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NUCLEAR REGULATORY COMMISSION

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NUCLEAR REGULATORY COMMISSION

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BRIEFING ON STATUS OF EFFORTS FOR  
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

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## 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

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

2:00 p.m.

1  
2  
3 COMMISSIONER ROGERS: Good afternoon,  
4 ladies and gentlemen.

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

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

15 By way of introduction, let me recount  
16 just the most essential details of our dialogue with  
17 EPA on risk harmonization. In March of 1992, we were  
18 able to successfully conclude an effort to put in  
19 place a memorandum of understanding with EPA to help  
20 resolve issues of concern to both agencies. The March  
21 1992 MOU represents a major step forward to foster  
22 cooperation between the Nuclear Regulatory Commission  
23 and the Environmental Protection Agency in carrying  
24 out agency mandates to protect the public health and  
25 safety and the environment on matters related to

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1 radiation in the environment.

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

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

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

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

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

8 Do my fellow Commissioners have anything  
9 before we begin?

10 Mr. Taylor, please begin.

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

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

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

19 MR. WEBER: Thank you.

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

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

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

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

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

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

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

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

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

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

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

7 COMMISSIONER ROGERS: Just before you move  
8 on, Mike.

9 MR. WEBER: Yes.

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

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

19 COMMISSIONER ROGERS: Okay. Thank you.

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

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

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

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

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

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1 1983 report called the red book, informally, on risk  
2 assessment. Based on those earlier discussions in the  
3 1980s, a distinction was drawn by a variety of  
4 agencies, including NRC and EPA, on the difference  
5 between risk management and risk assessment, and also  
6 the difference between health risk assessment which  
7 would involve basically assuming that exposure will  
8 occur and then trying to estimate the risk associated  
9 with the exposure versus engineering risk assessment  
10 which involves consideration of failure of engineered  
11 barriers or natural systems which eventually might  
12 lead to human exposure. So, that's an important  
13 distinction.

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

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

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

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

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

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

19 MR. WEBER: Sure.

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

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

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

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

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

11 MR. BERNERO: Yes. Okay.

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

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

18 COMMISSIONER REMICK: Yes. Okay.

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

21 COMMISSIONER REMICK: Right.

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

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

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

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

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

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

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

12 COMMISSIONER de PLANQUE: Go ahead.

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

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

25 COMMISSIONER REMICK: The difference being

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

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

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

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

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1 about the differences and the similarities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 MR. TAYLOR: I want to be sure that went

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1 on the record, sir.

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

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

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

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1 concentration limits for uranium mills.

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

5 MR. WEBER: No.

6 COMMISSIONER CURTISS: What does it spring  
7 from?

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

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

21 MR. WEBER: That's right.

22 COMMISSIONER CURTISS: Is that a fair  
23 statement?

24 MR. WEBER: Yes.

25 MR. BANGART: In fact, the EPA indicated

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

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

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

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

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

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

18 COMMISSIONER CURTISS: All right.

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

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

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

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

25 The first one was that both agencies

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

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

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

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

7 Generally the --

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

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

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

3                   MR. BERNERO: Yes, it is.

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

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

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

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

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

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

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

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

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1 understand that.

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

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

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

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

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

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

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

6                   COMMISSIONER REMICK: Yes.

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

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

14                   COMMISSIONER REMICK: That's right.

15                   MR. WEBER: And some people find that --

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

18                   MR. WEBER: Right.

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

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

7 MR. BERNERO: Let me speak to that because  
8 that has come up already. You may be familiar with it  
9 that in the, oh, past month or so, a little over a  
10 month, the staff reviewed the Energy Policy Act of  
11 1992 and possible impacts on the high-level waste  
12 standard and had a dialogue with the Advisory  
13 Committee on Nuclear Waste and they wrote a letter and  
14 this very issue came up. The Advisory Committee, not  
15 surprisingly, said, "You really ought to focus on the  
16 critical population group as against the individual  
17 risk for that issue."

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

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

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

12 COMMISSIONER CURTISS: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 COMMISSIONER REMICK: Unless you have it  
18 cut-off.

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

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

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1 slide, please?

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

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

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

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

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1 risk coefficient for low LET ionizing radiation of  
2 about  $5 \times 10^{-4}$  fatal cancers per person rem. In contrast  
3 to that, at the time EPA was using  $4 \times 10^{-4}$ . So at that  
4 time there was a difference in the risk coefficients  
5 for converting dose into risks, however EPA generally  
6 prefers at least today to go directly from the intake  
7 of the radioactive material to a risk and therefore  
8 bypass the dose altogether except in those programs  
9 where dose is an important element of a compliance  
10 determination. And so, they're using in some ways  
11 more sophisticated modeling to relate the intake of  
12 the radionuclide to a risk by looking at organ-  
13 specific risk factors and age-specific risk factors.

14 What I'm trying to get at is they're  
15 relying less on some lumped risk coefficient like  
16 we've used,  $5 \times 10^{-4}$ , and instead preferring a more  
17 sophisticated analysis to relate the dose to the risk  
18 or the intake to the risk. So, that's one of the  
19 differences that you were asking about earlier.

20 COMMISSIONER REMICK: I remember back when  
21 the Commission was reviewing the BRC policy statement  
22 I asked the staff the question why we're using  $5 \times 10^{-4}$   
23 rather than  $4 \times 10^{-4}$  and the staff made a very strong  
24 defense of  $5 \times 10^{-4}$ . What's EPA's excuse for using  $4 \times 10^{-4}$   
25 ? At that time, I read BEIR V saying  $4 \times 10^{-4}$ .

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

12                   Did you want to say something?

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

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

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

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

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

3 COMMISSIONER REMICK: I see.

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

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

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

20 COMMISSIONER REMICK: Fine. Okay.

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

23 At the time we were holding the discussion  
24 that you referred to, the BEIR V report and the  
25 UNSCEAR report had just come out. EPA's  $4 \times 10^{-4}$  value

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

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

17 COMMISSIONER REMICK: Thank you.

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

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

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

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

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

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

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

25 COMMISSIONER CURTISS: Okay.

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

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

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

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

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

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

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

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1 organ and the age-specific risk factors, that in some  
2 cases their risk coefficients may be considerably less  
3 than the ones that we're currently using. One case  
4 comes to mind and that's for thorium-232. I believe  
5 the difference in the risk factors is on the order of  
6 140 times, which may have significant implications in  
7 terms of how either agency proceeds. In fact, EPA is  
8 now looking at its whole approach on converting dose  
9 and risk as part of their drinking water standards.  
10 So, we're going to watch that closely and interact  
11 with them so that we're sure we're kept abreast of  
12 what they're doing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 MR. WEBER: Based on the linear dose  
4 hypothesis.

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

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

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

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

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

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

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

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

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

2 (Slide) If we can have the next slide.

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

25 Those are the areas that we're exploring.

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

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

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

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

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1 differences where they exist.

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

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

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

25 MR. BERNERO: No, we hadn't specifically

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

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

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

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

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

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1 MR. WEBER: They did that --

2 COMMISSIONER REMICK: I put it in the  
3 abstract.

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

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

25 COMMISSIONER de PLANQUE: Let me follow

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

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

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

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

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

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

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

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

23 MR. TAYLOR: Sorry.

24 COMMISSIONER REMICK: The EDO just gulped.

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

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

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

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

21 COMMISSIONER CURTISS: We do too.

22 COMMISSIONER ROGERS: Jim?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 Bob?

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

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

25 One could argue wait for the white paper,

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

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

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

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

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

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

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

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

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

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

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

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

22 COMMISSIONER CURTISS: Yes.

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

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

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

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

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

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

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1 understanding the differences or similarities between  
2 the two agencies.

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

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

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

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

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

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

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

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

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1 legislation which might call something some particular  
2 thing.

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

6 COMMISSIONER de PLANQUE: Right.

7 MR. TAYLOR: Very important.

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

11 COMMISSIONER de PLANQUE: Right.

12 MR. BERNERO: Because, terminology is so  
13 different.

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

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

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

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

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

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

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

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

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

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

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

22 I'd like to thank the staff.

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

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

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

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

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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

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

***BRIEFING FOR THE COMMISSION***

**May 26, 1993**

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## **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**



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## **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**



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## **Risk Harmonization Components**

- ***Risk Assessment***

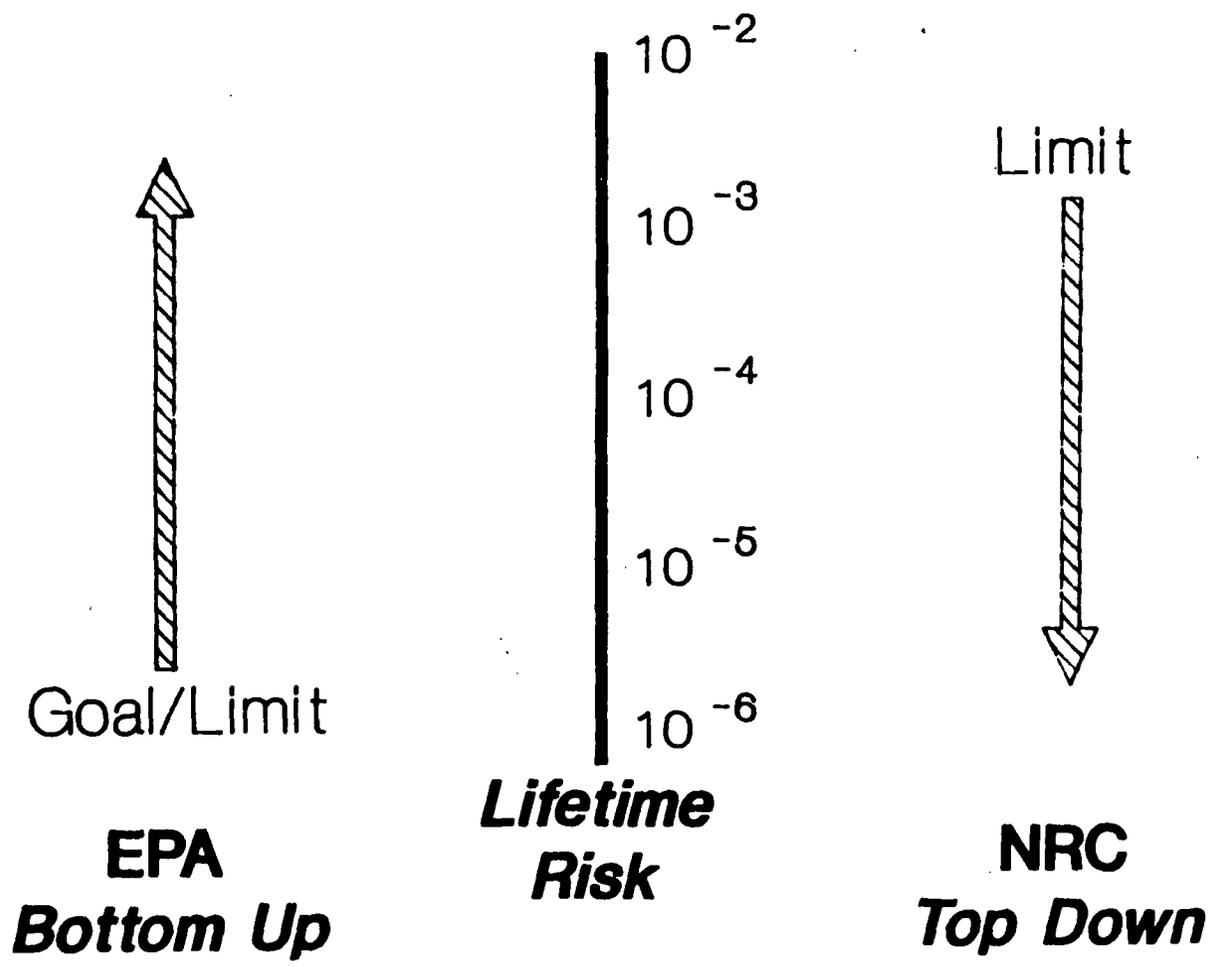
**Methods, assumptions, and other considerations involved in quantifying or estimating health risk**

- ***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





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## **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**



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## **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**



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## **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**

- **Limit on individual risk**
- **Use of radiological dose in rulemaking and compliance assessment**
- **Truncation of population dose in terms of time and space**

### **EPA Risk Assessments**

- **Limit on population risk**
- **Use of health risk**
- **No truncation of population dose if it affects control options**



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## **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**



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## **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**



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## **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:

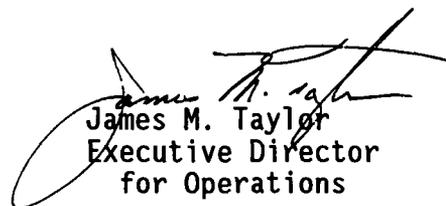
- There are more similarities in risk assessment than differences.
- Resolution of the differences in risk assessment approaches is not likely to affect significantly the outcome of agency decisions in most program areas, i.e., the quantitative risk estimates, in most cases, will not change significantly 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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