The Commission was asked by S-1070 to address soil cleanup standards, however, we believe that it is now appropriate to broaden the focus to apply to all media, soil, water and air.

We also agree with the Commission's note that the total population exposed to a contaminant should be factored in to the development of a risk based cleanup number. Our members support and applaud the Commission's recommendations concerning the severance of liability for properties remediated to the permanent level. We would also support the use of a surcharge dedicated for costs of additional remediation due to a change in the standard or the discovery of undetected contamination. However, we are concerned about the vulnerability of dedicated funds to raiding by opportunistic administrations, i.e., Hazardous Waste Disposal Fund \$250,000,000, Unemployment Insurance Fund, \$1,600,000,000 and Litter Tax Fund, \$10,000,000.

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102 West State Street
Trenton, NJ 08606-1102

The Commission appears to have gone beyond its legislative mandate by venturing into the area of remedy selection when it proposed a slightly off balance risk scheme geared toward permanent cleanups. It is difficult to understand the relative advantages to society of suggesting that the standard of acceptable risk should be 10 times lower for a permanent cleanup than an industrial/commercial property with an engineered barrier that essentially reduces exposure to site contaminants to zero. The Commission should also provide additional documentation to support its 10^{-4} baseline for cleanups prior to engineered solutions. This may void a number of completed transactions. It may apply to contaminated soil near or under buildings and may require the use of unnecessary pump and treat remedies to get residual groundwater down to one in 10,000 even though there is no chance of the contaminant traveling off-site.

ISRA envisioned the provision of remedial solutions that are protective of human health and the environment but do not require overly protective cleanups driven by conservative risk assessment assumptions. The Commission appears to have embraced the goal of encouraging permanent cleanups, but we believe that this goal is an inappropriate criterion to be inserted into the development of risk standards. The economic determinant for permanent vs. temporary cleanup is a function of the potential reuse of the property. The Commission's proposal will put an unnecessary burden on individuals interested in economic revitalization of industrial properties. The issue of setting a proper risk level is very different than the institutional/legal mechanism to be utilized in dealing with remediated sites. The potential encumbrance of the property with a Declaration of Environmental Restriction (D.E.R.) is a key factor in remedy selection. The Commission is attempting to add additional disincentives for choosing engineering controls. In recent months, there has been an increased interest in economic development on brownfield sites by developers who are willing to take an economic risk on a property in an urban area that has historic problems. The use of institutional and engineering controls are making the redevelopment of these properties possible. We must make sure that we do not jeopardize real development in the quest of a theoretical goal.

Given the uncertainties associated with risk calculation, the Legislature in passing ISRA, expressly prohibited the DEP from calculating cumulative risk values for a specific pathway. The Commission in recommendation #4 introduces the use of cumulative risk into the risk equation.

We also support the Commission's tiered approach to risk setting based on known or suspected carcinogens. However, we are somewhat confused by the use of noncancer endpoints. We would request that the Commission provide a fuller explanation of the use of the matrix especially in the use of noncancer endpoints. The recent publishing of chromium cleanup standards has shown how a noncancer standard can drive a cleanup standard.

Sincerely,


Jim Sinclair, P.E.
First Vice President

regulatory brief

NJBIA

NEW JERSEY BUSINESS
& INDUSTRY ASSOCIATION

102 West State Street
Trenton, NJ 08608-1102
609-393-7707

#39

Issue:

Draft Report of the Environmental Risk Assessment and Risk Management Study Commission

Background:

As required by Section 47 of Industrial Site Recovery Act (ISRA) P.L. 1993, c.139, the State Environmental Risk Assessment and Risk Management Study Commission was set up to "examine and assess the scientific basis for selecting the risk management standard of one in a million and examine and assess the methodologies of risk assessment and their efficacy and applicability for the purpose of establishing remediation standards."

Status:

The draft version of this report was released in November 1995. It was originally scheduled for December 1993. A public hearing on the draft report was held on Tuesday, December 5, 1995. NJBIA submitted written testimony to the Commission.

Description:

The report says that the use of the one in a million excess cancer risk (10^{-6}) is an issue of public policy not science. The Commission found that the history of 10^{-6} does not reveal intent for use in any application other than food safety. It was intended to limit exposure to carcinogens in the food supply.

In order to achieve remediation of affected sites, the Commission recommends that standards be flexible and reflect the future use of the site. Therefore, the Commission recommends that the remediation goals be set as a function of anticipated use and that standards be adopted which consider noncancer endpoints, that is the effects other than cancer, which are caused by a hazardous material.

The Commission also recommends that site remediation goals can be achieved through treatment and removal or by exposure control technologies such as capping. However, when exposure control technologies are used, the standards are more strict and deed restrictions must be applied.

Further, the Commission recommends severing 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 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 would be used in the event that previously undetected contaminants, with greater health impacts than those previously remediated are detected or if federal or State standards for residual contaminants are decreased by at least a factor of 10. The third requirement for severance is that the escrow account cannot not be used in the event of fraud.

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The Commission recommends adoption of a three-tiered approach to site remediation.

Tier 1 is a restatement of the current New Jersey Department of Environmental Protection (NJDEP) soil cleanup 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 present in column III (Residual Risk of Permanent Remedy) in Table 1). Tier 1 and 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.

Risk Management Standards
Table 1

I USEPA Carcinogen Class.	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
Noncancer Endpoints ⁴	1	2	2	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 the 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/DfD).

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NJBIA Position:

The most important finding in the report is the fact that an official Commission of New Jersey government, filled with highly qualified and knowledgeable scientific experts, has finally declared that the one in a million excess cancer risk is an inappropriate standard for derivation of soil cleanup standards.

"..the literature revealed no scientific basis for the selection of a one in a million as the criterion for developing remediation standards for environmental pollutants".

The Commission has accurately stated that the definition of acceptable risk in public standards is a political call, not a scientifically derivable factor. It is within the mandate of the Commission's charter to build an argument for an acceptable risk level to be utilized by elected representatives to fashion workable cleanup standards that meet the environmental, human health and economic goals of society. We support the Commission's concept of establishing a range of acceptable risk that starts at 10^{-5} and the need for differing clean-up requirements for different land uses (e.g., residential, commercial, industrial). The Commission was asked by ISRA to address soil cleanup standards. However, we believe that it is now appropriate to broaden the focus to apply to all media, soil, water and air.

We also agree with the Commission's note that the total population exposed to a contaminant should be factored into the development of a risk based cleanup number. Our members support and applaud the Commission's recommendations concerning the severance of liability for properties remediated to the permanent level. We would also support the use of a surcharge dedicated for costs of additional remediation due to a change in the standard or the discovery of undetected contamination. However, we are concerned about the vulnerability of dedicated funds to raiding by opportunistic administrations, i.e., Hazardous Waste Disposal Fund, \$250 million; Unemployment Insurance Fund, \$1.6 billion; Litter Tax Fund, \$10 million.

The Commission appears to have gone beyond its legislative mandate by venturing into the area of remedy selection when it proposed a slightly off balance risk scheme geared toward permanent cleanups. It is difficult to understand the relative advantages to society of suggesting that the standard of acceptable risk should be ten times lower for a permanent cleanup than an industrial/commercial property with an engineered barrier that essentially reduces exposure to site contaminants to zero. The Commission should also provide additional documentation to support its 10^{-4} baseline for cleanups prior to engineered solutions. This may void a number of completed transactions. It may apply to contaminated soil near or under buildings and may require the use of unnecessary pump and treat remedies to get residual groundwater down

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to one in 10,000 even though there is no chance of the contaminant traveling off-site.

ISRA envisioned the provision of remedial solutions that are protective of human health and the environment but do not require overly protective cleanups driven by conservative risk assessment assumptions. The Commission appears to have embraced the goal of encouraging permanent cleanups, but we believe that this goal is an inappropriate criterion to be inserted into the development of risk standards. The economic determinant for permanent vs. temporary cleanup is a function of the potential reuse of the property. The Commission's proposal will put an unnecessary burden on individuals interested in economic revitalization of industrial properties. The issue of setting a proper risk level is very different than the institutional/legal mechanism to be utilized in dealing with remediated sites. The potential encumbrance of the property with a Declaration of Environmental Restriction (D.E.R) is a key factor in remedy selection. The Commission is attempting to add additional disincentives for choosing engineering controls. In recent months, there has been an increased interest in economic development on brownfield sites by developers who are willing to take an economic risk on a property in an urban area that has historic problems. The use of institutional and engineering controls are making the redevelopment of these properties possible. We must make sure that we do not jeopardize real development in the quest of a theoretical goal.

Given the uncertainties associated with risk calculation, the Legislature in passing ISRA expressly prohibited the DEP from calculating cumulative risk values for a specific pathway. The Commission in recommendation #4 introduces the use of cumulative risk into the risk equation.

We also support the Commission's tiered approach to risk setting based on known or suspected carcinogens. However, we are somewhat confused by the use of noncancer endpoints. The Commission should provide a fuller explanation of the use of the matrix especially in the use of non-cancer endpoints. The recent publishing of chromium clean-up standards has shown how a noncancer standard can drive a cleanup standard.

NJBIA Contact:

Jim Sinclair, 609-393-7707, Ext. 236—Fax: 609-695-9597.

December 19, 1995

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State of New Jersey

THE PINELANDS COMMISSION

PO Box 7

NEW LISBON NJ 08064

(609) 894-9342

CHRISTINE TODD WHITMAN
Governor

December 14, 1995

Judith L. Horowitz
Aide to the Commission
Environmental Risk Assessment and
Risk Management Study Commission
Legislative Office Building
CN 068
Trenton, N.J. 08625-0068

Re: Draft Report
Environmental Risk Assessment
and Risk Management Study
Commission

Dear Ms. Horowitz:

Thank you for providing a copy of the draft report produced by the Environmental Risk Assessment and Risk Management Study Commission.

The report contains a statement which indicates that the Commission was not charged with consideration of issues relating to ecological risks associated with hazardous waste sites. It is suggested that the same statement be incorporated into the Executive Summary in order to avoid the potential misunderstanding by the public that the Commission's recommendations address ecological risks.

If you have any questions concerning this matter, please contact me.

Sincerely,

William F. Harrison, Esq.
Assistant Director

WFH/ks

cc: Kathleen Swigon
Susan Uibel



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and an International Biosphere Reserve

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PPG Industries, Inc. One PPG Place Pittsburgh, Pennsylvania 15272 (412)434-2811

Leonard S. Bryant
Manager, Environmental Projects
Environmental Affairs
Chemicals Group

December 18, 1995

Ms. Judith L. Horowitz
Office of Legislative Services
Docket # 4445(b)
Environmental Risk Assessment and
Risk Management Study Commission Report
State House Annex
Room 381, CN-068
Trenton, New Jersey 08625-0068

RE: Comments on the Report of the Environmental Risk Assessment and Risk
Management Study Commission

Dear Ms. Horowitz:

I. Introduction

PPG Industries, Inc. (PPG), appreciates the opportunity to review and comment on the work of the Environmental Risk Assessment and Risk Management Study Commission (the Commission). We commend the Commission's efforts in grappling with these fundamental, yet highly controversial, issues directed toward establishing a workable approach to safely returning contaminated sites to productive use.

The specific charge given the Commission by the Legislature was:

- 1) To examine and assess the scientific basis for selecting the risk management standard of one in one million for the purposes of P.L. 1993, c. 139 and to consider and assess alternative scientific standards and criteria for that purpose; and
- 2) To examine and assess the methodologies of risk assessment and their efficacy and applicability for the purposes of establishing remediation standards.

From the description of the evaluations and assessments to be made by the Commission, it is anticipated recommendations would include:

- 1) a risk management standard and a framework for applying the risk management standard in the management of site risks; and
- 2) a risk assessment methodology and framework for use by the New Jersey Department of Environmental Protection (NJDEP) in developing minimum remediation standards.

We have organized our general comments into sections to reflect the charges to the Commission and the recommendations anticipated from the Commission as well as comments on the risk assessment approaches recommended by the Commission. The last section presents detailed comments on the report.

II. Scientific Basis for Selecting the Risk Management Standard of 10^{-6} and Assessment of Alternative Scientific Standards

PPG agrees with the Commission that the selection of a risk management standard of 10^{-6} theoretical excess cancer risk has no scientific basis for use in developing remediation standards for contaminated sites.

PPG also agrees that the application of a theoretical excess cancer risk of 10^{-6} has been a matter of public risk management policy derived from federal food-additive regulations that was applied to public policy involving the remediation of contaminated sites. The direct application of the 10^{-6} de minimis value to the remediation of contaminated sites is unnecessarily conservative and inappropriate from a scientific perspective since exposure at contaminated sites is fundamentally different from exposure to food additives. There are far greater uncertainties at contaminated sites associated with the duration of exposure and the occurrence of the exposure in the population. The Commission report should provide a discussion calibrating the public health risks associated with voluntary actions or exposure (e.g., air travel, motor vehicle travel) with involuntary (e.g., contaminated site exposure or exposure to food additives). The Commission report should provide a discussion of the differences in the uncertainties among involuntary exposures as justification for proposing alternatives to a 10^{-6} risk management standard.

In 1973, the Food and Drug Administration developed the concept that a certain level of exposure could be tolerated without creating unacceptable public health problems. The federal policy resulting from this concept defined 10^{-6} as the upper bound theoretical excess cancer risk providing protection from the potential health effects of chemical additives in the food supply, in effect, a lifetime exposure from which the entire U.S. population could not avoid and would occur involuntarily, no matter where they lived or moved. In contrast, the evaluation of risks at contaminated sites is generally based in federal guidance on an individual level using what is termed "Reasonable Maximum Exposure" (RME). In this approach, no attempt is made to incorporate consideration of the potential for exposure or size of the potentially affected population near the site. As indicated by the Commission, "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." We do not see evidence that the Commission has attempted to justify modification of risk based on the concern expressed.

PPG does not agree with the Commission's inference (page 19, second paragraph) that public policy generally has resulted in the establishment of a single acceptable risk management standard (10^{-6}). While the Legislature specified use of a 10^{-6} theoretical excess cancer risk as a basis for establishing

minimum remediation standards. management of site-specific risks within a range of 10^{-4} to 10^{-6} is more the rule. From the perspective of federal risk management policy applied to contaminated sites, the USEPA implements the application of a risk range using a two step approach. The USEPA uses a 10^{-4} point estimate risk management standard in comparison to site-specific baseline risk assessment as a threshold criterion above which (i.e., greater than 10^{-4}) remedial action is generally warranted. Once a decision has been made to take remedial action at a site, the USEPA has expressed a preference for managing risks to achieve the more protective end of the range although reductions in site-specific risks anywhere within the risk range (i.e., 10^{-4} to 10^{-6}) may be acceptable.

In context of the need under HDSRA to define minimum remediation standards, the Commission recommends a three tiered system based on a default risk of 10^{-5} . The generic use of 10^{-5} (Group A & B carcinogens) as a residual risk from a permanent remedial measure is similar, but more conservative, than the USEPA's use of the site-specific 10^{-4} threshold for deciding whether remedial action is warranted. The proposed policy of balancing a site-specific risk assessment for a 10^{-1} incremental risk in the generic management of sites does not appear unreasonable. However, the option of a responsible party to perform a site-specific risk assessment should not be forfeit through this approach.

The use of 10^{-4} as a maximum risk of failure from an exposure control remedial measure is without comparable USEPA policy. Due to the need under HDSRA to develop a single set of narrative or numeric-based minimum remediation standards, the Commission's proposal of a 10^{-4} residual risk is more stringent than federal public policy, as implemented by the USEPA, which does not restrict the level of residual risk with exposure control failure. Rather than driving remedial action to permanent remedy, this could delay or prevent action by a property owner, thus preventing the return of the property to productive use on expanded tax rolls.

III. Assessment of Methodologies of Risk Assessment and their Efficacy and Applicability for Establishing Remediation Standards

The Commission has presented and assessed the general methods used in risk assessment but has presented very little in regard to the efficacy and applicability of the general methods for establishing remedial standards. The Commission should also provide guidance to the NJDEP to allow it to move ahead in the development of cleanup standards.

The Commission strongly recommends the development and validation of standard probabilistic approaches that can eventually be used to better define risk. We strongly support such efforts to base standards on better defined risk and agree with the Commission that a single point estimate of risk does not adequately describe the uncertainty inherent in the factors used in the calculation. While a probabilistic approach can better quantify and bound uncertainty in risk, the time required to implement such an approach will preclude expeditious standard promulgation. The Commission should provide guidance to NJDEP in selection of the appropriate risk probability to develop a workable standard. In the interim, the Commission must recommend the

methods to use in developing standards under HDSRA. We suggest the use of the USEPA protocols presented in the Risk Assessment Guidance for Superfund (RAGS, Parts A and B) as HDSRA currently directs NJDEP to utilize in the interim period pending standard promulgation.

Section 12a of HDSRA clearly established that prior to promulgation of minimum standards, remediation standards should be developed on a case-by-case basis using the guidance of the USEPA under CERCLA. In responding to the Commission's charge to assess methodologies for the purposes of establishing minimum remediation standards, the Commission should state whether they are recommending the use of procedures, endpoints and scenarios contained in USEPA RAGS Part A or Part B methodologies, ASTM methodologies, or Monte Carlo methods or some combination thereof.

The Commission has not exerted sufficient control of the standards development process by neglecting to specify the use of generally accepted procedures and inputs. It has been our experience that state cleanup programs outside New Jersey modify risk management strategies while maintaining compliance with federal risk assessment methodologies (USEPA RAGS). In contrast, NJDEP has utilized non-standard risk assessment methodologies to maintain a rigid risk management strategy. In the context of the development of standards for chromium in New Jersey, PPG has encountered considerable delay as a result of NJDEP's approach of using non-standard endpoints (allergic contact dermatitis) and using risk assessment and fate and transport methodologies that are not generally accepted or contained in USEPA guidance and applying such methods with minimal data and without validation.

Without specific guidance by the Commission, development of standards may repeat the problems contained in the proposed NJDEP 1992 Standards (later withdrawn) for the Remediation of Contaminated Sites. This proposal allowed limited site-specific input into the risk assessment to develop alternate remediation standards. The risk assessment inputs and fate and transport modeling contained extremely conservative and unrealistic, non-peer reviewed default assumptions designed to preclude generation of cleanup levels that differed from the generic default values.

We believe the NJDEP needs specific guidance on recommended methodologies that will lead to the development of cleanup standards that will allow for modification by site-specific inputs, if appropriate, and flexibility in development of risk management strategies.

IV. Risk Assessment Approaches Recommended by the Commission

Implicit in the debate surrounding the Industrial Site Recovery Act is the presumption that existing risk assessment and risk management policies are not responsive to the needs of the people of New Jersey.

Clearly the Commission recognizes that if "workable" standards are not developed, then the goal of HDSRA will not be achieved.

The legislature, in S-1070 declared "that it is the policy of the state to protect public health, safety and the environment, (and) to promote efficient

and timely cleanups, and to eliminate any unnecessary financial burden of remediating contaminated sites." ((and) and emphasis added)

We concur with the recommendation of the Commission that the best available scientific information and judgment be used to predict human health risk. Accurately predicting the degree of hazard is fundamental to the identification of public health issues as well as formulating a basis for their correction. As the Commission has pointed out, risk equals hazard times exposure. Yet the Commission recommends incentives for hazard reduction and disincentives for exposure reduction. While quantification of hazard is an issue, it is not the only issue to resolve in developing "workable" standards.

The balance among the three declarations called for by the Legislature must be achieved to facilitate protective, timely, and cost-efficient remediation of contaminated sites. There is an overwhelming over-conservatism and imbalance toward protection of public health at the exclusion of timeliness and cost-effectiveness in the regulations serving to implement these three declarations. This imbalance has resulted in reclamation gridlock dealing with "brownfield" sites. If a balance is not achieved, the public will face continued delay in remediation and continued delay in obtaining the protection of public health that was the Legislature's goal in enacting S-1070.

The Commission's report perpetuates this imbalance and mistakenly assumes that more stringent cleanup levels, in themselves, will result in public health protection. The Commission's recommendation of different standards to reflect differing land use (with which we agree), could promote efficient remediation of brownfield sites by adjusting the cleanup level to better reflect the anticipated exposure. However, the Commission thwarts this by linking "permanent" remediation to achievement of residential cleanup levels. Those seeking to use exposure control approaches are penalized with deed restrictions. Persuading property owners to accept deed restrictions is difficult since remediation to non-residential standards is viewed to "doom" the site forever. This policy will only serve to delay the return of sites that have historically been commercial or industrial, currently lie within commercial or industrial zoning areas, and are likely to remain so in the future. Policies such as these reinforce the regulatory imbalance and encourage the development of greenfield sites either within, or outside the state at the expense of redevelopment of existing sites. For example, the Commission assumes total failure of institutional controls and requires de minimis cleanup to a risk level of 10^{-4} prior to allowing use of exposure control remediation. These are super-conservative requirements serving only to increase cost and discourage development. Creating disincentives to remediate to anything but residential standards raises cost, in many cases to a level exceeding property values. Such approaches encourage property owners to abandon properties or fence them off rather than remediate and redevelop.

Similarly, the Commission's attempts to address severance of liability further reinforce the imbalance among the Legislature's policy directives. The Commission's recommendations provide incentives for severance of liability through use of hazard control remedies to achieve residential (i.e., what the Commission terms permanent) cleanup standards. As a basis for regulatory development, this incentive perpetuates the prejudice against exposure control remedies that can be very effective in providing cost-effective risk control

under non-residential land uses. Bases for regulation development such as these incrementally act to influence development decision in favor of greenfield sites, thereby delaying the return of brownfields to productive use.

The Commission's overall recommendations are unsatisfactory because they perpetuate regulatory concepts that result in delay of remediation and increased cost of remediation beyond what is required to protect public health. We offer the following concepts directed toward fostering a more workable balance among the Legislature's directives:

- Manage risk based on differential cleanup levels associated with current and reasonable future land uses.
- Consider hazard reduction and exposure reduction as equivalent approaches to managing risk and do not provide differential preference or incentives for their application.
- Consider permanence only as a preference discriminating between hazard control and exposure control alternatives where the achievement of risk levels and implementation costs are similar.

V. Detailed Comments on Report

No.	Page	Comment and Rationale

1	8	"...the Commission recommends that site remediation standards be flexible and reflect the future use of the site."

We agree with the Commission that it is important to realistically define the future land use to appropriately establish the site remediation goals. EPA has been criticized for too often assuming that future land use will be residential. The USEPA has provided guidance on considering land use in making remedy selection decisions (OSWER Directive No. 9355.7-04, May 25, 1995). This directive promotes the use of realistic assumptions regarding future land use and clarifies how these assumptions fit in and influence the baseline risk assessment, the development of alternatives, and the CERCLA remedy selection process.

2	9	"First, that a site be remediated to the permanent standards in effect at the time of the remediation" (In context with severance of liability).

The Commission appears to equate "permanent remediation" to compliance with residential standards, i.e., unrestricted land use standards. The permanence of the remediation, (in effect, the degree to which maintenance is required over time to maintain the remedial goals) has little to do with how the land is used.

Many areas in New Jersey have historically been used for non-residential purposes and are classified as such according to local

zoning laws. Responsible parties should not be required to perform additional remediation to restore existing non-residential land to unrestricted (residential) land use. If the current owner of a non-residential property that had been sold by a responsible party wants to change the land use, it should be the owner's responsibility to perform the additional remediation, if any, to achieve the residential land use remediation standards.

- 3 9 "The escrow account will be used in the event that previously undetected contaminants with greater health impacts than those previously remediated are detected..."

This statement appears to allow use of the escrow account for remediation that would not be the responsible parties liability under HDSRA 58:10B-12j. Under this section, the department can compel the use of a different remediation standard only when the new remediation standard and the remediation standard approved in the workplan differ by an order-of-magnitude. There is no mention of the situation described by the Commission.

- 4 10 "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 matters regarding site remediation, site reutilization and evaluation of future risk assessment policy."

We agree with the Commission. While we agree that this may be of benefit to interpreting and aiding in implementation of the Commission's recommendations, we are not certain under what authority this could be implemented or who would be appropriate members of such an advisory board.

- 5 10 We agree with the Commission's recommendation to use the best available scientific information and judgement to predict hazard and the use of site-specific data rather than default assumptions. We concur with the Commission's encouragement to use probabalistic analysis, pharmacokinetic modelling, bioavailability and environmental fate and transport modeling to predict current and future environmental risk. The application of these methods should be based on generally accepted procedures and guidance available from the USEPA.

- 6 11 Table 1, Footnote 1. The requirement for "irreversible transformation" or "irreversible immobilization" in the definition of permanent remedy severely restricts applicable treatment methods for inorganic chemicals such as metals. Proving that a remedial technology results in "irreversible" changes is extremely difficult without specification of a time period and control limits on the allowable amount of transformation or mobilization. Without these controls being specified, the requirement is unworkable.

In a larger perspective, off-site removal and disposal could be considered as an extreme example of exposure control and may not be considered a "permanent remedy". Off-site removal is a "permanent remedy" for the site only because the contaminant is removed from the location of the receptors being considered. The contaminant is controlled at the disposal site using exposure controls, such as liners, caps, and monitoring systems.

A permanent remedy for metals, for example, does not have to completely eliminate transformation or migration to be effective in meeting remediation goals as defined through risk reduction or reduction in hazard quotient. Slowing the release or the transformation of a chemical to a more toxic constituent such that risks are reduced below cancer or non-cancer thresholds should also be considered a permanent remedy.

- 8 11 Table 1, Column titled "Population Based (event/70 years)"

Does this column heading imply that the risk levels cited apply to exposed populations between 10,000 and 1,000,000 persons over a 70 year lifetime such that risks in the range of 10^{-4} and 10^{-6} result in the potential for 1 event. Please clarify the meaning of this heading.

- 9 21 V. RISK ASSESSMENT METHODOLOGIES. "Subsequently, a discussion of the limitations of the currently applied methodology is presented."

It is unclear whether the Commission is referring to the methodology currently applied by the NJDEP or the USEPA. Please clarify.

- 10 23 "In Summary 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."

We agree that a single point estimate of risk does not adequately describe the uncertainty inherent in the factors used in the calculation. A probabilistic approach can be used to quantify and bound the uncertainty. However, the regulatory agency must be provided guidance in justifying selection of the appropriate risk probability to have a workable standard.

- 11 24 "The primary consideration for utilization of any reference or toxicity data base is peer review to assure reviewed scientific validity."

We concur with the Commission's statement. However, controversies regarding scientific issues abound in the peer-review literature. Selective use of the peer-review literature can, and has been used to support extreme positions differing greatly from those practices and methodologies accepted by the majority of experts

and defined in federal guidance and regulation. The Commission must be vigilant in the differentiation between appropriate conclusions supported by most experts and regulatory bodies and inappropriate conclusions based on skewed interpretation by a minority.

The Commission references the USEPA Integrated Risk Information System (IRIS), Health Effects Assessment Summary Tables, and toxicity factors developed by the Safe Drinking Water Quality Institute pursuant to the 1984 A-280 Amendment to the Safe Drinking Water Act. The Commission also indicates that for some chemicals, the primary toxicology literature must still be reviewed to develop benchmark doses. The Commission has not indicated what scientific methods must be followed to derive a RfD or RfC of equal scientific "quality" as those contained in IRIS, HEAST, and the Safe Drinking Water Quality Institute. We assume the most advanced methodologies utilized by the USEPA would be appropriate, such as the Benchmark Dose Model ⁽¹⁾.

- 12 24 "The primary components of a risk assessment include an evaluation of existing toxicology data, identification of appropriate exposure routes (inhalation, ingestion, etc),..."

We request that the Commission complete the listing of appropriate exposure routes by including those generally accepted for use in risk assessment by the U.S. EPA, in effect, inhalation, ingestion, direct contact and indirect pathways in specific cases.

- 13 29 "The process of developing an RfD requires that scientific judgement be applied to a weight of evidence evaluation..... At RfD for a particular chemical may change when additional health effects data become available."

Refer to Comment No. 11. If only federal sources of RfD values will be supported by the Commission for use within the state, a methodology for deriving RfD values is not necessary. However, if the state will develop RfD values that differ from, or address chemicals or pathways not regulated by the USEPA, a scientific methodology should be recommended.

- 14 31 "..., the Commission strongly recommends the development and validation of standard probabalistic approaches that can eventually be used to better define risk."

PPG agrees. Refer to Comment No. 10. The Commission should provide recommendations on the use of probabalistic approaches in risk assessment to establish cleanup standards. Many distributions utilized for probabalistic risk assessment have been developed and validated by USEPA. NJDEP should be encouraged to

¹ Crump, K.S. (1984). A New Method for Determining Allowable Daily Intakes. Fund. Appl. Tox. 4:854-871.

utilize such data.

- 15 32 "Testing and evaluation protocols which are predictive of actual release potential under varied management scenarios need to be developed and implemented."

We agree that accurate prediction of release potential is essential to obtaining data that are representative of the exposure and preclude the application of excessively conservative assumptions. Field validation of any method used to predict release potential should be considered as a prerequisite for approval prior to use in the regulatory process.

- 16 35 "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."

While we agree with the conclusion reached by the Commission, we are concerned over the imprecise language of the statement and believe the ramifications of the conclusion have not been fully considered and developed to a useful conclusion.

The Commission uses imprecise language in stating that the risk "results in an additional 10 cancers" and when it states "when it produces 0.1 cancers in 70 years". The whole risk assessment approach is theoretical and its validity is dependent on scientific concepts which are not validated in all cases (such as animal versus human comparative responses and high to low dose comparative responses). The appropriate terminology in referring to risk is the theoretical lifetime excess cancer risk. It is a theoretical value of excess risk in a lifetime, i. e., that increment above the background lifetime population risk of about 0.25 for cancer. Given that the background lifetime population risk is much larger (1 in 4) than the theoretical excess cancer (10^{-4} to 10^{-6}), it is unlikely that the environmental effects could be separated from the background. To state that this theoretical lifetime excess cancer risk unequivocally "results" or "produces" cancers is imprecise.

The Commission provides no indication of how exposed population size would be incorporated or translated into an influence on the standard developed. In virtually every hazardous site case, the exposed population is small. One method would adjust the target theoretical lifetime excess cancer risk (target TLECR) using an estimated exposed population factor, such as

$$\frac{10^7 (\text{estimated exposed population})}{10^6 (\text{base population})} \times 10^{-6} (\text{target TLECR}) \\ = 10^{-5} (\text{"adjusted allowable risk" for an exposed population of } 10^7)$$

Which would drive remediation due to the potential for greater than 1 lifetime theoretical excess cancer risk in the population.

or

$$\frac{10^5 (\text{estimated exposed population})}{10^6 (\text{base population})} \times 10^{-6} (\text{target TLECR}) \\ = 10^{-7} (\text{"adjusted allowable risk" for exposed population of } 10^5)$$

Which would not drive remediation due to the potential for less than 1 lifetime theoretical excess cancer risk in the population.

- 17 35 "The proposed remediation criteria (Table 1) require an order-of-magnitude more stringent standard when exposure controls are employed...This "safety-net" imposes a more stringent requirement than current regulations."

The "safety-net" imposes a residual risk of 10^{-4} for all exposure control remedies. In effect, if the site risks are $> 10^{-4}$, selective removal, destruction, irreversible transformation, or irreversible immobilization are required prior to allowing the use of exposure controls. In this context, Table 1 for USEPA Carcinogen Classification "C" equates permanent remedy and exposure control remedies at a 10^{-4} residual risk. In this case there would be no incentive to use exposure control since the maximum risk with failure of an exposure control remedy is the same as the residual risk of the permanent remedy.

- 18 36 "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, notwithstanding the success in achieving the individual risk based standards, would not be acceptable."

We assume that the word "adverse" should be "excess". Conversely, the opposite should also be acceptable, in effect if < 1 excess lifetime event was projected theoretically, the risk would be adjusted downward. As an example, if a 10^{-4} theoretical lifetime excess cancer risk was projected to influence an exposed population resulting in 0.1 adverse lifetime events, the theoretical risk could be adjusted downward to 10^{-5} .

- 19 37 "In many cases, the generic remediation standards may be more stringent than necessary to protect groundwater quality."

With few exceptions, cleanup standards based on protection of groundwater quality are more stringent than soil cleanup standards for inhalation, ingestion or direct contact with soils. Site-specific cleanup standards should be allowed to better reflect the influence of the site on exposure and reduce reliance on default assumptions.

- 20 43 RECOMMENDATION 1. We agree with this recommendation subject to the concerns expressed in Comment No. 11.
- 21 43 **RECOMMENDATION 2. While we agree in principle with the need to incorporate consideration of a risk range into the development of cleanup standards, we do not agree with the Commission's recommendation for Group C carcinogens. The Commission's incentive is flawed in regard to the management of Group C carcinogens which practically eliminates exposure control remedies by equating the residual risks using a permanent remedy with the maximum risk with failure using exposure control remedies. This goes beyond the "preference" for permanent remedies contained in HDSRA 58:10B-12 g.(1) and the SARA amendments to CERCLA.**

- 22 44 RECOMMENDATION 4. "The Commission strongly supports a risk management standard of 1×10^{-5} for Class A&B carcinogens for calculation of soil remediation standards."

The Commission does not provide a clear rationale for the use of a 1×10^{-4} risk management standard for Class C carcinogens as is contained in Table 1. A more defensible basis should be developed.

- 23 44 RECOMMENDATION 4. "Previous discussions have demonstrated that USEPA endorses and utilizes a flexible risk management structure."

The risk management structure utilized by the USEPA and within the NCP is flexible, but is significantly different than that proposed by the Commission. The USEPA approach (OSWER Directive 9355.0-30) defines a 10^{-4} theoretical lifetime excess cancer risk obtained from the site-specific baseline risk assessment as a threshold criteria; remedial action is not warranted for risks below this value and is generally warranted above this value. The Commission's risk management structure does not contain the concepts of threshold risk or the use of site-specific information in the first decision tier.

- 24 44 RECOMMENDATION 4. "The Commission recommends adoption of a three-tiered approach to site remediation. Tier one is essentially equivalent to the current NJDEP soil clean-up criteria with the exception that all values should be recalculated to the risk management standards of 10^{-5} ."

We are uncertain whether the Commission is recommending the approach contained in the current NJDEP soil clean-up criteria regarding the use of a generic risk assessment approach or is recommending the approach and technical methodology used within the current NJDEP soil clean-up criteria. We can understand how the content of the Commission's report could be used to justify recommending the approach, but the report does not specifically discuss or critique the technical methodology used by the NJDEP to arrive at the specific soil clean-up criteria. The public has not had an opportunity to formally review or comment on the technical approach taken by the NJDEP in arriving at soil clean-up criteria

since the 1992 proposed soil clean-up standards were withdrawn after a public comment period. The methodology and approach used by NJDEP in 1992 was inconsistent with USEPA methodologies. The content of the Commission's report does not justify a conclusion to recommend adoption of the technical approach used by NJDEP in deriving the internal NJDEP soil clean-up criteria since these were never formally adopted nor reviewed by the Commission. It would be premature for the Commission to recommend adoption of the technical methodologies at this time.

- 25 44 RECOMMENDATION 5. "The Commission endorses the NJDEP policy of differential remediation criteria for residential and non-residential sites, consistent with Table 1."

Table 1 does not explicitly differentiate between residential and non-residential land uses; it only differentiates between permanent and non-permanent remedies as defined by the Commission.

- 26 44 RECOMMENDATION 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."

We praise the Commission in attempting to deal with the issue of long-term liability and the finality of cleanup.

- 27 45 RECOMMENDATION 7. "The Commission recommends a surcharge of approximately one to five percent be assessed on all remediations initiated after the adoption of this report."

An assessment to all sites is not equitable unless all sites can receive benefit from the assessment. Sites remediated using non-permanent remedies would be assessed the surcharge without gaining any advantage. Thus the incentive offered is not provided by the state but by other responsible parties.

- 28 45 RECOMMENDATION 8. "The Commission recommends the development and validation of standard probabilistic approaches that can be used to better define risk."

As indicated in Comment No. 10 and 15, we agree that a single point estimate of risk does not adequately describe the uncertainty inherent in the factors used in the calculation. We would suggest that a time frame be suggested within which probabilistic approaches would be incorporated.

We recognize the important influence the Commission can have through their recommendations on either rebalancing the direction of, or perpetuating the present imbalanced direction of site cleanup in New Jersey. The scope of the concepts in offered in Section IV may be beyond the charge of the Commission. However, the Commission can consider these concepts in formulating recommendations within the scope of their charge.

We hope our comments have been useful to the Commission in their efforts.

Sincerely,

Leonard S. Bryant *ETM*

Leonard S. Bryant



ENGINEERING & ENVIRONMENTAL SCIENCE
116 Village Boulevard
CN 5331
Princeton, NJ 08543-5331
609-967-2500
Fax: 609-243-0120

December 18, 1995

VIA FAX 292-0561

Ms. Judith Horowitz
Environmental Risk Assessment and Risk Management Study Commission
State House Annex
CN-068
Trenton, NJ 08625-0068

Dear Ms. Horowitz:

I am pleased to provide you with the following comments concerning the Risk Assessment and Risk Management Study Commission's Risk Assessment Report:

1. The Commission should be commended for putting forward many recommendations which should serve to move cleanups of contaminated sites forward.

Specifically:

- The Commission has rightfully recognized that the appropriate risk associated with a cleanup is a policy decision rather than a scientific technical call.
- Site specific risk assessment using site specific data, including fate and transport modelling is appropriately used for determining site remedial goals.
- The need to establish different cleanup requirements for different land uses.
- Establishing a 10^{-5} risk level as the target risk associated with site remediations.

There are some issues, however, which need to be addressed concerning recommendations of the commission and we offer these in the spirit of constructive criticism in hopes that they will be considered by the Commission:

- An expressed intent of ISRA was to provide remedial solutions which would protect human health and the environment while not requiring overly protective cleanups driven by conservative risk assessment assumptions. Engineering

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controls which essentially reduce the exposure to site contaminants to zero were recognized as appropriate remedial solutions. Such solutions and required declaration restrictions (DER), and, therefore, are to a degree somewhat unattractive for projects which will be transacted in the future. For said sites, there may be a defacto preference for selection of permanent remedial solutions so as not to encumber the property with DER. Therefore, it would be inappropriate for The Risk Commission to undo an intended consequence of the Legislature by providing additional disincentives for those choosing engineering controls. However, this is exactly what The Commission has done by requiring one order of magnitude less risk for sites selecting non-permanent remedial strategies than those selecting permanent remedies. In the report, it is ambiguous as to how the committee would have The Department apply the 10^{-6} remedial standards to non-permanent remediation. This needs further elaboration prior to serious consideration. Additionally, it appears that the committee recommends that any site which is being remediated to a non-permanent solution reduce the level of contamination so that, if in fact, the engineering control fails, that no greater than 10^{-4} risk would be imposed by the contamination present. It is important to realize that the 10^{-4} calculation would be based on a 70 year exposure assumption. It is doubtful if an engineering control were to fail that it would fail for any length of time approaching 70 years. Nevertheless, it seems that this recommendation would serve to poison the remediation of previously utilized sites and undo a lot of positives that have been done toward bringing brownfield sites back into economic utility. If all sites, irrespective of the use of engineering controls, are to be cleaned up to the point that they impose no greater risk than one in ten thousand (10^{-4}), clearly, this will provide strong economic disincentives to develop formerly utilized property.

- Given the uncertainties associated with risk calculation, the legislature, in passing ISRA, expressly prohibited The Department from calculating cumulative risk values for specific pathway. The Commission has chosen to go contrary to this position. In their recommendations, The Commission suggests that the cumulative risk for a specific pathway should not exceed 10^{-5} . Alternatively, we recommend, again recognizing the extremely conservative nature of risk calculations, that the cumulative risk for Class A carcinogens only be less than less than 1.0×10^{-4} .
- Most importantly, The Commission has failed to frame the perspective of risk in an overreaching context so as to give the legislature a basis and background on which to move from 10^{-6} to 10^{-5} . Everyday risks that we assume ought to be posed so as legislatures can understand a comparable 10^{-5} risk posed by contaminated sites vs. a 10^{-5} risk that we experience on an everyday basis in society. This is the most glaring failure of the report. Clearly, as stated in the report, an appropriate cleanup risk level is a policy decision made by policy makers. Policy makers must be given the opportunity to understand in a lay



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perspective how the impact of such a decision will affect the population impacted. The report fails to do this. There are ample publications that can be cited, such as much of the work done by Harvard's Professor Wilson, in which relative risk is portrayed in lay terminology. The inclusion of such examples must occur if this report is to be effective in implementing its recommendation in moving away from 10^{-6} to 10^{-5} risk.

I appreciate having the opportunity to comment on The Commission's recommendation and hope they will be successful in providing a studied approach in establishing appropriate risk levels for site remedial work in this state.

Yours very truly,

SADAT ASSOCIATES, INC.

By:

Jorge H. Berkowitz, Ph.D.
Vice President

JHB:gj

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SADAN04B7.WP5

Written Comments For Environmental Risk Assessment and Risk Management Study
Commission Report Dated November, 1995

Compiled by Alicia Randolph
Shell Oil Company
December 18, 1995

One of Shell Oil Products Company key objectives is to "continuously improve our environmental performance." As such, we welcome the opportunity to comment on the Risk Assessment and Risk Management Study Commission's ("Commission") November, 1995 report. The protection of human health and the environment is New Jersey's environmental legislation's the ultimate goal; however, not all contaminated sites present an equal amount of risk. We commend the Commission for recognizing the need for incentives for more sites to be cleaned up and the need for risk-based policies.

We recognize that the Commission has to address the public perception of the amount of remediation activities occurring within the state of New Jersey. However, we stress that there should be a system of practical, cost-effective remedies based on consistent decision-making. Without this, there will be a financial drain on both public and private entities, primarily municipalities and small businesses.

Shell supports the general findings of the Commission, but feels that some items need to be clarified. More support will probably need to be given as the scientific basis for numbers used due to the public perception of the Commission's "weakening" of the assessed standard of one in a million.

We feel that ASTM E1739 should be used as framework. ASTM E1739 addresses all media (soil, groundwater, surface water, air); groundwater, air, and surface waters issues are not addressed directly in the Commission's report. Risk-based decision making allows sites of greatest risk to receive dedicated resources more effectively. Less resources could be used on sites of little risk thus freeing resources for sites of larger risk. This approach is currently used by several states, including Pennsylvania and New York.

The use of site specific information should be enhanced in this risk-based decision-making environment, rather than relying on default assumptions. We appreciate the Commission "embracing" this approach (p. 10). "The Commission recommends that site remediation standards be flexible and reflect the future use of a site" (p. 8). Site specific information is applicable to the entire process of risk analysis, not just to final remediation techniques. The acceptance of valid new data, innovative methods and the technical feasibility should all be considered. The zoning of a site (residential, commercial, or industrial) should also be a consideration when assessing risk.

On page 38, the Commission states that Tier 1 is a restatement of the current NJDEP soil cleanup criteria. This statement by the Commission validates a set of numbers that have not yet been promulgated by the DEP. The cleanup numbers are based on a set of default site conditions that are assumed to be representative of the entire state of New Jersey. Why should a remediation take place to these values if they do not represent site specific conditions and site specific risks? The Commission should not be accepting the soil cleanup criteria. Instead, the DEP should be re-evaluating the proposed Cleanup Standards that have yet to be promulgated as regulation in light of the recommendations

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of the Risk Commission. It should be made clear that Tier I values use default assumptions that are not site specific and therefore do not represent site specific risks. Furthermore, by eliminating the potential for exposure under Tier I, the risk can be eliminated without destruction of contaminant mass. If the risk can be eliminated, why isn't this an acceptable corrective action?

Also on page 38, the statement is made that in Tier II, site specific characteristics and exposure scenarios are used to develop remediation criteria. Remediation under these criteria are considered permanent. If you consider exposure pathways on a site specific basis in many cases, there is no exposure and consequently no risk. In this case, risk reduction is achievable without contaminant mass reduction. Previously, it was stated that exposure reduction was not permanent. This statement seems to contradict this. Please re-evaluate the notion that exposure pathway elimination is not permanent.

The difference between Tier II and Tier III appears to be the level of effort placed into incorporating site specific factors (p. 38). Was this the Commission's intent? Using permanent and non-permanent remedies in the discussion of the three tiers creates a gray area in the objective of risk reduction. One difference between Tier II and Tier III is that Tier II is permanent and Tier III is not. Please explain.

However, in many cases, default cleanup values are applied regardless of site specific conditions. Cleanups are required due to a default cleanup level being exceeded, not because of an unacceptable level of risk. Secondly, the level of risk should not change when moving from one tier to another; instead the quality and site specificity of the risk assessment should be improved as one moves to a higher tier.

Overall more information should be given regarding the use of Table I. For instance, with respect to recommendation 5, it is not clear which items are addressing residential standards and which are addressing non-residential.

Adverse effects (cancer, other health items trespass, etc.) are not defined in the Commission's report. Furthermore, the Commission states that toxicology information is subject to peer review. This acceptable "peer group" should be defined by the Commission in its study.

The report discusses impediment to remediation. How were these determined? (Which reference was used?) How is the surcharge (p. 45) assessed? What is the basis for the percentage -- total cost of remediation, some set standard, ...? The entire issue of the surcharge is debatable since this is not an incentive to remediate. Due to extensive pre-remedial and post-remedial sampling already required by the DEP and the limited number of "clean closures", the necessity of revisiting a location is minimal.

The Commission should address how this new approach would apply to sites with current active remediation systems. Issues should be re-evaluated with regard to risk since many targets for closure were established without regard to risk previously. Non-permanent remedies and exposure control limits should also be risk based.

The establishment of a Risk Advisory Board should be postponed until the New Jersey legislature and DEP accept a risk-based corrective action decision-making process fully. If this board is formed, it should include several disciplines, including the regulated community, EPA and DEP personnel, consultants, hydrogeologists, and public health representatives.

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There are currently several mechanisms in place which should be addressed by the Commission. The Cooperative Venture program between the NJDEP BUST organization and industry should be mentioned. Also the use of deed restrictions should be more fully discussed.

Overall, the Commission's report appears to be a step in the right direction for the state of New Jersey. By promoting risk-based decision-making, the Commission will allow for better use of available resources.

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1275 K Street, N.W., Suite 400
Washington, D.C. 20005
(202) 371-5200
FAX 371-1022

December 18, 1995

Ms. Judith L. Horowitz
Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, New Jersey 08625

Re: Comments on the Draft Report of the
Environmental Risk Assessment and Risk
Management Study Commission

Dear Ms. Horowitz:

The Society of the Plastics Industry, Inc. ("SPI")^{1/} commends the recommendations contained in the "Draft Report of the Environmental Risk Assessment and Risk Management Commission" ("Commission") concerning the assessment of risks at industrial sites and clean-up criteria. The Commission's recommendations reflect practical scientific methods for evaluating risks at, and accelerating the cleanup of, contaminated industrial sites in New Jersey while ensuring the actual protection of human health and the environment. The recommendations will benefit New Jersey by reducing the backlog of sites in need of remediation. Moreover, implementation of these recommendations will more firmly establish New Jersey's place as a leader among the states in

^{1/} SPI is a 2,000 member not-for-profit trade organization representing all segments of the plastics industry in the United States. The Society's members include processors and manufacturers of plastics and plastics products, suppliers of raw materials, processors and converters of plastics resins and manufacturers of accessory equipment for the plastics industry. Founded in 1937, SPI is the major national trade association of the plastics industry.

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ensuring the environmental protection of its citizens. SPI, therefore, urges the prompt adoption of the recommendations contained in the Commission's draft report. SPI, however, disagrees with the Commission's characterization of the Monte Carlo analysis.

1. Monte Carlo Analysis is Sound

SPI does not agree with the Commission that the Monte Carlo analysis leads to faulty and misleading risk estimates. In the document, the Commission notes the weakness of this approach is that it is "dependent on the quality of input information." Traditional linearized multistage models often used for risk analysis are also dependent on the quality of the studies used to do the extrapolation from high dose to low dose predictions.

Much work in exposure assessment has been conducted in the past few years on the development of distributional data for input parameters in risk analysis (AIHC, Exposure Factors Sourcebook, 1995). The quality of these distributions is evidenced by the fact that they are based on real data as opposed to statistical extrapolation from a linear model which may not represent the true nature of the dose-response curve.

It is well known that many non-cancer toxicity endpoints, nongenotoxicity carcinogens, and even several genotoxic carcinogens have been shown to elicit threshold responses. Also, hormetic effects have been demonstrated for several compounds at low doses (Calabrese, 1994).

From a public health perspective, it is important to consider the uncertainty in risk estimates. Traditionally, this has led to the use of linearized models to derive estimates of risk which are extremely conservative. These numbers fail to represent real-life exposure scenarios and actual risk. Probabilistic analyses based on the use of distributions lead to more realistic estimates of the range of risks and should be employed whenever possible to allow for cost-effective, practical remediations that are fully protective of public health.

2. SPI Supports Commission's Recommendations

Certain recommendations from the Commission's draft report are of particular importance because they represent a significant advancement in environmental management that involve the proper assessment of risk and methods to encourage more prompt remediation of contaminated sites. SPI highlights these recommendations because they expose both the fallacies underlying existing risk assessment and the cleanup practices that have hindered the rapid remediation of contaminated sites. The

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recommendations provide a clear process for accelerating New Jersey's risk assessment and remediation program. These advances in environmental thinking are briefly set forth below.

- The Commission courageously notes that the standard application of the 10^{-6} guideline applied to risk management situations is not supported by biological or medical science. The Commission clearly places risk in perspective by explaining the scientific principle that the risk management standards, applied to site remediation when a small population is at risk, must be different from the standards utilized for determining risk when large numbers of individuals are involved, e.g., risk associated with drinking water or food additives. Application of this distinction along with the Commission's recommended consideration of the site's characteristics, the nature of the remediation effort and the future land uses, will allow a substantially greater number of sites to be remediated and at lower cost, while still achieving the same or greater levels of protection for human health and environment.

We agree with the Commission that non-cancer endpoints should be considered when setting remediation standards to provide adequate public health protection. To this end, SPI would promote the use of the Bench-Mark Dose approach for determining the level of risk for non-cancer endpoints. This method has been shown to be more statistically robust than the traditional Hazard Index method and incorporates the shape of the dose-response curve in the calculations (EPA, Great Lakes Water Quality Initiative Supporting Document, 1994).

- The Commission finds that each site is a unique constellation of physical and chemical properties and that patterns which result in a probability of human exposure may be different at different sites. No single value can adequately represent an entire contamination distribution because of differences in daily inhalation volume, soil and/or water ingestion, rate, time spent inside and outside a residence, body weight, and consumption rate. The Commission clearly articulates a dramatic fact that public policy has previously avoided. Now that this truism has been stated, the recommendation should be implemented to avoid approaching site cleanup with incomplete or inaccurate data which often times results in faulty and misleading risk estimates. Frequently, these inaccurate and sometimes exorbitant estimates result in costly remediation or no remediation until the termination of liability disputes and litigation.

- The Commission expressly accepts that "generic remediation standards" are problematic because the soil-to-groundwater pathway is highly site specific and transport of the

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contaminants to the aquifer is complex. Moreover, the Commission's recognition that the appropriate remediation standard should account for physical site dimensions (e.g., location of contamination, rate and potential extent of contaminant release, and distance to water table) demonstrates that generic remediation standards have a greater degree of uncertainty and are more stringent (costly) than necessary to protect groundwater quality because such standards are based on theoretical assumptions, not science and fact. Encouraging site-specific cleanup standards and the use of site-specific information, is a major break-through toward achieving cost-efficient cleanups that protect public health and safety. We applaud the Commission's promotion of the use of site-specific data for cleanups at contaminated sites as being the most appropriate and cost-effective use of hazard assessment data. We also strongly agree with the Commission that future use of a site should be considered when determining site-specific clean-up goals.

- The Commission recommends the elimination of the long term liability of the responsible party when such party completes a permanent remedy at the site in accordance with the standards in effect at the time of the remediation and pays a small (1-5%) surcharge on the remediation. The surcharge amounts are placed into a fund and used for any additional remediation activity that might be required after the responsible party has been relieved of future liability because it completed a permanent remedy. We strongly agree with the Commission's proposal to sever the liability of the responsible party if remediation goals are met. This recommendation brings certainty to the responsible party. The provision of certainty will encourage cleanups because costs can be assessed in present dollars and long term contingent liabilities eliminated. The Commission labels the present policy of "liability in perpetuity," as poor public policy. The Commission should be commended for its leadership on this issue and the courage to follow its vision and recommend the elimination of a "poor public policy" which has hindered the cleanup of contaminated sites for decades. We do not agree, however, with the use of "bright line" risk estimates in determining the success of remediation or containment efforts and, therefore, corresponding liability.

- SPI agrees with the Commission that the determination of a risk level for a specific scenario should be based on the best available science and engineering. For someone to be at risk, that person must have the opportunity to be exposed. Even at sites where the remedy involves in situ containment of contaminants rather than removal or disposal, therefore, risk may be minimal due to physical barriers of potential exposure. In these situations, penalty should not be incurred by the

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requirement of more stringent risk levels. If a residual risk of 10^{-4} is deemed appropriate as a matter of public policy for permanent removal, then this level should also be appropriate for sites where exposure controls are applied.

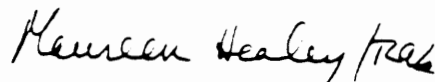
3. Conclusion

The Commission's recommendations, some of which we have highlighted, represent a commendable and comprehensive effort to achieve cost efficient remediation of contaminated sites while protecting human health and the environment. The Commission's draft report attempts to displace current practices, such as generic cleanup standards consisting of the broad-based application of redundant, conservative default assumptions, because such remediations are not based on sound science or public policy. While there is no one Commission recommendation that is so significant that the draft report would fail without it; it is the cumulative impact of all the recommendations that truly advances the public's thinking about risk and cleanup criteria.

For the reasons stated above, SPI urges the adoption of the recommendations and commends the Commission's efforts. SPI also urges the Commission to reconsider its assessment of the Monte Carlo analysis in its final report. The Commission's recommendations promote the use of science and the management of risk to protect real people and the environment. Neither New Jersey nor any other state has the resources to waste on protecting the public from theoretical risks. The Commission's recommendations can lead the way toward implementing health-based cleanups while conserving the public's funds.

If you have any questions or wish to discuss this matter further, please call me at 202-371-5219.

Sincerely,



Maureen Healey

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SCHIFFMAN ASSOCIATES, LLC

CONSULTING SERVICES IN GROUND WATER AND SURFACE WATER CONTAMINATION

December 8, 1995

Dr. Michael A. Gallo, Chair
Environmental Risk Assessment and Risk Study Commission
Office of Legislative Services, Legislative Office Building
CN-068
Trenton, New Jersey 08625-0068

RE: Comments to the November, 1995 report of the Commission

Dear Dr. Gallo:

I strongly recommend that you modify the "Environmental Fate and Transport Considerations in Risk Assessment" section of the report. You must delete statements that infer fate and transport models are inadequate and thus that fate and transport considerations are inappropriate for setting soil cleanup standards. This old idea is not applicable to remediation although it may have merit in other areas of risk assessment. The problem is the constant concentration assumption inherent in the back-calculation algorithms in RAGS. Constant concentration is not a conservative assumption but a physically impossible assumption that is technically and legally indefensible. It is a difficult problem to address as this assumption is reasonable for setting risk-based standards in other situations such as drinking water. For drinking water standards, we assume that the contaminant dose received is constant over the exposure duration used in the back-calculation. This is true as the contaminant is normally present in the water source. Setting a risk-based soil standard (assuming constant concentration) means a finite quantity of chemical mass or dose (e.g., 1 mg/kg or about 1,500 mg in a cubic meter of soil) that, for most chemicals, cannot possibly persist over the long exposure durations used for the cancer endpoint. To some degree, chemicals volatilize, leach and degrade. Less dose, less exposure, less risk.

This issue has had some presence in the literature either as discussion of constant concentration or the broader category of mass balance. My contribution is to point out that for remediation of contaminated soil, this assumption is a physical impossibility and not "conservative." We cannot assume zero rainfall (no leaching), infinite atmospheric pressure (no volatilization), sterile environment (no degradation), and that the same mass of a contaminant can be in different environmental media simultaneously. The issue is not the adequacy of fate and transport models as algorithms for intake rates and dose are not perfect either. Arguments should be about an appropriately conservative assumption for contaminant loss rates from soil. Under the constant concentration assumption, we never get to the valid scientific arguments. It turns out that when

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approximate mass balance corrections are made to the risk algorithms. numerical soil standards for most chemicals become much greater and the risk management standard (e.g., 10^{-6}) becomes a secondary consideration.

I have enclosed a paper I presented at the Superfund XVI Conference in November, 1995 that uses degradation as an example of the problem with constant concentration. If you are really interested in this subject, I can send you another similar (but longer) paper using leaching as an example. These papers have not been peer-reviewed, but I have discussed them with enough people to know that they are on target.

USEPA is using risk algorithms that correct for some loss mechanisms in their "Hazardous Waste Identification Rule" (HWIR) scheduled for the Federal Register this month. There are problems with their algorithms, but at least there are substantive scientific issues to debate. Unfortunately, EPA programs are fragmented and the RCRA staff doing HWIR often do not agree with Superfund staff. Contact EPA at (202) 260-6557 for copies of the HWIR documents and the report of the EPA Science Advisory Board reviewing the HWIR proposal. This issue is related to comments you will receive on "Risk-Based Corrective Action." The main difference is correcting for mass loss in the standard setting process versus correcting during site-specific evaluations. New Jersey needs to pay attention to what is happening elsewhere.

The Commission was asked to delve into the netherworld of regulation where policy and science meet and the devil is indeed in the details. A distinguished panel of scientists was assembled to deal largely with a social political issue—the risk management level. Although it is probably too late to change, most of the report's content should have been on the risk assessment methodologies. The Commission is operating under a peculiar framework and I am sure you will receive many comments that some of your conclusions are wacky. My general rule is that a wacky framework yields wacky conclusions that are independent of the quality of the people who made them.

It is my opinion that a scientifically-sound risk assessment process is critical to the future of environmental programs. Work on trivial environmental problems will drive out needed work on substantive environmental problems. Attached is a discussion on why this is so along with some details on regulatory frameworks. Perhaps this will tilt you in the direction of modifying your report.

Sincerely,

SCHIFFMAN ASSOCIATES, LLC



Arnold Schiffman, P.G., P. Hg.
President

enclosures: 2



SHIELDALLOY METALLURGICAL CORPORATION

DAVID R. SMITH
DIRECTOR OF ENVIRONMENTAL SERVICES

WEST BOULEVARD
P.O. BOX 768
NEWFIELD, NJ 08344
TELEPHONE (609) 692-4200
FAX (609) 692-4017

December 19, 1995

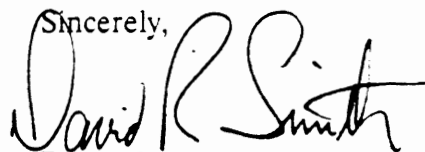
Ms. Judith L. Horowitz
Office of Legislative Services
State House Annex
Room 381
CN-068
Trenton, New Jersey 08625-0068

RE: Comments on the Report and Recommendations of the Environmental Risk
Assessment and Risk Management Study Commission

Dear: Ms. Horowitz:

Shieldalloy Metallurgical Corporation (SMC) is pleased to be able to submit comments on the referenced report in accordance with Notice of Public Hearing published in the New Jersey Register, Monday, November 6, 1995. Fifteen copies of our comments are enclosed with this letter which is being sent via an overnight delivery service. A facsimile copy of SMC's comments are being transmitted today to insure that they are received by the published deadline of December 19, 1995.

If the Environmental Risk Assessment and Risk Management Study Commission has any questions regarding the enclosed comments please feel free to contact Mr. C. Scott Eves, Vice President, Environmental Service or me.

Sincerely,

David R. Smith

cc:

W/Enclosure:

Michael A. Finn	SMC
Kenneth R. Pugh	SMC
C. Scott Eves	SMC

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New Jersey State Library

Shieldalloy Metallurgical Corporation (SMC) has studied the Environmental Risk Assessment and Risk Management Study Commission report (November, 1995) with interest. SMC supports many of the Commission's conclusions and recommendations, particularly those concerning the lack of a scientific basis for the conservative 10^{-6} risk standard, provisions for maintaining flexibility in the setting of remediation criteria, and the use of alternative methodologies and "best available science" in the risk assessment process. SMC would like to take this opportunity to expand the discussion of these important topics and introduce new arguments in an effort to help develop an effective and economical site remediation policy in New Jersey.

Selection of Target Risk Levels Should Remain Flexible and Subject to Chemical- and Site-Specific Considerations under Tier 2 (i.e., Site-Specific Permanent Remedies) and Tier 3 (Exposure Control Remedies).

SMC concurs with the Commission's statements on p. 19 that:

- (i) "...establishment of a single risk management standard (10^{-6}) for all site remediation structures has been an issue of public policy",
- (ii) "Determination of [a] risk level for a specific scenario should be based on the best available science and engineering", and
- (iii) "...remedial risk management policy options should be influenced by the characteristics of the site(s), the nature of the remediation and future land use."

As a matter of public policy and regulatory efficiency it may be reasonable for New Jersey Department of Environmental Protection (NJDEP) to establish a fixed target risk level for default standards under Tier 1 (permanent remedies achieved through the application of NJDEP's default standards). However, the selection of target risk levels for incorporation into the development of site-specific standards under Tiers 2 and 3 should remain flexible within the United States Environmental Protection Agency's (USEPA's) acceptable risk range of 10^{-6} to 10^{-4} , with the selection of the final target risk level governed by site-specific and chemical-specific considerations.

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Note that although the 10^{-6} to 10^{-4} risk range spans two orders of magnitude, such absolute risk levels are low when compared to the background cancer rate in the human population. As stated in the Commission report (p. 18), the current lifetime risk of developing cancer in the U.S. from all causes is roughly 1 in 4. Thus, a target risk level of 10^{-6} would increase an individual's hypothetical risk of cancer from 1 in 4 to 1.000004 in 4. Similarly, a 10^{-4} target risk level would increase an individual's hypothetical risk of cancer from 1 in 4 to 1.0004 in 4. These risk considerations must be borne in mind when developing site remediation policies that will have an effective impact on public health yet still be cost-effective.

There are additional factors, including unique site characteristics, nature of the remediation, and planned land use, that should also be considered in selecting a target risk level for application to a site-specific remediation. The USEPA addresses this issue in its 1991 OSWER Directive entitled Role of the Baseline Risk Assessment in Superfund Remedy Decisions (No. 9355.0-30) and its 1995 OSWER Directive entitled Land Use in the CERCLA Remedy Selection Process (No. 9355.7-04). In the 1995 document, USEPA states that the 10^{-6} to 10^{-4} risk range:

"...provides the necessary flexibility to address the technical and cost limitations, and the performance and risk uncertainties inherent in all waste remediation efforts".

In the 1991 document, USEPA also indicates that:

"...the upper boundary of the risk range is not a discrete line at 10^{-6} ..." and,

"A specific risk estimate around 10^{-6} may be considered acceptable if justified based on site-specific conditions."

Thus, it is clearly not USEPA's intention to identify a single target risk level which should be used in the development of cancer risk-based cleanup criteria/standards for all situations at all sites. Further, USEPA specifically cautions against rigidly partitioning the risk levels within the 10^{-6} to 10^{-4} risk range based on categories (e.g., of land use, USEPA cancer classifications). Since USEPA risk policy generally forms the basis of individual state remediation regulations and as the Agency is specifically cited in the New Jersey Industrial Site Recovery Act (ISRA; §35.b.3) as an appropriate

guidance source, USEPA recommendations on target risk flexibility should not be ignored or minimized

The Commission departs from its commitment to incorporate science, engineering and site-specific information when it proceeds to assign fixed target levels in Tiers 2 and 3 to the three listed classes of carcinogens (A, B and C). From a toxicological viewpoint, such rigid levels infer a high degree of faith in default regulatory assumptions and ignore uncertainties and inconsistencies in the underlying science. From a risk assessment point of view, they belie the flexibility intended by USEPA in establishing the 10^{-6} to 10^{-4} risk range under the National Contingency Plan (40 CFR 300.430e). In addition, they go against statutory language contained in ISRA §35.b.2 and 35.b.3 requiring "reasonable assumptions of exposure" and the avoidance of "redundant conservative assumptions". Finally, they contradict the Commission's own suggested policy of flexibility based on "best available science and engineering". In view of the lack of scientific credibility for fixed, conservative risk standards (i.e. $<10^{-5}$) and the USEPA policy that higher theoretical risks are acceptable under certain conditions, SMC urges the Commission to avoid any rigid proscription of target risk levels.

Incorporation of Alternative Methodologies and "Best Available Science" into the Risk Assessment Process

The risk assessment process relies upon numerous assumptions and extrapolations with questionable scientific justification. Examples of these disputed issues include the validity of animal-to-human toxicity data extrapolation, the use of the no-threshold linearized multistage model (or other procedures) for dose extrapolation over many orders of magnitude, uncertainties in exposure assessment, and the effect of multiple, highly conservative default assumptions on resulting risk estimates. ISRA specifically prohibits use of "redundant conservative assumptions" (ISRA, §35.b.3) and the Commission's report discusses several of these issues in detail. While it is not SMC's intent to reiterate these points, we believe that all of these factors contribute to the argument for a more rational and flexible approach to setting risk-based target remediation criteria. SMC endorses the Commission's recommendation to more extensively utilize "scientifically defensible tools", including

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physiologically-based pharmacokinetic modeling, mechanism of action information, and environmental fate and transport modeling in risk assessment.

As discussed in detail by the Commission, one promising approach to developing more realistic risk assessments is the use of probabilistic techniques to more effectively characterize human exposure parameters. The use of single point estimates of exposure parameters leads to a false impression of high accuracy and precision for the resulting risk estimates. It is clear, based upon rapidly accumulating scientific data, that human exposure parameters (e.g. breathing rate, drinking water consumption, days spent outdoors per year, etc.) are characterized by distributions rather than unique values. Probabilistic techniques, such as Monte Carlo analysis, incorporate the full range of exposure data to yield a corresponding range (with a maximum likelihood value) for the exposure parameters and, hence, the risk estimate. These estimates are invaluable in demonstrating the extent of uncertainty associated with the input exposure parameters. SMC agrees with the Commission's recommendation for increased use of this statistical tool, and further suggests exploration of its value in characterizing other risk assessment input parameters, including dose-response data and animal-to-human scaling values.

The quality of the scientific data that represent the many inputs to the risk assessment process for site remediation is critical to developing effective clean up goals. SMC concurs with the Commission's view (p. 20) that

“...development of remediation standards should establish a basis for consistent decision-making that is supported by *sound, peer-reviewed toxicological...data.*”

In addition, ISRA (§35.b.1) includes a similar provision for high data quality when they require “generally accepted and peer reviewed scientific evidence” in developing remediation standards. One scientific issue not specifically examined in the Commission's report concerns the significant uncertainty inherent in the process of developing carcinogenic potency factors for individual chemicals from animal or human tumor incidence data. The levels of confidence associated with potency factors for particular carcinogens vary greatly. USEPA generally provides a discussion of the strength of evidence for each determination. However, once formal potency criteria are set, the

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distinctions become lost and risk assessment proceeds as if all underlying data are of equal quality. USEPA has addressed this uncertainty issue to some extent in their 1994 Draft Revisions to the Guidelines for Carcinogen Risk Assessment. Those revisions propose new weight-of-evidence category descriptors that explicitly take into account data inadequacies and inconsistencies in addition to negative data that provide evidence for the lack of carcinogenic potential.

An approach to this problem, as suggested above, is the use of probabilistic (such as Monte Carlo) techniques applied to carcinogenicity data sets to generate ranges of cancer potency values rather than single numbers. This proposal has merit and should be pursued. In the interim, however, the degree of confidence in the underlying toxicological data used to set cancer slope factors and unit risks should be reflected in the level of flexibility employed in selecting target risk levels for site remediation. This is particularly true when a single or small number of components is "driving" the risk assessment process at a particular cleanup site, a situation that is frequently encountered.

A related concern is the quality and relevance of route-specific toxicological data. Route of exposure is an integral component in the development of target risk levels for remediation sites since scenarios include several primary human exposure pathways. It is recognized that the highest confidence risk estimates are associated with cancer slope factors and unit risks derived from well-conducted animal or human studies employing the route of exposure most pertinent to actual site conditions. Conversely, risk estimates based on cancer factors developed using marginal (or, in some cases, negative) data from an appropriate route of exposure, or those based on irrelevant routes, should inspire considerably less confidence. The level of confidence should in turn influence the degree of flexibility applied to the selection of target risk levels. The importance of route-specific data in generating cancer potency factors is recognized in the 1994 USEPA Draft Revisions document when it states (p. 36) that:

"Note that one agent may fit more than one descriptor, if, for instance, the agent were likely to be carcinogenic by one route of administration and not by another."

SMC believes that the Commission could usefully discuss the significance of route-specific extrapolation and its impact upon the development of site-specific criteria.

Beryllium: An Example of Inadequate Science as a Basis for Regulatory Standard Setting

Although numerous examples can be given that illustrate the concerns presented above, a particularly important one is the evaluation of risks associated with exposure to beryllium. This naturally occurring metal is frequently detected in soil at remediation sites and is present at significant background levels in the general environment. Beryllium exists in soils primarily as the oxide or metal, although beryllium salts can form under appropriate conditions. Except for certain salts, these forms are insoluble in water. Beryllium compounds are not bioavailable by the dermal route, are poorly absorbed following ingestion, but are retained following inhalation exposure.

Beryllium (and its compounds) is classified by USEPA as a Group B2 carcinogen, i.e. a probable human carcinogen based upon the results of animal studies. A unit risk cancer potency factor for inhalation exposure was calculated based on data from eight animal studies using various chemical forms of beryllium, and from several human occupational exposure studies. Because of the numerous exposure and dose assumptions utilized in these calculations, USEPA's confidence in this inhalation potency value is not high. A slope factor for oral ingestion of beryllium has also been calculated by USEPA, based on data from a beryllium sulfate drinking water study in rats with *one dose level* and *no significantly increased tumor incidence* results. For the majority of regulatory (and scientific) purposes, a study with a single dose level would not be considered valid for constructing dose-response relationships, and the lack of tumorigenic effect would be considered as evidence against carcinogenic potential at that dose level. USEPA provided the following caveat regarding this oral slope factor in their 1987 Health Assessment Document for Beryllium:

"The question of beryllium potency by ingestion is highly uncertain and debatable due to the equivocal or negative results from ingestion studies. From a weight-of-evidence point of view, the potential for human carcinogenicity by this route cannot be dismissed. *For practical purposes however*, the potency of beryllium via ingestion must be considered as largely unknown."

It is likely that, using the criteria of the 1994 USEPA Draft Revisions document, beryllium would be assigned either a "cannot be determined" or a "not likely to be carcinogenic" descriptor for the oral

route. Such a classification would eliminate beryllium as a compound of concern by this pathway under current or proposed NJ risk management standards. Some regulatory bodies, such as California EPA in their Proposition 65 regulations, already classify beryllium as non- carcinogenic by oral ingestion, thereby not requiring a risk assessment.

This example calls attention to the scientific uncertainties associated with cancer potency factor derivation for specific constituents, and support arguments for a linkage between the level of that uncertainty and the range of flexibility afforded in the development of site-specific target risk levels. SMC urges the Commission to consider uncertain toxicological data quality as a compelling justification for not setting fixed target risk levels.

Summary

SMC shares many of the concerns of the regulated community with regards to establishing the most effective and economical site remediation criteria and procedures. In view of the rapidly changing scientific basis of the risk assessment process, that goal is best achieved by maintaining maximum flexibility in designing site-specific remediation plans. Accepting alternate exposure and risk assessment methodologies and recognizing the importance of chemical- and site-specific factors are critical to achieving this flexibility. SMC strongly recommends that the Commission (i) re-emphasize its support of "best available science" and alternative methodologies for assessing exposures and risks, and (ii) avoid the adoption of any rigid target risk levels under Tiers 2 and 3 of the proposed remediation regulations.

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