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# NUCLEAR REGULATORY COMMISSION

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**NUCLEAR REGULATORY COMMISSION**

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RISK HARMONIZATION

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PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Wednesday, May 26, 1993

The Commission met in open session, pursuant to notice, at 2:00 p.m., Kenneth C. Rogers, Commissioner, presiding.

COMMISSIONERS PRESENT:

KENNETH C. ROGERS, Commissioner
JAMES R. CURTISS, Commissioner
FORREST J. REMICK, Commissioner
E. GAIL de PLANQUE, Commissioner

STAFF SEATED AT THE COMMISSION TABLE:

JOHN C. HOYLE, Assistant Secretary

MARTIN MALSCH, Deputy General Counsel for Licensing and Regulations

JAMES TAYLOR, Executive Director for Operations

ROBERT BERNERO, Director, NMSS

RICHARD BANGART, Director, Division of LLW Management and Decommissioning, NMSS

JOHN AUSTIN, Chief, Decommissioning and Regulatory Issues Branch, NMSS

MICHAEL WEBER, Section Leader, Regulatory Issues Section, NMSS

P-R-O-C-E-E-D-I-N-G-S

2:00 p.m.

COMMISSIONER ROGERS: Good afternoon, ladies and gentlemen.

The Commission is meeting at this time to receive a briefing from the NRC staff on the status of efforts for risk harmonization. The staff has already provided the Commission with an information paper on this matter and copies should be available here in the conference room.

Before we begin our discussion of this important topic, Chairman Selin has asked me to express his regret that he's unable to attend today's meeting due to other government business.

By way of introduction, let me recount just the most essential details of our dialogue with EPA on risk harmonization. In March of 1992, we were able to successfully conclude an effort to put in place a memorandum of understanding with EPA to help resolve issues of concern to both agencies. The March 1992 MOU represents a major step forward to foster cooperation between the Nuclear Regulatory Commission and the Environmental Protection Agency in carrying out agency mandates to protect the public health and safety and the environment on matters related to

radiation in the environment.

The MOU is essential for constructive interactions between the agencies because it establishes a framework for: first, resolving issues of mutual agency concern; second, avoiding unnecessary duplication of regulation; and finally, focusing priorities on the most significant safety and environmental problems.

The MOU also includes an important provision, Section D, calling for NRC and EPA to actively explore ways to harmonize health-risk goals and to cooperate in developing a mutually agreeable approach to health risk assessment methodologies for radionuclides. Risk harmonization is a critical activity under the MOU because differing risk management approaches have been a root cause in areas of disagreement between the two agencies. NRC and EPA are actively pursuing health risk harmonization both in a generic manner and through ongoing cooperative activities to resolve specific issues in program areas.

The most basic prerequisite for the cooperative efforts contemplated under the MOU is prior agreement between the agencies on acceptable risk limits or in reality a common answer to the

question how safe is safe enough. It is with this in mind that the MOU calls for the agencies to actively explore ways to harmonize risk goals.

Since this question is of such importance to making the MOU work, the Commission is keenly interested in the staff's efforts in this area and anxious to hear what the staff has to say today.

Do my fellow Commissioners have anything before we begin?

Mr. Taylor, please begin.

MR. TAYLOR: Good afternoon. With me at the table are Bob Bernero, Mike Weber, Dick Bangart and John Austin, all from NMSS.

As you know noted, Commissioner Rogers, this is a status update of where we are on the subject of risk harmonization.

To kick it off, Mike Weber will be the principal presenter.

MR. WEBER: Thank you.

Good afternoon. We certainly appreciate the Commission's interest in this topic and also the briefing this afternoon.

It is interesting to note that EPA also holds risk assessment in high regards and risk management. Recently the issue of the EPA Journal

featured a whole issue on risk assessment and there's a lot of useful insights in there from a variety of different perspectives.

(Slide) Commissioner Rogers, if I could have the first slide, please.

As you pointed out, the focus of this effort is derived from the Memorandum of Understanding that the EPA Administrator and the Chairman signed back in March of last year. That MOU provides the basic framework for cooperative activities between the agencies on a wide variety of subjects, in addition to laying out the goal and principles that would guide those cooperative activities. It also provides implementation guidance and it is in the implementation guidance, Section C, that the staffs of both agencies are directed to actively explore harmonization activities both in terms of risk goals, in other words risk management activities, as well as mutually agreeable approaches for risk assessment. We'll be getting into some of those terms as we proceed through the briefing.

(Slide) If I could have the next slide, please.

Shortly after the MOU was signed, the staffs met to discuss the implementation of the MOU.

That meeting identified five priority issues for pursuit under the framework established by the MOU. Clean Air Act regulation of radionuclides, the Subparts I, T and W of EPA's regulations in 40 CFR 61, EPA's draft Low Level Radioactive Waste Standards, groundwater protection standards for uranium mill tailings, principally agreement on guidance and criteria for approving alternate concentration limits for contaminants in groundwater at the uranium mill sites, radiological criteria for decommissioning. This principally involves our enhanced participatory rulemaking on the radiological criteria as well as EPA's parallel efforts to establish generally applicable standards. And then EPA's high-level waste standards, what we commonly refer to as the Yucca and the Non-Yucca standards, which are being pursued.

One common theme of all these issues is the need for an effort on risk harmonization because, Commissioner Rogers, as you pointed out, it has been identified as a root cause of the differences between the agencies.

In each program area there exists both real and perceived differences in both the risk goals and assessments. These need to be addressed head on and it's through the cooperative efforts both on a

generic level through the generic activities on risk harmonization as well as the individual program areas that the staffs have been pursuing those. The status of those activities is described in the SECY paper which is available at the entrance to the Commission meeting room.

COMMISSIONER ROGERS: Just before you move on, Mike.

MR. WEBER: Yes.

COMMISSIONER ROGERS: I think you said it, but I thought I'd just check again. These five priority issues were mutually agreed upon between NRC and EPA at that first meeting. Is that what you --

MR. BERNERO: Yes. That first meeting, Mike Shapiro, the Deputy Assistant Administrator for Air and Radiation, and I, with our staff, went over all of the issues. These represent a combined priority, EPA's and NRC's.

COMMISSIONER ROGERS: Okay. Thank you.

MR. WEBER: (Slide) If I could have the next slide, please.

There are various components to our efforts on risk harmonization. Consistent with the Memorandum of Understanding, the staff differentiated early in its efforts the difference between risk

assessment and risk management. Risk assessment principally attempts to answer the question how risky is something. It includes the consideration of the methods, the assumptions that are made and other considerations involved in quantifying or estimating health risks. This would also include to a certain extent the uncertainties associated with those risk estimates.

Risk management, in contrast, would answer the question what should be done about something that poses a risk, which is especially important to a regulatory agency, both NRC and EPA. It involves the selection of risk goals and associated measures in attempting to achieve those goals. It also involves things like value judgments, considerations of uncertainty and how that should play into the regulatory decisions, technological feasibility in demonstrating compliance or in meeting the regulatory requirements, as well as cost effectiveness and other considerations.

I should point out at this point that by risk we're principally referring to health risk assessment and management. That's to distinguish it from engineering risk assessment. You may be familiar with the National Academy of Science's report, the

1983 report called the red book, informally, on risk assessment. Based on those earlier discussions in the 1980s, a distinction was drawn by a variety of agencies, including NRC and EPA, on the difference between risk management and risk assessment, and also the difference between health risk assessment which would involve basically assuming that exposure will occur and then trying to estimate the risk associated with the exposure versus engineering risk assessment which involves consideration of failure of engineered barriers or natural systems which eventually might lead to human exposure. So, that's an important distinction.

In the environmental protection area, human health risk assessment and management is the principal focus. That's not to exclude engineering risk assessment, but generally EPA has not delved into that arena, whereas our agency certainly gets involved in those things on things like severe accidents and similar matters.

I should also point out that the agencies first focused on risk assessment. In other words, as we pursued the generic efforts on risk harmonization, we felt it was important first to look at risk assessment for two reasons. One, because it appeared

simpler at the outset, delving only into the scientific aspects, how does one estimate the risk associated with an exposure, and also it seemed to be a necessary prerequisite to the discussions which would follow on risk management. If we were going to look at the levels that were being achieved in the various regulatory programs, it was important that we speak with a common denominator and to achieve that common denominator in terms of an estimated risk, we first needed to address risk assessment.

(Slide) If I could have the next slide, please.

COMMISSIONER REMICK: Mike, how difficult is risk assessment since I believe, at least I assume, that we and EPA pretty well follow ICRP and NCRP in many ways in determining health consequences?

MR. BERNERO: I'd like to interject if I could, Mike, here.

MR. WEBER: Sure.

MR. BERNERO: Basically in radiation, I think it's fair to say that the Environmental Protection Agency has a tendency to track and participate in ICRP, NCRP activity, but they act independently and they aren't always coincident in the identification of risk coefficients or any other

measures of ways to link radiation exposure to health consequences. They're close --

COMMISSIONER REMICK: But you could say that about us too.

MR. BERNERO: Yes. Yes. But they're close, but fairly consistent. The biggest problem is that the Environmental Protection Agency has other actions deriving from non-radiological risk.

COMMISSIONER REMICK: No, I'm talking about radiological risk.

MR. BERNERO: Yes. Okay.

COMMISSIONER REMICK: Yes. I'm talking about the two agencies. I'm not surprised. We come pretty close together in risk assessment techniques since we rely at least to some extent --

MR. BERNERO: For radiological risk assessment, that is a fair comparison.

COMMISSIONER REMICK: Yes. Okay.

MR. BERNERO: But it's when you get into risk management that you're going to get a different--

COMMISSIONER REMICK: Right.

COMMISSIONER ROGERS: Well, I take it though from the SECY paper that there are considerable differences, for example in modeling methods. Several examples were given there, in particular carbon-14

problem and how that seemed to arise from a difference in how one might model situations and with a simpler model one feels more comfortable setting higher requirements than with a model which perhaps may be more realistic and therefore you might find you could not achieve those requirements. I think that's precisely the case with carbon-14, isn't it? So, that's in the assessment area. That's not in the management area.

COMMISSIONER REMICK: No, but it's engineering, as I see it. I see that as part of engineering risk. You're modeling the release.

MR. BERNERO: Again, take the carbon-14 and high-level waste, which is a very difficult subject. I think if you speak of radiological exposure and consequences, given the presence of a certain amount of carbon-14, its half-life and so forth, and given that one is calculating a collective dose, we would agree with the assessment that EPA has. Now, there is an element of engineering risk assessment here, how does the carbon-14 come out of spent fuel right away or slowly or whatever and how does it get through the package? But those considerations aren't really the dominant consideration and the dominant controversy. The

dominant controversy is risk management. Given that you calculate a collective dose over that many generations from carbon-14, is it significant? It is an amount of carbon-14 that meets the Clean Air Act for an operating facility, but from the perspective of a collective dose over 10,000 years, a risk-management consideration, that's where we have the problem.

So, radiologically we agree on what carbon-14 is and how it exposes the body, but the management thereof is where we find difficulty.

MR. WEBER: I think it -- oh, excuse me.

COMMISSIONER de PLANQUE: Go ahead.

MR. WEBER: As we proceed, we're going to get into some of these differences that we did identify and it's a fair question.

As we've addressed risk assessment, we have included those analyses that are done to estimate human exposure to the contaminant, whatever that contaminant may be. So, if it involves transport of a contaminant in the groundwater or in the atmosphere, that would fall under the risk assessment area. If the release of that contaminant was triggered by the failure of a valve or something like that, that would be more an engineering risk analysis.

COMMISSIONER REMICK: The difference being

in the health area we're just talking about the consequence side, health consequences and not the probability event that causes it. So, we're looking as we used to do in the reactor area too. Look at consequences, not the probability of the occurrence.

COMMISSIONER de PLANQUE: Let me go back to what Commissioner Remick initially asked because I saw something on page 4 of the paper which I couldn't reconcile. If you're going to get to this later on, you don't have to answer it now, but what I couldn't reconcile, which is what I think he was after, on the top you have a group of bullets that say to discuss the similarities. One of those, the third bullet, is both agencies translate exposure and intakes into dose and risk using internationally acceptable standards. But then in your bullets on the differences, the third and fourth ones, especially the fourth one, you say NRC and EPA use slightly different risk coefficients to convert doses and health effects. I was having trouble reconciling those two and I think that's probably where you were confused too.

So, I'm not sure which is the overriding consideration there or if they're somewhat inconsistent.

MR. WEBER: We'll get into that as we talk

about the differences and the similarities.

(Slide) If I could have the next slide, please.

I think this graphic depicts where the agencies currently are in terms of risk harmonization. We have a risk barometer, a thermometer down the middle of the page. Those are lifetime risk estimates, a cancer that could be attributed to the exposure to contaminant, ranging from $10^{-2}$ or one in 100 at the upper end of the scale, to $10^{-6}$ to a one in a million at the lower end of the scale.

The NRC's traditional approach consistent with international and national recommendations and health physics practices has primarily been driven by a top down approach whereby the NRC establishes an adequate protection threshold and then applies various mechanisms like ALARA or the concept that doses should be kept as low as reasonably achievable to drive those doses or the risks associated with the exposures down well below that safety limit. That, based on the information that we have, has been effective in protecting members of the public as well as the environment.

In contrast to that, the EPA program we characterize there as a bottoms up approach. This is

a very crude comparison because we're talking in EPA's case about many statutes, many different regulatory programs and often times we find that their programs are, of course, driven by the statutory language. Some cases they can consider practicality and technological feasibility. In other cases it's an absolute risk standard that's driven by the legislation.

So, in EPA's case, we often find rulemaking that would establish what would be perceived as more restrictive requirements or better levels of protection and then the application of practicality concerns or technological feasibility often comes in either through the regulation itself in considering things like what is best demonstrated available technology, as well as in the permitting process or things like that where perhaps the absolute level established in the regulation is not attained but something that EPA finds acceptable is and that's done within the context of the regulatory framework.

COMMISSIONER de PLANQUE: The primary cause for this stems from the original legislation, the language in the original legislation? Is that the --

MR. WEBER: I think that's the driver of

the programs. Of course this has a long history and often times the $10^{-4}$, $10^{-6}$ risk framework that we often hear spoken about in terms of the EPA's drinking water program, the Superfund Program, the Clean Air Act now, those programs can trace their concentration on that risk range back to the delaying clause and de minimis concepts that were derived from those earlier legal constructs.

MR. MALSCH: Just to add something. In the case of some statutes, EPA regulation is not even risk-based, it's based upon technology. So, whatever risk level it achieves is sort of coincidental. In one area that you can make a direct comparison, Clean Air Act regulation, you can actually look at -- they have a two stage regulatory process that corresponds pretty closely to our two stage process, adequate protection and we have safety enhancements above that. They have something like that. There you can draw exact comparisons because the language is somewhat similar. But once you get outside comparable programs, it's very hard to draw comparisons. That's why this is very, very crude.

MR. WEBER: (Slide) If we turn to the next slide, you'll see the variety of programs that the staff focused on as part of our analysis or

comparison of risk-assessment techniques employed by the two agencies. I won't run down through all those different regulatory areas, but what we're attempting to do is to have a broad enough scope so that we would get a sense of how various non-radiological programs might also influence EPA's decisions in rulemaking actions or implementation actions that would affect radionuclides in the environment.

For example, often for consistency reasons EPA would prefer to ensure that waste disposal activities do not end up violating requirements set under the Safe Drinking Water Act. Even though those requirements may not have been specifically set for radiological protection purposes, nevertheless for consistency there's a policy driver there to attain a comparable level. So, where some of these influences may come from non-radiological programs, we wanted to be sure that they were included within the scope of our comparison.

COMMISSIONER REMICK: Do you have any way of judging how consistent they are in these various programs, realizing that some it's driven by statute? I realize we're always consistent with home we -- and so forth and I was wondering how they compared us.

MR. TAYLOR: I want to be sure that went

on the record, sir.

MR. WEBER: I think it's fair to say that both agencies are not consistent and that is what we're getting at in what we're doing now in the risk management area because that's where we're looking at risk objectives. But as we'll see later on, it is difficult. It's one thing to be able to compare what are the stated risk objectives. It's another matter to be able to estimate or evaluate what level is actually being achieved. That's a complex undertaking and I hope we can get to that.

COMMISSIONER CURTISS: Mike, in the list of programs that you looked at at EPA, did you look at EPA's groundwater policy as a discreet regulatory topic or is it captured somewhere in these topics that you looked at?

MR. WEBER: I think it's captured in the program under the Safe Drinking Water Act. As you're aware, the groundwater protection strategy that EPA has outlined primarily references back to those drinking water protection standards or the maximum contaminant levels as the points of reference with respect to implementing that program. So, that becomes the driver in things like the draft low-level waste protection standards and the alternate

concentration limits for uranium mills.

COMMISSIONER CURTISS: Is the groundwater protection strategy itself a regulation or a policy that implements a particular statute or --

MR. WEBER: No.

COMMISSIONER CURTISS: What does it spring from?

MR. WEBER: I think the motivation for EPA's development of that was a recognition back in the '80s that EPA was not dealing with groundwater protection in a consistent fashion. So, as a policy matter, they sought to develop an approach that would enhance or foster some consistency between the various programs, principally the Hazardous Waste Program under the Resource Conservation Recovery Act, the Superfund Program, various activities like that.

COMMISSIONER CURTISS: But the groundwater protection strategy and the risk levels reflected therein are not driven by any particular statutory requirement.

MR. WEBER: That's right.

COMMISSIONER CURTISS: Is that a fair statement?

MR. WEBER: Yes.

MR. BANGART: In fact, the EPA indicated

that with the flexibility that they now have, and if they can implement a consistent program throughout the states and across the country, then it would eliminate the need for legislation that would drive the program and they're comfortable with that kind of an approach.

COMMISSIONER CURTISS: I was really picking up on -- and that's a key point. I was picking up on Marty's earlier comment that in some of these cases the risk level is pretty well established in the statute itself. The Clean Air Act, as interpreted by the courts, is probably --

MR. MALSCH: Not so much risk level. In fact, actually the first I've ever seen of risk level actually established in the statute was in the recent Clean Air Act amendments. What I really meant to refer to would be a statute which directed regulation based upon risk management as opposed to regulation based upon technological availability or some other kind of a concept. See, if you can fashion a program based upon, let's say, best available technology, you end up with risks, but what you end up with is sort of a coincidental because it's driven by the technology, not risk management concepts.

COMMISSIONER CURTISS: The challenge that we face in the Clean Air context, of course, is

dealing with what has been construed by the courts and explained by EPA as a statutorily mandated level, quantitative level of protection, and the distinction that I'm attempting to draw is that in the case of the groundwater protection -- back up. And hence, very little flexibility on their part in terms of how they interpret that, what they call a fuzzy bright line. In the context of the groundwater protection strategy which is in turn an issue implicated in a lot of the areas where we have disagreements with EPA, the degree of constraint is much less at least insofar as the statute is concerned because it's not driven by the statute.

MR. MALSCH: Yes. I'm not aware that the particular risk management levels chosen by EPA for its groundwater strategy were actually dictated by statute.

COMMISSIONER CURTISS: All right.

MR. WEBER: In fact, I believe the EPA has consistently maintained that it is through other rulemakings where EPA does have statutory authority that they would seek to implement that strategy. And, in fact, we see that in the mill tailings area, in the draft low-level waste standards, in the high-level waste program.

I should point out that in the comparison of the various programs, the staffs focused on routine operations for the most part. So, we did not consider severe accidents or things like that. We also focused on public or environmental protection as compared to occupational protection. This was done for the most part because it helped us pare down the problem so that it was manageable. As you're well aware, the regulations that both agencies have are very diverse and comprehensive and it would be a very formidable task to try to tackle that in one shot.

(Slide) If I could have the next slide, please.

We completed the comparison last year and in a briefing last November we identified a variety of similarities. It was a joint briefing by both the EPA staff involved in the Office of Radiation and Indoor Air and our own staff. These are very approximate statements of what the conclusions of that comparison were. There's more detail, some more detail, in the Commission paper. There's even more detail in the briefing charts that were used for that briefing. But I'll try to go through these and stop me if you've got questions.

The first one was that both agencies

generally use deterministic risk assessments. As we've already talked about, a decreased emphasis on looking at the probability of some of the exposures, as maybe driven by failure of various components.

Of course there are notable exceptions to that. For example, the high-level waste standards are probabilistic in nature because they deal with the containment requirements and there is probability incorporated directly in there. There are also such things in our own program, for example under Appendix I of 10 CFR Part 50. The standards for effluence, the design objectives were based on technology, what technologies were available at the time, and then the risks associated with it or the doses in that case were then back calculated based on what technologies could achieve.

The second one, both agencies generally assess exposure to reasonably -- maximally exposed individuals and usually consider the same exposure pathways. Again I'd have to caveat by saying that in high-level waste, certainly for things like the carbon-14 element of the containment requirements and other areas, it's not always true that it was set based on exposure to a maximally exposed individual. I'd emphasize we use the word "reasonable" there

intentionally to reflect that in all cases we're not using worse case assumptions. What we generally attempt to do, both agencies, is look at it and attempt to create a scenario of exposure which would reasonably bound but not capture perhaps the upper five percent or so of the distribution of exposures.

Generally the --

COMMISSIONER REMICK: Excuse me, Mike. What is the apparent lack of interest on both the NRC and EPA to go to the critical group concept?

MR. BERNERO: I think what happens, if you use maximally exposed individual without reasonable in front of it, there is a tendency to need the critical population group as a more representative limit. Our agency and EPA, as a matter of modeling practice, are using a reasonable choice for the maximally exposed individual. There's a lot of latitude there and that's why there is less interest in or need for consideration of using a population group as against an individual. It's really a matter of -- there used to be a tendency of using the fencepost cow or the fencepost goat around a reactor station, taking the worst theoretical person and not real person. When you do that, that's when you need the moderation that you get with a critical population group.

COMMISSIONER REMICK: But reasonable, of course, is in the eye of the beholder.

MR. BERNERO: Yes, it is.

COMMISSIONER REMICK: How have we used reasonable? Have we used it in any cases?

MR. WEBER: Well, for example, I can think of one recent case and that's the development of our methodology to convert residual reactivity levels into doses, the NUREG-5512 effort that we have through our Office of Research and Pacific Northwest Labs. There we attempted to identify parameters that would define -- it would be a conservative representation of how someone may be exposed, but it would not be the ultimate maximum exposure. For example, you wouldn't assume that somebody is going to eat perhaps ten times what a typical individual would ingest in terms of plants grown on site or in terms of meat that might be produced on site.

COMMISSIONER REMICK: How about location? How do you determine the location of an individual for --

MR. WEBER: That depends on the program. Certainly for something like effluence, you may choose the closest location that somebody could live to the site while the site was operating. In contrast, in

the decommissioning area, you might choose a location that would be right on the contamination. So, it's going to vary from site to site.

COMMISSIONER REMICK: And if you expose the person that could live the closest, isn't that the maximally exposed individual -- well not necessarily, depending on plumes and so forth. But in general, it would be.

MR. BERNERO: Well, Commissioner, the real test of it is when you're doing it, when you do such an analysis, if there is reasonable judgment in selecting a maximally exposed individual, you ought to be getting the same sort of result you get from a critical population group. For instance, when we're doing calculations of decommissioning residues, assuming a factory is built and workers are in that factory, you should get nearly the same result from the maximally exposed individual or from the average of the workers in the factory. I think it's a fair thing to say that we are using modeling techniques that will come out fairly close together and therefore it reduces the need.

COMMISSIONER REMICK: I guess I don't understand how you say if you take the maximally or the average how it's going to be the same. I don't

understand that.

MR. BERNERO: Because by -- the way it was chosen. One is not choosing a worker who would work in the factory and be a resident night watchman as well and somehow or other get 24 hours a day exposure, whereas the typical worker would only have eight hours a day or nine hours a day exposure.

COMMISSIONER de PLANQUE: Try as an example the situation where a child might be much more radiosensitive to the particular element you're talking about. In that case, would the child be the reasonable maximally exposed individual?

MR. BERNERO: I don't think we do.

MR. WEBER: In most of those programs we looked at a lifetime of exposure. So, that would capture the full range on radiosensitivities and that would be reflected in the risk coefficients that we would use.

What we did is compare what the agencies have done over the years because this has been developing over the last two decades. That's not to mean that we will come out of this saying, "Yes, let's keep doing what we've been doing." In fact, as we get together, we may identify the need to go with more of a critical group type concept.

COMMISSIONER REMICK: Am I correct the only way in which we come close to using critical group was in the safety goal policy statement?

MR. BERNERO: To my knowledge that is. The ACNW regularly recommends it to us.

COMMISSIONER REMICK: Yes.

MR. BERNERO: But to my knowledge that's the only place where we have used it.

MR. WEBER: One other concern that has been raised about the use of a critical group concept is that by its very nature looking at the average exposure to the critical group means that somebody is going to be exposed to a higher risk.

COMMISSIONER REMICK: That's right.

MR. WEBER: And some people find that --

COMMISSIONER REMICK: And somebody's going to be lower.

MR. WEBER: Right.

COMMISSIONER CURTISS: If I could just take a topic that's on our agenda right now in the high-level waste area. If we were to move to an individual dose standard, which is one of the considerations that the Academy is looking at in fact this very week, are the differences that you've seen in our historical approach to this issue so minimal

that you would expect -- and I realize I'm asking you to speculate here -- that we and EPA could reach agreement on issues such as the point of exposure and uptake pathways, what have been referred to as the static biosphere questions? Are we close enough to reach agreement on that?

MR. BERNERO: Let me speak to that because that has come up already. You may be familiar with it that in the, oh, past month or so, a little over a month, the staff reviewed the Energy Policy Act of 1992 and possible impacts on the high-level waste standard and had a dialogue with the Advisory Committee on Nuclear Waste and they wrote a letter and this very issue came up. The Advisory Committee, not surprisingly, said, "You really ought to focus on the critical population group as against the individual risk for that issue."

What you have just said, Mr. Commissioner, is the big uncertainty is not whether one is doing the critical individual or the critical population group. In the staff's view, the big uncertainty is what is the biosphere for reference purposes? How are we going to model this thing if you're speaking of a dose out over say a 10,000 year period? I can only suggest that yes, that is something that would have to be

developed a clear consensus on such modeling, that is the dominant uncertainty. It is the uncertainty already prevalent in all foreign programs because foreign high-level waste programs aren't all based on dose to an individual as against release quantities such as we have in the U.S.

So, it's a formidable task, but it's one that's already on the table for all the other programs, foreign programs, and I'm confident we could deal with it. It won't be easy, but we could deal with it.

COMMISSIONER CURTISS: Okay.

MR. WEBER: One other important similarity here is that in some cases both agencies have saw fit to protect a real person as compared to a hypothetical person. For example, EPA standards under 40 CFR 190 are designed to protect an actual person rather than a hypothetical person. The same can be said for our requirements, the public dose limits under Part 20.

Moving to the third similarity, both agencies translate exposures and intakes into doses and risk using internationally accepted techniques generally. To get back to our earlier discussion of this point, certainly NRC has followed the recommendations of, to a great extent, the National

Council on Radiation Protection Measurements, the International Commission on Radiological Protection, other advisory groups or scientific peer groups like UNSCEAR, BEIR IV and the BEIR V Committee.

EPA generally has done the same. However, in some of their programs, for example, we recently reviewed the draft -- or the proposed drinking water standards for radionuclides. In those cases, EPA saw fit to develop their own dosimetry and their own modeling to estimate the risk associated with the intake of radionuclides from drinking water. They felt that they were doing the best science based on the epidemiological work that had been done. That does, however, take them away from some of the risk coefficients and dose conversion factors that are included in their own federal guidance to the other agencies, like Federal Guidance Report Number 11.

We, in fact, had a meeting with the EPA staff on this and so earlier this year the similarity is that by and large we both subscribe to these recommendations, but there are some differences, and we experience those differences in the various program areas.

Both agencies assess risk primarily in terms of cancer fatalities or in terms of mortality as

compared to morbidity. Once again, there are some exceptions. In the Superfund program the risk range is applied for morbidity so that for radiological exposures that would include both fatal cancers as well as nonfatal cancers. There's a lot of uncertainty and controversy associated with that approach because that will vary based on the cure rate and various other medical treatments that are available, how early is the cancer detected and things like that.

Both agencies also sometimes truncate risk assessment, so the similarity here is that, yes, in certain cases we have truncated, however there is also a difference. And when I talk about truncation here, I'm referring to deciding at some distance from a facility or at some time into the future to stop counting the exposures or the risks based on the recognition that as time continues certainly the uncertainties associated with making long-term projections of the risks or the doses increases substantially so that at some point you come to the point where it's questionable whether you can justify looking beyond a certain time period.

COMMISSIONER REMICK: When I read that, Mike, "both agencies sometimes truncate risk

assessments," I was reminded of the saying, "Old Bill Bailey goes to work daily, sometimes." That means sometimes he doesn't too.

How consistent are we in our truncating out in distance? I was under the perception that a few years ago at least sometimes we would go out and integrate out to 250 miles around the reactor and sometimes 50 miles. Of course, the Safety Goal Policy Statement basically says, for cancer, out to ten miles and for prompt fatality one mile. How consistent are we, do you know, within the Agency when we're thinking about distance?

MR. BERNERO: Well, I would say in general the principle that people try to follow in truncation is, if it's the tail of a curve where I have calculated in the first 50 miles, say, the predominant impact, there is little justification to calculate out to a greater radius as long as it's the tail of the curve and the dose calculated is not a significant addition for the purposes of the calculation. Then I can truncate, because I have the essential story or the essential facts already.

Where you run into a difficulty is where collective dose is itself the objective and the High-Level Waste Standard is the classic example of that

where it is collective dose that is the primary standard and therefore one does not truncate, except, as in high-level waste, one truncates at 10,000 years for the reasons evident in that proceeding. There we are not consistent. I should say, that is a non-truncation case that is quite different, but it has a reason and that's where much of the controversy comes.

I don't think we have differences where either agency is calculating a point source diffusing from, say, a single reactor station or something like that, a point source going out where you could do a ten mile radius or a 50 mile radius and get the bulk of the impact and therefore reasonably truncate going beyond that point. But where collective dose is itself the object, I don't think we are entirely consistent and we would tend --

COMMISSIONER REMICK: Unless you have it cut-off.

MR. BERNERO: Yes. The NRC would tend to say you need to have a different risk perspective on use of collective dose and, of course, the High-Level Waste Standard, that is one of the long-standing criticisms, this comparison to other risks and so forth.

MR. WEBER: (Slide) Could I have the next

slide, please?

Turning now to some of the differences that we identified, certainly the use of risk assessment in the agencies is somewhat different based on our differences in mission.

In the radiological area, EPA's mission is primarily one of developing standards. In contrast, NRC's program includes both rulemaking to implement generally applicable standards and other requirements as well as the implementation of those requirements through licensing and various other regulatory reviews, so our programs tend to use risk assessment more in terms of compliance determinations or implementation aspects. EPA's generally are applied more to support generic actions like rulemakings.

Of course, as I pointed out, both agencies have their share of rulemakings and EPA also has implementation responsibilities in programs like the Hazardous Waste Program, the Drinking Water Programs, Clean Water Act Programs, things like that, so they too do site-specific risk assessments.

Both agencies use risk coefficients for converting doses into risks, however the risk coefficients that are used vary. When we put this together at the time last November, NRC was using a

risk coefficient for low LET ionizing radiation of about $5X10^{-4}$ fatal cancers per person rem. In contrast to that, at the time EPA was using $4X10^{-4}$. So at that time there was a difference in the risk coefficients for converting dose into risks, however EPA generally prefers at least today to go directly from the intake of the radioactive material to a risk and therefore bypass the dose altogether except in those programs where dose is an important element of a compliance determination. And so, they're using in some ways more sophisticated modeling to relate the intake of the radionuclide to a risk by looking at organ-specific risk factors and age-specific risk factors.

What I'm trying to get at is they're relying less on some lumped risk coefficient like we've used, $5X10^{-4}$, and instead preferring a more sophisticated analysis to relate the dose to the risk or the intake to the risk. So, that's one of the differences that you were asking about earlier.

COMMISSIONER REMICK: I remember back when the Commission was reviewing the BRC policy statement I asked the staff the question why we're using $5X10^{-4}$ rather than $4X10^{-4}$ and the staff made a very strong defense of $5X10^{-4}$. What's EPA's excuse for using $4X10^{-4}$? At that time, I read BEIR V saying $4X10^{-4}$.

MR. WEBER: I'm probably not the best person to answer that, but what I am aware of is that EPA believes, because of its mission and its statutory responsibilities, that it independently needs to develop conclusions on the risk associated with exposure to radiation. And therefore, when it gets a BEIR V report it will scrutinize that report and I think with that scrutiny there's the expectation that they may come out at a different place. They also rely on data that I believe the BEIR V committee did not place a great deal of emphasis on.

Did you want to say something?

MR. BERNERO: Yes. I just wanted to add, I was trying to allude to that much earlier in the briefing. The EPA looks at a BEIR V report as a base of comparison for what they're doing to see if they're generally in agreement, whereas we are tending to use it as a reference.

If I recall correctly, when we had the discussion of 5 versus 4 in using BEIR V directly, I believe there was an age of the population interpretation that was necessary between 5 and 4.

COMMISSIONER REMICK: And I think somehow age related to workers or something else.

MR. BERNERO: Yes, but I don't think that

pertains to the EPA usage. The EPA usage is actually independent of BEIR V and only compared to it.

COMMISSIONER REMICK: I see.

MR. AUSTIN: If I could add to that, one should recognize that when we went into this comparison it was with the idea of trying to identify differences that could influence the decision. That is, if we both did an analysis, would one agency conclude one thing and the other something different? And I think the message is here that we didn't really find in most cases any significant difference that would influence the decision.

COMMISSIONER REMICK: Yes, I understand. It just seemed like a unique opportunity with a group of experts around here to explore some of these things that are in the back of my mind.

MR. BERNERO: I'd like to have Doctor Cool from the Office of Research speak to it. He is an expert.

COMMISSIONER REMICK: Fine. Okay.

DOCTOR COOL: Good afternoon. I'm Donald Cool with the Office of Research.

At the time we were holding the discussion that you referred to, the BEIR V report and the UNSCEAR report had just come out. EPA's $4X10^{-4}$ value

was based on where they had been prior to coming out with those reports. Since that time, they have been taking a relook as we had taken our relook in the same time frame and two things come out of that which I think are relevant here.

First of all, they do prefer to use organ-specific numbers rather than going to a sum total. They sort of dislike going to a single bottom-line number. But if you add all of those values up at this point, they would end up, if you pushed them to it, to a number which is now in fact very close to 5 also. They have adopted nearly an identical methodology to what we have in our NUREG-4214, the health effects criteria associated with accident analysis, so that has actually come more closely together since the time of those discussions two years ago.

COMMISSIONER REMICK: Thank you.

MR. WEBER: Another difference that was identified is that there are differences in the assumptions made in terms of long-term exposures of members of the public or the environment. These are things like to what extent is inadvertent intrusion considered. You're probably all aware in the Hazardous Waste Program inadvertent intrusion isn't even considered, whereas in our Low-Level Radioactive

Waste Program the requirements themselves are based on assessments which contemplated intrusion into the waste and in fact that was the basis for developing the waste classification system, so there are differences of that nature.

There are differences in terms of how long is the person assumed to be exposed to the contaminant. Many of our programs assume a 70 year lifetime, therefore the person would be exposed for 70 years. EPA generally uses 70 years, but in some programs, notably the Superfund program, they've now gone to 30 year exposure, which of course if you're looking at the risk, that's a factor of two when you implement the assessments.

There are other differences such as the reliance on institutional controls. NRC generally tends not to rely on institutional controls after a certain point, for example 100 years. EPA, in some of their programs, takes the same approach. In other programs, however, they place greater reliance on institutional controls. Just like we were talking about inadvertent intrusion for a hazardous waste site, the same can be said for reliance on institutional controls. There's a presumption that the deed restrictions and other constraints that will

be placed on a property after it's been used for land disposal of hazardous wastes will remain effective on into the future. That earlier assumption has not been found to be acceptable in our rulemakings on low-level waste and other programs.

COMMISSIONER CURTISS: Mike, is there a clear practice at EPA insofar as how they handle human intrusion? Do they -- and here more specific in my question. In establishing requirements, for example, for the stabilization of hazardous waste sites or other activities of that nature, do they in establishing those requirements assume and permit reliance on institutional controls to prevent human intrusion at some subsequent point, in particular way out in the long-term horizon?

MR. WEBER: Yes. I think that's an implicit assumption in their regulatory program. They haven't come out and said that per se, but certainly to the extent that inadvertent intrusion is not considered in designing a facility or looking at the wastes that are going into the facility, barriers are not constructed. The only thing that remains after the facility has been closed are those institutional controls, to prevent human intrusion.

COMMISSIONER CURTISS: Okay.

MR. AUSTIN: We actually have a case now that eventually will come to the Commission where it is a RCRA site being closed at which thorium has been buried. The question is if the license had not been terminated, we would have to make a determination of unrestricted use at a site where EPA tells us there will never be human involvement again. In that case, eventually we'll be coming to the Commission. It's an interesting --

COMMISSIONER CURTISS: That issue is, of course, at the heart of the Academy's review of the high-level waste issue and the question of the reasonableness of relying on institutional controls to prevent human intrusion is a very complicated one, but it sounds like the practice has been all over the map at least at EPA and perhaps within our own agency on that question.

MR. WEBER: In other programs, for example our mill tailings program, there is reliance on institutional control in perpetuity. Not to the extent that you would decrease the level of protection in terms of the radon barrier or the rock rip-rap for erosion protection, but certainly land ownership and preventing somebody from going on the site and building a home, things like that.

Other differences that we identified, NRC's risk assessments generally focus on limiting individual risk. EPA risk assessments will look at usually both individual risks and population risks, especially where those population risks, they believe, determine which control option is preferable. We got into that a little bit before about collective dose and critical population group and the carbon-14, I think, is a good example of that.

NRC typically uses radiological dose for both its rulemaking activities as well as implementation and compliance assessment. EPA, in contrast, typically today relies more on health risk than a radiological dose. That's certainly evident in the Superfund program and drinking water program where the driver is the risk determination and then that risk is then back calculated into what the resulting dose would be.

COMMISSIONER de PLANQUE: But by and large in the radiological area the results should be the same except for the few cases you pointed out, the example being LET.

MR. WEBER: Right. However, it is important to point out, at least based on what Doctor Cool said earlier and EPA's ongoing assessment of the

organ and the age-specific risk factors, that in some cases their risk coefficients may be considerably less than the ones that we're currently using. One case comes to mind and that's for thorium-232. I believe the difference in the risk factors is on the order of 140 times, which may have significant implications in terms of how either agency proceeds. In fact, EPA is now looking at its whole approach on converting dose and risk as part of their drinking water standards. So, we're going to watch that closely and interact with them so that we're sure we're kept abreast of what they're doing.

COMMISSIONER REMICK: Mike, I'd like to go back a minute to make sure I understand the statement you made about EPA. I think you said they implicitly rely on institutional controls. Now, am I correct in adding to that passive institutional controls? I could interpret institutional controls being guards or an agency patrolling and so forth. Are you including that or are you talking about deeds, restrictions and things like that?

MR. WEBER: They're passive, but to remain effective there has to be some active body there that's empowered to enforce things like deed restrictions. If the deed restriction includes

consultation with an agency, there would have to be the reliance on that consultation to ensure that that restriction was carried out and the protection were achieved through the application of that control. But if you define passive controls as things like deed restrictions, restrictive covenants, things like that, yes. That's to prevent against inadvertent intrusion. Certainly the RCRA landfills are designed to minimize infiltration and to minimize transport of the contaminants after the operation of the facility.

COMMISSIONER CURTISS: As you've described it, it sounds more like an active institutional control than a passive one.

MR. WEBER: Right. Well, I think what we've found all throughout this discussion with EPA is that you have a spectrum. Some institutional controls are more active than others. But when you're racking them up against each other, you may find that they're both more or less an active type control.

COMMISSIONER CURTISS: And at least insofar as those active institutional controls are applied in the area of hazardous waste under RCRA and Superfund, where the risks of some of the -- the toxicity of some of the substances continues essentially undiminished over a long period of time as

opposed to the diminished radiological risk, would one infer from that that those active institutional controls in that context might suggest they'd be reasonable to rely on in less risky situations? That's the high-level waste question where the issue of active institutional controls is squarely before us. As you compare what is done in the RCRA context for a longer term, essentially unabated risk, is that inferring too much from what you said?

MR. BERNERO: We don't have in the NRC, nor do I think EPA has, a consistent approach to the use or reliance upon institutional controls. If you take the uranium mill tailings as a starting point, in uranium mill tailings we look rather strongly at the first couple of hundred years and look long-range toward a thousand year stability of the as-built configuration. We mandate state or federal ownership custody to avoid interruption or disturbance of the tailings impoundment. We're making an assumption that it's good enough for a thousand years because it will be undisturbed and therefore one can reasonably extrapolate beyond that, even though the half lives involved go far beyond a thousand years.

The level of risk may be quite reasonable because if you look at what the consequences of

disturbance are, it's not the end of the world. It's not a real big release, real big source term.

In contrast, if you look at RCRA, at a hazardous waste site, it's not biodegradable generally. The mercury is mercury for centuries, for millennia to come and the time horizon that appears to be within EPA's frame of reference is to look at a few decades really and to assume custody, deed restrictions and what have you will assure -- it's really an assumption that one has assured undisturbed performance and that you can rely on some analysis that shows that there will be no migration from this undisturbed performance that would cause off-site hazard.

It's not consistent with many other areas. In high-level waste, the issue takes on a different complexion. Presumably the risk is high if you do disturb it or get near it because it is high-level waste, but that's the principal reason you have remoteness. You're down deep in some geologic formation. Now the disturbance has to be of a more elegant type, a drilling for resources or massive excavation or something like that.

There is no a consistent policy in the EPA or in the NRC for that and it's a major issue really.

MR. WEBER: In fact, to foreshadow a little bit about next Friday's briefing on the enhanced participatory rulemaking, one of the things that we quite clearly heard in the workshops by a number of different representatives is that the Commission ought to revisit the definition of decommissioning because continued reliance on the unrestricted use requirements may be in some cases too stringent. In other cases, the thought of releasing a former nuclear facility for unrestricted use was implausible. So, that was an interesting observation that we had in those workshops and you'll hear more about that next Friday.

COMMISSIONER REMICK: One further question on the institutional controls. Has anybody tried to lay out what -- when we say passive or active what were we talking about, institutional controls? Has anybody laid out the type of things that might be passive, the type of thing -- I get confused, I must admit, as we throw them around. I don't think I understand. I know I don't understand completely. Has anybody tried to do that?

MR. BERNERO: I don't know of any compendium of that. It might be a constructive thing to do. I hate to invite a mandate.

MR. WEBER: We did explore that in both the uranium mill tailings rulemaking and in Part 40 and EPA did as well in 40 CFR 192. We also did that, I believe, as part of our Part 61 rulemaking for low-level waste where I think we give examples of what we would consider active and what we would consider passive.

COMMISSIONER REMICK: It would be helpful if you just give us those past things that have been done. It would help me anyhow.

MR. WEBER: We've already talked about the difference there in the bottom. We commonly truncate population dose in terms of space and time. EPA prefers to conduct the assessment of the population dose and only truncate it if they're convinced that what the residual is will not significantly affect their selection of the control option.

COMMISSIONER REMICK: This is where we run into the problem though. If you integrate this out over great distances and then you're adding up what I might call insignificant doses to a large number of people, I'm not sure the meaning of it.

MR. BERNERO: Unless your focus is on the collective dose itself, that the collective dose integrated at very low levels of radiation over very

large populations is the very thing you're trying to control.

MR. WEBER: Based on the linear dose hypothesis.

MR. BERNERO: Yes. That full extrapolation of the linear hypothesis is exactly the issue in carbon-14, high-level waste --

COMMISSIONER REMICK: I understand, but the uncertainties become so great that I just don't believe the numbers.

MR. BERNERO: Well, it takes the linear hypothesis as a very precise line even as it comes to zero on the graph.

COMMISSIONER REMICK: No, I understand that. But I'm saying when you determine that it's .02 whatever, millirem per year or whatever, that might be zero or it might be .04 or .2 and I just don't know -- adding up with that great uncertainty in the dose numbers, I'm not sure what meaning it has at all, assuming linear.

COMMISSIONER ROGERS: Well, logically I suppose it says that you have to integrate it out to include every individual in the whole world.

MR. BERNERO: It does, but that problem has come up time and again. Now, BEIR V or any other

expert group, they will tell you that as you get to ten rem or below ten rem you begin to incur greater and greater uncertainty on the hypothesis. You stick with the hypothesis, but the uncertainty is growing as you go down. And how you're way down on that curve. You're almost at the zero and you're getting micro rem to mega people. Adding it all up, like one is building a savings account, it's giving a certainty to a very uncertain impact. But that is the essential question when you're talking about integrated radon risks from uranium impoundment, mill tailings, impoundments, when you're talking about the entire concept of the high-level waste standard. That's why we have said over and over again, try to get some better risk perspective.

MR. WEBER: The bottom line in our comparison of risk assessment methods is that although differences exist, the similarities between the agencies approaches appear to be stronger than the differences. As John Austin pointed out, it was the attempt to identify those differences that may exist that could significantly effect the bottom line. At the time, last November, once we were through the risk assessment comparison, it was perceived that the risk management differences would be more significant and

I think we've seen that to be the case.

(Slide) If we can have the next slide.

On the risk management comparison, all we can say is that we're in the process of comparing the programs. We're comparing the same programs that we looked at in terms of the risk assessment comparison. We're looking at the attributes listed there in terms of the dose or the risk limitation. In other words, is the program driven by a decision that some dose or some risk is acceptable and, if so, what is that? Do we look at an individual risk or population risk? What is the basis for that limitation? Is it statutory? Is it a policy call? Is it based on a consistency determination with another program within EPA or within NRC? How is that risk objective or dose objective then implemented? Is it implemented simply as a single statement that that is the level to be achieved or does it come with a whole collection of requirements that add additional levels of protection above that fundamental risk or dose objective? What are the compliance mechanisms in place to ensure or to attempt to ensure that that objective is, in fact, achieved? And finally, under what conditions would the agencies consider exceptions?

Those are the areas that we're exploring.

We have a preliminary table comprised and we're in the process of reviewing that. Once EPA has had another chance to look at it, we will circulate that within the agencies again for staff level review and hope to complete that in the next couple months.

(Slide) If I could have the next slide, please.

Both the efforts on risk assessment and risk management comparisons will provide the basis for the preparation of the so-called white paper. We believe the white paper is important because it will provide a foundation for where we go from here in terms of risk harmonization, identifying both a consistent basis, where are we today as well as setting the groundwork for consideration of where we might want to be tomorrow and what it would take to get us there. Identifying opportunities both on harmonization of goals, if that's desired, or in terms of some of these assessment differences that we've identified.

Also flagging issues that deserve additional consideration. For example, we may not be able to identify that something can be fixed in a particular way or that it should be fixed. Perhaps we'll embark on a further consideration of those

differences where they exist.

And also to prioritize, recognizing that both agencies in an era of reduced resources need to focus on what's reasonable and in so doing prioritizing those activities that really promise the greatest potential for harmonization.

We hope to have a draft of that white paper complete late this summer and we'll again be going through the same internal review process to ensure that all the offices within the NRC, as well as the EPA that have a stake here have their chance to comment on that and provide input. We expect that it will probably take longer on the risk management because you do get into things like value judgments, policy considerations, cost benefit tradeoffs, technological constraints, things like that. So, it goes beyond the scientific realm and you're getting into some of the more fundamental policy issues.

COMMISSIONER REMICK: Assuming once that white paper is finalized, has any thought been given to the advisability of making that available to the National Academy of Sciences studying the high-level waste standard? It seems like it provides some very important background information.

MR. BERNERO: No, we hadn't specifically

thought of doing that, but it certainly would be available. It will be a public document.

MR. WEBER: (Slide) Could I have the last slide, please?

What's the future for the risk harmonization effort? As we've already identified, at least at this time we perceive that there are more similarities when you look at the programs across the board in risk assessment than there are differences and that the risk management differences appear to be more significant. Clearly the stated risk objectives of the two agencies differ. We talked about the top down, bottom up comparison, NRC principally being driven by a risk level on the order of $10^{-3}$, coupled with the ALARA concept and other regulatory mechanisms to drive the doses and the risks well down.

EPA, in contrast, having a stated preference for something in the order of $10^{-4}$ to $10^{-6}$ lifetime risk range, although there are differences even within the EPA programs as well may be expected and some of those differences are driven by statute more than anything else.

COMMISSIONER REMICK: Do they ever do comparative risk type of things, what the meaning of a lifetime risk of $10^{-6}$ in comparison to other risks?

MR. WEBER: They did that --

COMMISSIONER REMICK: I put it in the abstract.

MR. WEBER: No, they did that, in fact, in response to the Clean Air Act issues raised about benzene and vinyl chloride. That's how they selected that risk range as the presumptively safe level under the Clean Air Act.

MR. BERNERO: And one of the things that is even on the table now in the dialogue concerning the Clean Air Act Subpart I, we are in a situation where NRC with the 100 millirem with ALARA may have or appears to have consistency in outcome with an EPA Clean Air Act standard that would be ten millirem as a bright line standard. But one has to ask the question if the outcome is the same, is that really risk harmonization or is that fortuitous, because our objectives are essentially an order of magnitude apart? That pictorial that Mike showed earlier with the top down, bottom up approach, we have that difference and we are regularly now in the Clean Air Act finding that the outcome may be acceptable to both of us, but the rationale for acceptability is quite different.

COMMISSIONER de PLANQUE: Let me follow

that one step further. In spite of the difference of the bottoms up and the top down, in spite of that difference, if you woke up EPA at 2:00 in the morning and you woke up NRC at 2:00 in the morning, would they agree on what they think is safe? The fact that you fortuitously get to the same place so often, if you put the question in those terms, would it be answered the same?

MR. BERNERO: I would say no. I would say no because what we are saying is safe, is 100 millirem a year a very conservatively drawn limit? Anything below it is as reasonably achievable. But push comes to shove 100 millirem a year to a member of the public is safe. I believe the risk objective, the statement in the Clean Air Act is ten millirem a year, or more accurately three millirem a year is what is safe. What we're doing is shuffling on cases to see if ALARA gets us to the point where there is a coincidence of objectives or rather a coincidence of results and that's why we still have a debate about whether or not a regulatory guide has sufficient teeth or strength in its language to make sure it comes out that way rather than as reasonably achievable.

MR. MALSCH: Commissioner, that comes out most clearly if you look at some of EPA rulemakings in

the Clean Air Act where they struggled with defining what is a, in our terms, adequate protection. They use different statutory terms, but it was the same basic objective and they clearly came out with a different risk level in so defining than we would.

COMMISSIONER CURTISS: Yes. It seems what we're doing is applying a technology-based component to our risk-based standard or health-based standard. The technology component being how low can you reasonably get it given current technology and cost considerations, which is another way of stating maximally achievable control technology or best available control technology. I think you're correct, and I share that view, that the underlying risk question which is in turn the objective of the Section D of the MOU, that effort, the underlying risk question tends to get finessed in that context because we take advantage of the technology-based character of what could be done to get it down below -- I'm not suggesting we ought not to have ALARA. We do and it's a good idea. But it does circumvent or finesse the risk question. We don't have an agreement on what level of exposure is safe.

MR. WEBER: The level of protection that the programs achieve, of course, that's a difficult

question, what is the level of protection that's achieved. The reason it's difficult is it's clouded by differences in regulatory programs. In some cases NRC's requirements or EPA's requirements may have a defense in depth type approach so that it goes considerably beyond merely stating, here's the dose or here's the risk objective that you're to attain.

ALARA is something that's difficult to quantify. Often times it's situationally dependent. It depends on what kind of facility you are, how you're operating, what kind of people you have there, what kind of technology, what are the radionuclides you're dealing with? So, that's difficult to quantify. The level of review is also something that varies between the agencies and, in fact, varies between programs. What kind of licensing or permitting reviews are involved prior to giving somebody a permit or a license? And finally, the inspection and the enforcement efforts differ. Certainly EPA doesn't have the luxury of having resident inspectors on many of their facilities, whereas -- some would consider it a luxury.

MR. TAYLOR: Sorry.

COMMISSIONER REMICK: The EDO just gulped.

MR. WEBER: In other cases, in EPA's

programs, there are such things as citizen suits, citizen suit provisions in the statutes so that there is a driver there from the standpoint of if members of the public are concerned enough about a facility down the street that may not be operating in compliance, there's a legal mechanism there to force the compliance. There are also things like the toxic emissions reports that are required under EPCRA for many of the facilities that process materials.

So, all these things complicate our lives in terms of assessing, going beyond the state of comparing merely the stated risk objectives and looking at what is the actual level that's achieved. But we're going to persevere and hope to address those things as part of our white paper and try to shed some light on some of these factors that may contribute to the overall assessment.

MR. TAYLOR: That concludes our presentation. We look forward to this white paper. I'll hold my breath.

COMMISSIONER CURTISS: We do too.

COMMISSIONER ROGERS: Jim?

COMMISSIONER CURTISS: I just have a couple of questions here. This has been a very good briefing. The background materials that you prepared

in preparation for this I thought gave us a good sense of where you are and where you're going. It's really that later question, where we're going with this, that I'd like you to expand upon.

Your schedule to have the draft white paper complete in -- available in summer, this summer, can you expand upon what needs to be done in terms of the steps between now and then to get that done and, in that context, could you address whether this effort is receiving the same level of attention that it's obviously getting here over at EPA?

MR. WEBER: In terms of the steps that are involved in how we move from here and write the white paper, as I mentioned, we have prepared a table that racks out the various programs of both agencies looking at those attributes that I discussed. That's in a draft form. It's been around our offices once. It's down at EPA. They still have to fill in some of the blanks and, once we complete that, we can move to the next step of identifying where are we similar, where are we different and exploring why we may be similar or different. That all provides the grist for the development of the white paper. We've done that on risk assessment and so we have that piece. We have the thinking for the most part completed there.

We now need to complete the piece on risk management, so, once we complete the table we identify similarities and differences, move on to identifying opportunities for pursuing risk harmonization and then writing the paper.

MR. BERNERO: But I think it's worth speaking directly to your later question about priority. I hesitate to say this in front of the EDO.

It appears and has appeared as long as we've been working on the risk harmonization that the NRC has a few more resources to dispose to this effort than EPA has and therefore we have tended to lead or draw the effort forward, and that's still going on right now. EPA is trying to participate, but in general they just don't have as much horsepower on it as we have.

MR. WEBER: In fact, this effort competes with the same resources that we're cooperating with EPA on the enhanced participatory rulemaking, because the same individuals are involved, so in some ways that's what delayed our efforts earlier this spring.

MR. BANGART: In fairness though, also, because of prompting by I think all levels of management here in conversations with counterparts in EPA, they have given it a higher priority than they

had initially, so they have moved forward at a faster pace in more recent weeks.

COMMISSIONER CURTISS: Well, I would hope that we would continue to emphasize the priority of this effort and that EPA in turn would be able to spare resources, and I know they are limited in their resources because of other activities going on, to support this effort in an active way.

In my view, this effort is really the linchpin to the MOU and I'm going to ask a couple of questions in a minute in that regard. It's essential that we come to grips with the issues that are raised and that we hoped to resolve when we wrote Section D of the MOU. I'm pleased to see that we've finished, largely finished the risk assessment part of this and concluded in large part that the differences are minor in terms of the outcome or impact on specific initiatives. But in the risk management area, that's really the key part of Section D of the MOU.

That really leads me to a question that goes to why this is important and what the practical impact is of it. We have several initiatives pending before the Agency right now, in fact a couple pending before the Commission right now that involve specific regulatory efforts. One that comes to mind is the

low-level waste standard that EPA is working on. Second that comes to mind is the question of what the appropriate risk level ought to be for ACLs where we've tentatively endorsed a $10^{-3}$ objective in the staff requirements memo.

Recognizing that this effort won't yield a product until later this summer and in addition recognizing that those two issues really involve questions of risk management, the low-level risk question and the ACL issue, what would the staff's recommendation be in terms of how we as an agency, and understanding of course that EPA has got a role in this, how we ought to proceed in addressing those issues? Should they be -- I'm inclined to say that it would make sense to hold up action on both of those until we've resolved the risk harmonization issues, the risk management issues that in turn will point the direction to how to address the low-level waste and ACL question.

Alternatively, I guess one could go forward with those prior to the resolution of these issues in the context of Section D, but then one is left asking what's the purpose of the risk management section of this MOU. But at a minimum, it seems to me that those two issues ought to be treated the same one

way or the other. Either we ought to go forward with both of them or we ought to, as I'm inclined to suggest, hold up action on both of them until we complete the risk management discussion.

Bob?

MR. BERNERO: Well, I would say that we have differences or regulatory overlap in a number of areas with EPA that are subject to the MOU. In the Clean Air Act, as you know, we are working to resolve them in spite of the fact that the risk objectives appear to be disparate. And if we can succeed, because I think we should succeed in that, obtaining rescission of those Clean Air Act regulations by EPA, we are proceeding on that course to do that in the Clear Air Act.

In those other areas where it really boils down to a difference of risk objectives, the MOU also calls for elevation in parallel with the development of this risk harmonization effort and cognizant of this risk harmonization effort and I think that's really what we need to do. I think we have to take the other areas and pursue them in a fashion consistent with -- we have different objectives. We are working to harmonize this.

One could argue wait for the white paper,

wait for the ultimate harmonization of risk assessment. Could take very, very long and leave a lack of decision, and yet those decisions on individual cases may be the fundamental way that one can drive toward and obtain risk harmonization.

COMMISSIONER CURTISS: Yes, although I'm not optimistic because what we've seen in the past, as Commissioner Remick has pointed out, is that as we've attempted to resolve issues in the context of individual cases a couple of things have happened.

First, our approach has been pretty disparate. We've been all over the map with the risk assumptions that we have used in various regulatory initiatives within each agency and between the two agencies and one of the central purposes in recommending a risk harmonization section in this MOU was to try to bring some harmony, if you will, to the risk basis upon which we regulate. And I'm not optimistic that going ahead with discrete initiatives is going to lead to a revealed standard, if you will, a risk standard that is going to be harmonious anymore in the future that it has in the past.

Secondly, what tends to happen in my view and I guess the low-level waste issue is perhaps an example of this is that the discussion oftentimes

devolves into is this technologically achievable. Is this something that can be done? What are the differences in terms of what we can achieve from a technical standpoint? And again, maybe that's a way to regulate based upon what's technologically achievable, but in my view it's not an approach that I would prefer. I'd prefer to see the risk-based approach that the MOU itself is focused on trying to achieve.

And so, as I say, recognizing that the EPA would like to go forward with the low-level waste initiative and we'd like to go forward with the ACL initiative and resolve those, it strikes me that some thought about how we treat those in the context of the Section D provision and treating them harmoniously one with the other needs to be given.

MR. BANGART: I just want to add, especially on the ACL issue, we have not started the process yet of working above the lowest rung on the ladder to try to resolve that before it gets up to the highest levels of the two agencies, so we likely will be proceeding up that management chain to try to reach some resolution.

But my prediction would be that in the ACL issue as the low-level waste standard issue they

probably won't get resolved in the kind of timeframe that it's going to take to put the white paper together and reach some conclusions as to where we go with that, so my suspicion is that they'll be captured in the broader effort to reach harmony, although we are going forward.

COMMISSIONER CURTISS: In the case of the ACLs, you do have a Commission-established $10^{-3}$ risk level in the SRM and the risk question has been addressed already at this level within this agency.

MR. BANGART: And we're planning to come back to the Commission with an update on where we stand on that.

MR. AUSTIN: This white paper, and we're talking about in late summer of this year, may be a far cry from resolution of the issues. It will address the things that ought to be taken into consideration, but I don't see how it could possibly resolve the order of magnitude difference between the two agencies. That will take a lot of interaction and fundamental considerations within both agencies.

COMMISSIONER CURTISS: Yes.

I don't have any other questions. I'd again like to commend you for the work that you've put in on this and encourage you to encourage EPA to keep

up or increase their level of effort so that you can achieve the schedules. They obviously impact on some of the things that are before the Agency right now in specific regulatory contexts.

I would encourage you as you work in this area to keep active track of what's going on in the risk community more generally and in particular I guess I would suggest that we follow the efforts of the risk group that's been established under the Clean Air Act and that is I think a group of appointees from various -- the President, the Senate and the House, that is working on the broader risk questions.

There is some interesting activity going on right now with legislation in the Senate that would have EPA focus on doing a risk assessment, risk management evaluation for each of their regulatory initiatives, so there's a lot going on in the risk arena as this document obviously points out and as we've seen in other contexts that would be worth keeping close tabs on.

But again, I thank you for this effort and commend you for the work that you've done.

COMMISSIONER REMICK: I certainly join in commending the staff both for the document and the presentation and discussion today. It's helped me in

understanding the differences or similarities between the two agencies.

And I agree very much with Commissioner Curtiss on the importance of the effort, particularly what follows beyond the white paper, because I think if we can truly work to get some resolution of these differences and a common understanding we'll determine whether what we intended when we worked on the MOU with EPA will actually come to fruition. And I assume that's why they wanted an MOU also, so that hopefully down the road when we're working on issues either where we have common authority or common interest that we'll have an understanding and a method for proceeding in a mutually acceptable way.

So, very important work. I'm glad the EDO is providing the resources that he is on this and I hope it will continue and I thank you very much.

COMMISSIONER de PLANQUE: I too am pleased with what you've done so far and cheer you on to continuing and getting EPA to do their share as well.

I was particulary interested in the efforts like the comparison charts. I think they're incredibly useful to us, as well as you, I'm sure, and I thought it was kind of interesting in the SECY paper one of the things you pointed out was this helped to

identify some internal inconsistencies and that's clearly a step in the right direction.

I would also add to Commissioner Curtiss' idea of looking at what's going on in the risk community in general to extending that to the international scene too, because this is really a very active issue.

If I have one particular message that I'd like to deliver, it's one of trying to stay as neat and clean with the terminology as you can. Often the problems in this area are ones of semantics more than real problems. I just noticed throughout here that the same thing was referred to using several different words just in these papers alone, "limit" and "goal" and "objective," same thing given several different terms, trying to make clear what we're talking about in all of these situations whether it's a goal, a limit, an objective or whether it's a real standard.

I think it's incredibly important that we try to be consistent in the terminology and try to carry that consistency for ourselves but also with EPA. Just using different words can lead to so much misunderstanding, so I would encourage you in that direction to be very careful and as precise as possible. I know in some cases you're limited by

legislation which might call something some particular thing.

MR. TAYLOR: That's an important element, particularly in the white paper which will be widely read and distributed.

COMMISSIONER de PLANQUE: Right.

MR. TAYLOR: Very important.

MR. BERNERO: In the white paper we did on engineering risk assessment that was a major problem right up front, get the semantics straight.

COMMISSIONER de PLANQUE: Right.

MR. BERNERO: Because, terminology is so different.

COMMISSIONER de PLANQUE: Well you can see it right in these two papers, different words used for the same thing, so the more you can do in that direction the better. I think you've seen that we've struggled at the Commission level with terminology used, particularly in the low-level waste area, and sometimes the differences aren't really there but they appear as if they're there.

But overall I commend the staff for what you've done. It's very good. Carry on.

COMMISSIONER ROGERS: Well, just let me add my own personal comments in agreement with my

fellow Commissioners here. I think that -- I don't have very much to add because I think they really have touched on some of the very important points.

I think this question of speaking the same language, not only not using different words for the same thing, but when you are using the same word that you agree on what it means. That's always not so clear.

So I do think that to me this is a very important activity. It's one that I suspect needs to be supported at the very highest level, though, because I suspect there will be times when real frustration will set in on everybody's part.

I would ask you to keep in mind the possibility at any rate at some time along the way of both agencies somehow or other perhaps maybe taking a little different approach, I mean, rather than -- maybe it's not that we have to agree with them and they have to agree with us, yet there may be a third approach here somehow that can emerge from this. I have no idea.

I'm just speaking in generalities, but I'm sure that we both approached these problems on a historical basis. We've built on what we've known over the years. They've done the same thing, and

there are times when you know you just are on parallel paths that are not going to come together and it may be that there's some way that a quantum step could be taken to bring these things together. It might be that you're just not going to automatically, even with good will, come together because you're not trying to achieve things in exactly the same way and maybe there's real value in trying to find a way that is common to both agencies.

Certainly the rest of the country I think would like to see a government position and a U.S. government approach rather than an agency one that a particular corporation, individual, is subject to two conflicting kinds of requirements and there they are. They have to resolve it, whereas we're the ones that ought to be resolving these things for them.

So I just would ask you to try and keep in mind the notion that perhaps there might be some way of breaking through some of these by a little different approach. I don't know what it would be, but sometimes that can help.

I'd like to thank the staff.

Particularly, Mike, you did I think an absolutely superb job and I want to just acknowledge that in my opening remarks I really plagiarized very

much from what you wrote in the SECY, so I really want to be honest and admit that.

So, thank you all very much. I think it's been an excellent briefing and we look forward to the paper, the white paper as soon as it's ready.

(Whereupon, at 3:37 p.m., the above-entitled matter was adjourned.)

CERTIFICATE OF TRANSCRIBER

This is to certify that the attached events of a meeting of the United States Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON STATUS OF EFFORTS FOR RISK HARMONIZATION

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: MAY 26, 1993

were transcribed by me. I further certify that said transcription is accurate and complete, to the best of my ability, and that the transcript is a true and accurate record of the foregoing events.

Carol Lynch

Reporter's name: Peter Lynch

*United States*
*Nuclear Regulatory Commission*

# NRC-EPA MEMORANDUM OF UNDERSTANDING: PROGRESS IN RISK HARMONIZATION

## *BRIEFING FOR THE COMMISSION*

**May 26, 1993**

# NRC-EPA Memorandum of Understanding

- **Signed by the EPA Administrator and the Chairman on March 16, 1992**
- **Basic framework for resolving interface issues related to the regulation of radionuclides in the environment**
- **Directive to explore risk harmonization**

# Need for Risk Harmonization

- **Five priority issues**
  - **Clean Air Act regulation of radionuclides**
  - **EPA low-level radioactive waste standards**
  - **Groundwater protection standards for uranium mill tailings**
  - **Radiological criteria for decommissioning**
  - **EPA high-level waste standards**
- **Exploration of risk harmonization is essential for resolution of the priority issues**

# Risk Harmonization
## *Components*

- ***Risk Assessment***

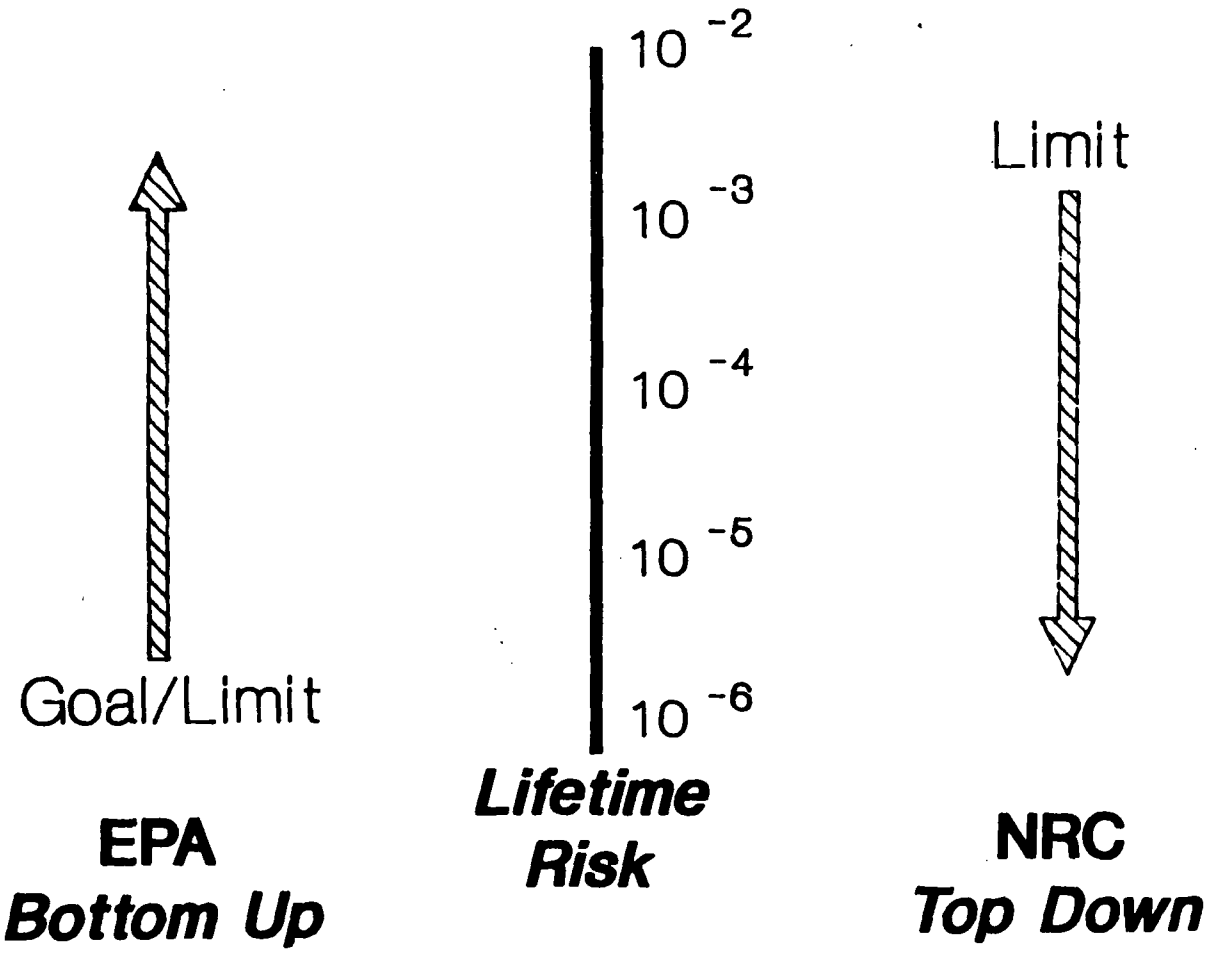
  **Methods, assumptions, and other considerations involved in quantifying or estimating health risk**

- ***Risk Management***

  **Selection of risk goals and associated measures to achieve the goals**

- **Agency-specific *risk management* approaches appear to be source of both real and perceived differences between NRC and EPA**

# Risk Harmonization



# RISK ASSESSMENT COMPARISON
## *Scope*

**NRC Programs**

- Decommissioning
- Low-level waste
- High-level waste
- Uranium Recovery
- Materials licensing
- Fuel cycle facility licensing
- Radiation protection standards
- Effluent requirements for reactor facilities

**EPA Programs**

- High-level waste
- Low-level waste
- Uranium mill tailings
- Indoor radon
- Superfund
- Hazardous and solid waste management
- Clean Air Act
- Safe Drinking Water Act
- Clean Water Act

# Risk Assessment Comparison

- **Similarities in Risk Assessment Approaches (November 1992)**
  - **Both agencies generally use deterministic risk assessments**
  - **Both agencies generally assess exposure to reasonable maximally exposed individual and usually consider the same exposure pathways**
  - **Both agencies translate exposures and intakes into doses and risks using internationally accepted techniques**
  - **Both agencies assess risk primarily in terms of cancer fatalities**
  - **Both agencies sometimes truncate risk assessments**

# Risk Assessment Comparison

- **Differences in Risk Assessment Approaches (November 1992)**

  - **Use of site specific vs. generic assessments**
  - **Use of slightly different risk coefficients for conversion**
  - **Assumption of different long-term exposure scenarios**

| NRC Risk Assessments | EPA Risk Assessments |
|---|---|
| - Limit on individual risk | - Limit on population risk |
| - Use of radiological dose in rulemaking and compliance assessment | - Use of health risk |
| - Truncation of population dose in terms of time and space | - No truncation of population dose if it affects control options |

# Risk Management Comparison

- **Comparison is currently in process**
- **Risk Management Attributes**
  - **Dose and risk limitation**
  - **Basis for limitation**
  - **Implementation considerations**
  - **Compliance mechanisms**
  - **Exceptions**
- **Range of NRC and EPA programs consistent with Risk Assessment Comparison**

# RISK HARMONIZATION WHITE PAPER

- **Results of Risk Assessment and Risk Management comparisons**
- **Foundation for risk harmonization process**
- **Consistent basis for future efforts**
- **Specific Highlights**
  - **New opportunities**
  - **Issues deserving additional attention**
  - **Priority issues for discussion**
- **Draft complete in late Summer 1993**

# Future for NRC-EPA Risk Harmonization

- **More similarities in risk assessment than differences**
- **Risk management differences appear to be more significant**
- **Stated risk objectives differ**
- **Level of protection is clouded by differences in regulatory approach**
  - **Defense in depth**
  - **ALARA measures**
  - **Level of review**
  - **Inspection and enforcement**
- **Risk management comparison and White Paper will attempt to address these factors**

May 14, 1993

# POLICY ISSUE
## (Information)

SECY-93-134

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: STATUS OF RISK HARMONIZATION WITH THE ENVIRONMENTAL PROTECTION AGENCY UNDER THE 1992 MEMORANDUM OF UNDERSTANDING

PURPOSE:

To provide the Commission with a status report on the staff's efforts to explore risk harmonization with the Environmental Protection Agency (EPA) under Section D of the March 1992 Memorandum of Understanding (MOU).

SUMMARY:

The March 1992 MOU represents a major step forward to foster cooperation between the Nuclear Regulatory Commission and EPA in carrying out agency mandates to protect the public health and safety and the environment on matters related to radiation in the environment. The MOU is essential for constructive interactions between the agencies because it establishes a framework for: (1) resolving issues of mutual agency concern; (2) avoiding unnecessary duplication of regulation; and (3) focusing priorities on the most significant safety and environmental problems. The MOU also includes an important provision (Section D) calling for NRC and EPA to actively explore ways to harmonize health risk goals and to cooperate in developing a mutually agreeable approach to health risk assessment methodologies for radionuclides. Risk harmonization is a critical activity under the MOU because differing risk management approaches have been a root cause in areas of disagreement between the two agencies.

NOTE: TO BE MADE PUBLICLY AVAILABLE AT COMMISSION BRIEFING ON MAY 26, 1993

Contact: Michael F. Weber, NMSS
504-1298

NRC and EPA are actively pursuing health risk harmonization both in a generic manner and through ongoing cooperative activities to resolve specific issues in program areas. The agencies have completed a comparison of risk assessment approaches. Based on the results of this comparison, there appear to be no significant differences between the agencies in risk assessment approaches that would influence ultimate decisions, other than in the area of high-level waste management. A similar comparison of risk management approaches is currently in progress. It appears that risk objectives are a fundamental area of disagreement between the agencies. However, it is difficult to compare the objectives with the risk levels achieved because of differences in regulatory approach and multi-layered, defense-in-depth regulations. NRC and EPA are exploring this issue in both the ongoing comparison of risk management approaches and cooperative activities on specific program issues.

BACKGROUND:

On March 16, 1992, the Chairman and EPA Administrator William Reilly signed an MOU that provides a basic framework for resolving issues of mutual concern that relate to the regulation of radiation in the environment. The MOU framework promotes continued cooperation in resolving high-priority issues of concern, with longer-term goals of improved cooperation and exploration of harmonization of risk goals and risk assessment methodologies. The MOU also establishes principles and procedures for avoiding unnecessary duplication of regulation and for focusing priorities on the most significant safety and environmental problems.

Staff has previously provided the Commission with detailed plans and objectives for implementing the MOU, including the risk harmonization provision in Section D (SECY 92-165; and the Memorandum from James M. Taylor to Commissioner Curtiss, July 1, 1992).

In addition, NRC and EPA staffs met on two occasions to discuss implementation of the MOU. Discussions centered on identifying priority issues of concern for resolution and exploration of risk harmonization. Based on discussions at these coordination meetings, NRC and EPA agreed that differences in risk objectives appear to be a root cause of the disagreements between the agencies. NRC and EPA also agreed that exploration of risk harmonization is critical to successful interagency cooperation and resolution of interagency disagreements.

DISCUSSION:

NRC and EPA are actively exploring risk harmonization on two fronts. The agencies are exploring risk harmonization in a generic manner. Concurrent with this generic approach, the agencies are cooperating to resolve a wide range of technical and policy issues that involve significant questions about risk assessment and risk management. These activities provide for ongoing exploration of risk harmonization in a realistic and focused context.

Generic Approach To Risk Harmonization

The first phase of the generic approach for exploring risk harmonization consisted of a comparison of risk assessment approaches used by each agency. The second phase consists of a similar comparison of risk management approaches. The agencies define *Risk Assessment* to include methods, assumptions, and other considerations involved in quantifying or estimating the health risk associated with a particular activity. In contrast, the agencies define *Risk Management* to include the selection of risk objectives and associated measures to achieve these objectives.

For each phase, the agencies are comparing and contrasting the approaches used by each agency, considering a wide spectrum of programs and applications. Based on this comparison, the staffs are identifying similarities and differences in approaches for risk assessment and risk management. NRC and EPA have completed the first phase on risk assessment. The examination of risk management objectives and regulatory approaches is in progress.

In profiling risk assessment methods, NRC and EPA agreed that the scope would be broad in terms of program areas and types of assessments. Within EPA, the risk assessment profile included the following program areas:

- high-level waste
- low-level waste
- uranium mill tailings
- indoor radon
- Superfund
- hazardous and solid waste management
- Clean Air Act programs
- Safe Drinking Water Act programs
- Clean Water Act programs

Examination of the risk assessment methods used by NRC included the following program areas:

- decommissioning
- low-level waste
- high-level waste
- uranium recovery
- materials licensing
- fuel cycle facility licensing
- radiation protection standards
- effluent requirements for reactor facilities
- supporting rulemaking activities.

The staffs identified several different types of risk assessment applications, including applications in support of rulemakings, compliance determinations, and event analyses. The staffs focused the comparison on health risk assessment approaches and techniques. The comparison did not consider engineering risk assessment, which considers the probability and consequences of failure of components and structures, because EPA generally does not

conduct such assessments. However, staff recognized that differences in engineering risk assessment could affect regulatory decisions in the high level waste and reactor programs.

On November 25, 1992, NRC and EPA staffs briefed senior agency management on the results of the risk assessment comparison. Staffs identified more similarities than differences in risk assessment approaches used by NRC and EPA. The specific similarities identified through the risk assessment comparison are as follows:

- Both agencies generally use deterministic risk assessment approaches (except high-level waste and nuclear power reactor routine emissions).
- Both agencies generally assess exposure to a reasonable maximally exposed individual and usually consider the same pathways for exposures.
- Both agencies translate exposures and intakes into doses and risks using internationally accepted techniques.
- Both agencies assess risk primarily in terms of cancer fatalities.
- Both agencies sometimes truncate risk assessments.

The staffs also identified the following differences between EPA and NRC risk assessments:

- For radionuclides, NRC generally conducts site-specific assessments in support of compliance determinations, whereas EPA generally conducts generic assessments in support of rulemakings. NRC conducts some generic assessments in support of rulemakings and EPA conducts site-specific assessments in programs where it has implementation authority (e.g., Superfund).
- NRC generally limits individual risk, whereas EPA may place greater emphasis than NRC on limiting population risk beyond individual risk limits.
- NRC has traditionally used radiological dose in rulemaking and compliance assessment, whereas EPA programs generally use health risk as the end point of concern.
- NRC and EPA use slightly different risk coefficients to convert doses into health effect estimates; dose and risk conversion factors may be considerably different for certain radionuclides that emit alpha radiation.
- NRC and EPA have assumed different exposure scenarios for long-term exposure (e.g., radioactive waste disposal).

- NRC generally truncates population doses in terms of time and space, whereas EPA for completeness prefers to assess population risk without truncation in time or space if it affects available control options.

Based on the comparison and relative significance of the similarities and differences, the staffs concluded that resolution of the differences in risk assessment approaches is unlikely to significantly affect the outcome of agency risk assessments in most program areas. Staff believes that significant differences in risk assessment approaches are evident in the high-level waste (HLW) area. EPA has defined several hypothetical HLW repositories and has evaluated their projected performance in support of its standard-setting activities. EPA's risk assessment approach is much less sophisticated than the techniques that are expected to be applied by NRC in evaluating compliance with EPA standards and NRC requirements. For example, EPA is currently using a single "pipe" model to simulate radionuclide transport from a repository to a well located two kilometers away. The simplicity of this model precludes simulation of fractures, potential failure of borehole and shaft seals, or other inhomogeneities in geologic media. The staff believes that the simplicity of EPA's modeling limits the ability to determine whether relatively rapid transport of small amounts of waste might occur, leading to potential violations of EPA's proposed standards. EPA's risk assessments for these hypothetical repositories largely determine the degree of stringency of EPA's HLW standards.

As an example of the limits of simplistic modeling, early models prepared by EPA and NRC in support of rulemaking in the HLW area overlooked possible release pathways, such as gaseous release of carbon-14. As a result, EPA could establish release limits for HLW disposal that are difficult, if not impossible, to meet. However, the more sophisticated modeling approaches that will likely be used by NRC to evaluate compliance may demonstrate that these individual pathways are unlikely or insignificant. Thus, differences in risk assessment approaches between NRC and EPA could significantly affect risk management decisions in the HLW program area. Similar differences could surface in other programs where risk assessment techniques continue to evolve, such as in EPA's development of standards for low-level radioactive waste management and NRC's development of enhanced performance assessment capabilities.

This comparison of risk assessment approaches has helped the agencies gain a better understanding of each other's internal practices and procedures for estimating doses and risks associated with radiation in the environment. The comparison has also provided the agencies with valuable insights into the companion review of risk management approaches. Specifically, staff noted that differences between risk management approaches appear to be more significant than the differences in risk assessment. Staff also noted that the risk management comparison would likely prove to be the more critical aspect of the risk harmonization effort because differences in risk management appear to be the underlying cause of disagreement on most issues.

NRC and EPA are currently involved in comparing and contrasting risk management approaches used by each agency. The first step in this process is

to collect and compare information about a variety of risk management attributes across a broad range of NRC and EPA programs. The risk attributes the agencies have selected include the following:

- dose/risk limitation
- regulatory, scientific, and policy bases for dose/risk limitation
- considerations associated with implementing the dose/risk limitation
- mechanisms by which compliance with the dose/risk limitation is demonstrated
- situations in which an exception to a dose or risk limitation would be allowed.

The range of programs being examined is consistent with the programs included in the risk assessment phase. NRC and EPA staffs have completed draft profiles of risk management approaches across each agency's programs. In addition to its value in risk harmonization with EPA, developing this profile proved to be worthwhile for NRC staff because it illustrated areas of internal NRC inconsistency in risk management approaches. The comparison also helps to preserve some institutional memory for the risk management decisions made in various NRC programs and rulemakings.

NRC and EPA are analyzing the profiles to identify similarities and differences between EPA and NRC risk management approaches in a manner similar to that used in the risk assessment phase. A joint briefing of senior agency management will then be conducted to present the results of the risk management comparison.

After completing the risk assessment and risk management comparisons, the agencies will consolidate the results and conclusions into a White Paper on risk harmonization. This paper will establish the foundation for the agencies to pursue risk harmonization by identifying:

- new opportunities to seek risk harmonization
- issues that deserve additional exploration
- priority issues for discussion associated with risk assessment methodologies and risk goals.

NRC has the lead responsibility in preparing the White Paper. The staff intends to prepare a draft of the White Paper by late Summer 1993. Completion of the White Paper on risk harmonization is an important step in implementing the MOU provision on risk harmonization because it provides the support and foundation for the beginning of the risk harmonization process. By identifying new opportunities to seek harmonization and issues that deserve further exploration, the paper will provide a strong and consistent basis for future efforts to resolve issues of concern between NRC and EPA.

Risk Harmonization through Specific Program Activities

While risk harmonization advances in a generic manner, NRC continues to interact with EPA to resolve areas of disagreement in specific program areas. In several of these program areas, the remaining unresolved issue with EPA is in the area of risk management. These program areas are as follows:

- Clean Air Act standards for air emissions of radionuclides;
- Radiological criteria for decommissioning;
- Low-level radioactive waste standards; and
- Alternate concentration limits for uranium mill tailings disposal.

The agencies have identified the underlying disagreement regarding these four program areas as the level of risk each agency considers to be sufficient protection of public health. This difference in the belief of what constitutes sufficient protection results from a fundamental difference between the agencies in regulatory approach, although current information suggests that the level of protection achieved under both agencies' programs is comparable. Assessment of the level of risk actually achieved in the programs is difficult because of differences in regulatory approach and the application of multi-layered, defense-in-depth regulations. For example, NRC's requirements in 10 CFR Part 61 embody a systems-based regulation that includes general performance objectives and a series of technical requirements on site suitability, waste characteristics, waste classification, design and operation, environmental monitoring, and institutional controls. These requirements may collectively achieve a level of protection that surpasses the performance objectives. In addition, NRC's licensing, inspection, and enforcement programs add to the level of protection. Thus, assessments of the level of protection associated with NRC and EPA programs need to consider both quantitative and qualitative factors.

EPA frequently establishes ambitious safety goals and then allows operators to achieve a relaxed risk level, to account for technology, cost, or practicality considerations. On the other hand, NRC sets a more pragmatic risk limit, but requires licensees to reduce doses to levels below the established safety limit, through radiation protection programs that employ the principle that doses should be as low as is reasonably achievable (ALARA). Application of ALARA considers cost, technology, and practicality. Although the practical effect of these two regulatory approaches is largely the same, there remains a difference of about a factor of 10 between NRC's acceptable lifetime risk level of excess cancer ($10^{-3}$), as embodied in the public dose limit in 10 CFR 20.1301, and EPA's acceptable lifetime risk range ($10^{-4}$ to $10^{-6}$), as described in the National Emission Standards for Hazardous Air Pollutants (40 CFR Part 61) and in the Superfund program (40 CFR Part 300). It is this fundamental difference in acceptable risk and regulatory approaches that the agencies need to explore in seeking harmony in public and environmental protection.

CONCLUSIONS:

Although the risk harmonization process is still in its early stages, NRC and EPA have reached several important conclusions. Based on the comparison of risk assessment approaches, the staffs have concluded that:

- There are more similarities in risk assessment than differences.
- Resolution of the differences in risk assessment approaches is not likely to affect significantly the outcome of agency decisions in most program areas, i.e., the quantitative risk estimates, in most cases, will not change significantly after resolution of differences is achieved.
- The most significant differences appear to be in the area of risk management.

In addition, interactions with EPA to resolve disagreements in specific program areas have highlighted fundamental differences between EPA and NRC in regulatory approaches and the level of acceptable risk for protection of public health and safety.

The current staff focus is on completing the comparison of risk management approaches. After completing the comparison, the staff intends to prepare a draft of the White Paper on risk harmonization by late Summer 1993. When complete, staff expects that the White Paper will highlight differences between the agencies and will help identify important opportunities for further risk harmonization.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

James M. Taylor
Executive Director
for Operations

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