NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

IN THE MATTER OF:

ORIGINA

SUBCOMMITICE MEETING

on

RELIABILITY AND PROBABILISTIC ASSESSMENT

Place - Washington, D. C.

Date - Wednesday, 5 December 1979

Pages 1 - 278

Telephone: (201) 347-3700

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ACE - FEDERAL REPORTERS, INC.

Official Reporters

444 North Capitol Street Washington, D.C. 20001

NATIONWIDE COVERAGE - DAILY

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	3	ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
	4	Wednesday, 5 December 1979
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	6	The contents of this stenographic transcript of the
	7	proceedings of the United States Nuclear Regulatory
	8	Commission's Advisory Committee on Reactor Safeguards (ACRS),
	9	as reported herein, is an uncorrected record of the discussions
	10	recorded at the meeting held on the above date.
	11	No member of the ACRS Staff and no participant at this
_	12	meeting accepts any responsibility for errors or inaccuracies
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	2	NUCLEAR REGULATORY COMMISSION
	3	ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
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	6	SUBCOMMITTEE MEETING
	7	on
	8	RELIABILITY AND PROBABILISTIC ASSESSMENT
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	10	Room 1046 1717 H Street, N.W. Washington, D. C.
	11	Wednesday, 5 December 1979
	12	The ACRS Subcommittee on Reliability and Probabilistic
	13	Assessment met, pursuant to notice, at 9:35 a.m., Dr. David
	14	Okrent, Chairman of the Subcommittee, presiding.
	15	PRESENT:
	16	DR. DAVID OKRENT, Chairman of the Subcommittee
	17	MR. HAROLD ETHERINGTON, Member
	18	DR. J. CARSON MARK, Member
	19	MR. JEREMIAH J. RAY, Member
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PROCEEDINGS

DR. OKRENT: Good morning. The meeting will now come to order. This is a meeting of the Advisory Committee on Reactor Safeguards Subcommittee on Reliability and Probabilistic Assessment. My name is David Okrent. I am the Subcommittee chairman. The other ACRS members present at this time are Mr. Carson Mark and Mr. Harold Etherington.

Also in attendance -- and Mr. Jerry Ray, Jeremiah
 Ray. Thank you.

Also in attendance are several ACRS consultants, Mr. Lave, Mr. Lowrance, Mr. Shinozuka. I think we will have one or more other ACRS members and consultants coming in later.

Also in attendance are two ACRS fellows,
Mr. Michael Griesmeyer and David Johnson, at the table.

17 The purpose of this meeting is to discuss the use of risk assessment methods and the establishment of risk 18 criteria by government agencies and other groups. We would 19 20 also like to get suggestions on appropriate goals and criteria which might be used for nuclear power reactors. 21 The meeting is being conducted in accordance with provisions 22 of the Federal Advisory Committee Act and the Government in 23 the Sunshine Act. 24

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Mr. Gary Quittschreiber, on my right, is the

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designated federal employee for the meeting. The rules for
 participation in today's meeting have been announced as part
 of the notice of this meeting, previously published in the
 Federal Register, November 20, 1979.

A transcript of the meeting is being kept and will be made available as stated in the Federal Register notice. And it is requested that each speaker first identify himself and speak with sufficient clarity and volume so that he can be readily heard.

Those around the table have nametags, so the recorder will know who you are, but if others would please identify themselves in at least enough time so that the recorder knows, that will be helpful.

We have received no written statements or requests for time to make oral statements from members of the public: however, I plan to run this meeting a little more like a panel discussion with reasonable participation from the audience, so if a member of the audience would like to make a point, please get the attention of the subcommittee chairman.

21 We will now proceed with the meeting. Let me 22 just, by way of brief introduction, for the benefit of those 23 who may not be aware of it — although the subject of 24 quantitative safety goals is not a new one in this society 25 and it is not a new one in the question of nuclear reactors,

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it has not been one that has been addressed to the point
 that the Atomic Energy Commission before, or the Nuclear
 Regulatory Commission now, have identified quantitative risk
 acceptance criteria.

In May - more specifically, on May 16, 1979, the 5 Advisory Committee on Reactor Safeguards wrote to the 6 Nuclear Regulatory Commission, recommending that 7 consideration be given by the Commission to the 8 establishment of quantitative safety goals for overall 9 safety of nuclear power reactors, and gave some reasons for 10 why they thought this would be a useful thing to try to .11 do. The next step chronologically was that one of the 12 commissioners wrote to the ACRS asking for further comments 13 in this regard. 14

And in August the ACRS said it would try to see if it could develop some possible proposed criteria that might be considered for use by the Nuclear Regulatory Commission, that could be published for comment, or this sort of thing.

I might note an additional item that has transpired in this regard — is that in NUREG-0585, which is entitled "TMI-2 Lessons Learned Task Force Final Report," this task force made one recommendation, namely, Number 11, which is entitled "Safety Goals for Reactor Regulation," and in this they recommended that the Commission develop definitive policy guidance or articulation of a basic safety

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goal for nuclear power plant regulation. They didn't specifically urge that this be strictly a quantitative goal, but they suggested that the goal would be supplemented, where possible, with quantitative risk criteria.

Then, more recently, on November 9, 1979, in a 5 letter from the chairman of the Nuclear Regulatory 6 Commission, Dr. Hendrie, to Dr. Frank Press, director of the 7 Office of Science and Technology Policy, in which the 8 Nuclear Regulatory Commission commented on the President's 9 Commission report with regard to the accident at Three Mile 10 11 Island. The Nuclear Regulatory Commission acknowledged the previous recommendations of the Advisory Committee on 12 13 Reactor Safeguards, that the Lessons Learned Task force -and stated that a safety goal of nuclear power plant 14 regulation in terms of clear subjective criteria is needed 15 and should be supplemented, where possible, by quantified 16 17 reliability criteria.

So, in any event, there is a small recent history of this topic within the last several months, and what the ACRS has tried to do in the last few months is to see whether, via this subcommittee, one could develop both background information and possibly one or more alternative proposals for risk acceptance criteria, quantitative if possible.

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But we shall see. In any event, the purpose,

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then, of this meeting, was to try to learn a little bit about what was being done in this regard in some of the other government agencies, and also to see what suggestions one might get for goals in quantitative risk criteria that might be used for nuclear power reactors.

5 So that is by way of brief introduction. And 7 since I am a minute ahead of the agenda, I will try to 8 continue that way, since it is probably the last time today 9 that will be the case.

10 Our first speaker is Dr. Vincent Covello of the 11 National Science Foundation, who I believe will discuss some 12 NSF sponsored programs on risk assessment. I might note 13 there are a few copies of the agenda on the table over 14 there if anybody doesn't have that and would like to have 15 one. So, Dr. Covello.

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(Pause.)

DR. COVELLO: My name is Vincent Covello. I am the Program Manager for the Risk Analysis Program at the National Science Foundation. I have been asked today to describe very briefly to you the program in risk analysis at the Foundation, as well as to answer any questions that you might have about that program.

First of all, the program is very new. It is approximately five months old. It is located in the Division of Policy, Research and Analysis in the

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Foundation. It is also part of the Technology Assessment
 and Risk Analysis Program as a whole. It is a subcomponent
 of that particular program.

Because it is located within the Division of Policy, Research and Analysis, all studies that are sponsored through this program have a policy focus, and I will come back to that later.

The program was created in response to several 8 requests, spacifically one from the House Committee on 9 Science and Technology, which asked the Foundation 10 specifically to develop a long-term program of research that 11 looks at methods of risk assessment. We have been asked to 12 sponsor research that would develop improved methods for 13 risk analysis and risk assessment. We also received several 14 requests from agencies including the Nuclear Regulatory 15 Commission to also look at questions such as risk 16 17 acceptability and general questions relating to issues and 18 risks.

In response to these various requests the Foundation, approximately seven months ago, created this particular program. It was formally announced five months ago, in August. We are engaged in two activities, in response to the request.

First we are engaged in planning activities. The planning activities are threefold. First, we have asked the

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National Academy of Sciences to assist us in planning a full-scale program in risk analysis. We hope that as a result of the Academy's work they will produce an agenda of research that we can use as part of our own planning for risk assessment. We expect that a program announcement will probably be announced and available to the public this coming summer.

8 Second, we have commissioned several papers on 9 risk assessment on the state of the art, surveying where we 10 are with regard to risk assessment and where we should be 11 going.

And third, we have also established a liaison activity with various agencies, trying to assess their own needs and what types of activities at the Foundation would support their particular programs.

In addition to the planning activities for the full-scale program once it is in place, we are also currently engaged in encouraging the submission of unsolicited proposals dealing with a wide range of questions related to risk assessment.

21 What we have done recently, if everyone has the 22 handout, we have sent out a letter to the research 23 community, to approximately 4000 people, announcing the 24 creation of the risk assessment program, and specifying the 25 types of questions that we are interested in and the type of

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proposals we would be interested in supporting. I think you 1 will see in the questions listed there they cover a wide 2 range of activities including how to determine how safe is 3 safe enough. a question dealing with the perception of risk. 4 risk acceptability, institutional/organizational constraints 5 on risk decision-making -- these are the types of questions 6 We are addressing. And they specify a very broad range of 7 activities and we expect, at a later date, to be more 8 specific in the types of proposals we are interested in. 9

10 At the present stage, though, since we are 11 primarily interested in obtaining some of the best 12 information and knowledge as to the state of the art, these 13 are the broad outlines of the program.

The program has several constraints on it, though. In addition to proposals that deal with those questions, we are also asking, first of all, that the proposals submitted to the Foundation deal with risk on a generic level as opposed to dealing with specific applications. As I mentioned before, our task is to develop improved methods of risk assessment.

As a result, if specific applications -- for example, to nuclear power or to other energy systems -- are suggested, we ask that those particular studies be considered as case studies addressing a more general, broad issue in assessment.

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The second constraint on the program is that all proposals have to have a policy focus. In other words, all the proposals and research responses should somehow or another address the questions that are being asked by decision-makers, and they should be addressing issues currently on the agenda, or expected to be on the agenda for risk analysis in the coming years.

8 The third constraint on the program is: we 9 primarily deal with technological risk and not with natural 10 hazards or with entrepreneurial risk. Technological risks 11 such as energy, toxic substances, the whole range of risk 12 that relate to science and technology — we cannot deal, 13 given our mandate, with risks that don't fall within that 14 category.

At the present stage, because we are involved in 15 our planning activities, the type of research we are 16 17 supporting range from between projects of \$150,000 to \$200,000, and a year to a year-and-a-half worth of effort. 18 We have received as a result of the addendum to our program 19 announcement approximately 150 letters of inquiry and 20 21 preliminary proposals. We are also now already reviewing several proposals that have come out as a result of that 22 letter. 23

24 We have also supported several studies that are 25 ongoing. These particular projects were not supported

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directly under the risk analysis program. They were taken 1 into the program after the creation of the program. The two 2 are as follows: the one project, by Robert Cates and Roger 3 Casperson at Clark University. The title of their proposal 4 is "Methods for Improving Public Policy for Technological 5 Hazard Management." The focus of that particular study is 6 to develop a taxonomy of risk and to use that taxonomy of 7 risk in developing approved methods of technological hazard 8 9 management.

10 The second major project we're supporting in 11 present times is one by David Okrent, the chairman of the 12 subcommittee at the meeting. The title of that project is 13 "Alternative Risk Managment Policies for State and Local 14 Governments." The focus there is looking at types of risk 15 that have to be dealt with at the local level and developing 16 improved methods for management of those types of risks.

17 On both of those projects, there is a subcontract 18 in Eugene, Oregon, which is looking at perception of risk 19 and feeding that material into the main projects.

At the present time, the program has a budget of approximately \$1.5 million. We expect within the next five years to increase the size of that budget to something larger than that, although it hasn't been exactly determined how large that budget will be. It will primarily depend upon the response of the research community to the types of

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questions we've asked. And as a result of that response we will determine how large the budget will be.

3 That is the general outlines of the program. I 4 think it's probably easier for me to address questions than 5 to go into too much detail about any of these particular 6 studies we are addressing.

MR. LOWRANCE: Bill Lowrance, consultant. I have 7 been concerned for a long time with how the NSF works with 8 the other mission agencies in supporting research of this 9 sort. I think this is a good example, where NSF could do 10 generic research that could serve the needs of anybody from 11 12 the FDA to EPA to NRC. And I wonder, mechanically, how you interact and whether you are soliciting those mission 13 agencies for ideas, either research needs or people who 14 15 might be interested.

DR. COVELLO: Well, first of all, one of the 16 activities we engage in is direct liaison with the mission 17 agencies. For example, the creation of the National Academy 18 of Sciences Committee on Risk and Decision-Making was 19 partially in response to a request from the Nuclear 20 Regulatory Commission, from the office of Saul Bean, to look 21 at questions of acceptability of risk. We discussed with 22 the NRC the various needs, concerns, and used that as the 23 basis for our own putting together of the Academy 24 25 committee.

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In addition we have liaison activities with each major agency that has risk assessment responsibilities. We share with them proposals for both review of our proposals to them -- we also review proposals on their side and that way we maintain a liaison of knowing what the other groups are doing and what their programs are.

A third things we are doing — and this is much more specific — is that we have asked the Academy to meet periodically with an advisory group we are at the present time establishing, of government regulatory agencies dealing with the question of risk. This will be approximately 14 individuals representing each of the mission agencies that has risk assessment responsibilities.

And we will have this advisory committee of government agencies meet with the Academy committee to indicate to them what the needs are of the particular agencies, and what types of questions they would like to see addressed from their perspective.

We hope through this interaction between the Academy and the advisory committee that the Academy will be more responsive to the needs of the mission agencies. We also hope to use that advisory committee as an information resource for our own program on the needs of the particular agencies.

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DR. MARK: You use the word "technology" and

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distinguish between and a schebite, for instance. How broad an area is covered by a schology? Is it all industrial? Or scientific analyticy that affects the population?

5 DR. COVELLO: The actual outlines of it are still 6 not clear. As you know, the definition of "technology" 7 varies from person to person and place to place.

DR. MARK: I mean, the release of carbon dioxide
by burning wood in Vermont isn't very technological.

DR. COVELLO: Right. But what we are looking for 10 in the proposals is connection to science and technology in 11 some direct, as opposed to an indirect or implicit way. So 12 13 carbon dioxide would not be, but if we looked at the technologies that produce carbon dioxide or carbon monoxide, 14 or other sort of types of toxic substances, we are looking 15 16 at the actual production of technology that produces it, as opposed to the product of that technology. 17

18 There is the focus. It has to be tied back to the 19 particular technology itself, as opposed to the product of 20 that technology.

21 DR. MARK: It seems to me that there is something 22 perhaps not caught up here that policy as well as technology 23 may result in carbon dioxide. And is that within the scope 24 of the matters of concern?

DR. COVELLO: I'm not sure I understand.

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DR. MARK: Well, I referred to the burning of wood in Vermont. People are saving enormous amounts on their gas bills by doing that, and if everybody in the country should do that, this is not so much a matter of technology as a matter of policy. And is that going to be caught up by your net?

DR. COVELLO: I will probably have to leave that 7 as a open issue, because we have not yet tried to strictly 8 define the boundaries of what would be considered within the 9 program, to find out what is technology and what is not. We 10 are hoping as a result of our own internal planning 11 activities and review to come to a more specific definition 12 of what science and technology related risks are, and to use 13 that as a boundary condition for the program. 14

Again, it is such an open area and subject to such controversy about what would be considered a technology and what is not a technology — there is no specification on what would be determining that, how that would be determined.

DR. OKRENT: Is there some reason why this is a new program in NSF? The question of risk and society and what constitutes acceptable risk, it seems to me, has been staring us in the face for some time. I would have expected NSF would have been ahead of the Congress, instead of behind it, in this regard.

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DR. COVELLO: Well, the NAE study was sponsored by the National Science Foundation for technology assessment and the RANN program, the one on risk benefit, is that the one you are referring to?

5 DR. OKRENT: In 1972, but there has been no 6 program.

DR. COVELLO: No. there has not been a specific 7 program in risk analysis or risk assessment at the 8 Foundation. Most of the activities have dealt with specific 9 technologies. There has been a program in chemical threats 10 to the environment. There is a program on earthquake hazard 11 mitigation. There are programs that deal with different 12 13 types of science and technology and risks associated with 14 them.

There hasn't been a program at the Foundation 15 which has focused on risk assessment per se. Questions 16 related to risk have been dealt with as part of those other 17 programs. What I believe has happened now is that as a 18 result of both the Congress and internal planning as well is 19 that it is decided that the Foundation should have a more 20 visible and centralized location for risk analysis studies. 21 And the importance of the question, the generic issues, that 22 crosscut various types of agencies and various problems are 23 being recognized -- and it is seen as beneficial to have a 24 centralized location for risk analysis programs that will 25

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coordinate with each of the separate programs within the Foundation.

DR. OKRENT: Because, in fact, there was no home within NSF that one could find for such a proposal a year or 4 year-and-a-half ago -- I know from my own experience. 5 6 Dr. Shinozuka.

DR. SHINOZUKA: You specifically mentioned that 7 your program excludes consideration for a natural hazard. 8

DR. COVELLO: Right.

DR. SHINOZUKA: It seems to me that a natural 10 hazard obviously is an important component when we assess, 11 say, safety of structures -- how we design structures 12 against such natural hazards -- result in different levels 13 of risk. I would like to know why, then, you do not 14 entertain the proposal that might involve natural hazard 15 consideration. 16

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DR. COVELLO: At the present time most of the 1 proposals dealing with natural hazards are dealt with by a 2 program is the Foundation's earthquake hazards mitigation 3 program, which primarily deals with earthquakes and natural 4 hazards as well, including generic questions relating to S natural hazards. It is possible that at some later date we ó will coordinate closely with that program. One of the 1 activities relating to the planning activities of the 8 Foundation is to determine whether or not those activities 9 should be joined together. At the present time there is a 10 functioning program dealing with natural hazards in the 11 foundation, and it wasn't seen to be --12

DR. SHINOZUKA: I am aware of that program that deals with earthquake hazard mitigation in the National Science Foundation, but I am not quite sure if they really focus on, let's say, the policymaking based upon risk analysis. That is my primary concern.

DR. COVELLO: There is one -- I brought along the program announcement for that particular -- the earthquake hazard mitigation program, and they do have a policy research section. And I will read from it:

Policy research: This particular element of the program strengthens and facilitates the adoption and implementation of technological, social, and management practices that minimize earthquake damage and facilitate

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rapid recovery from earthquake disasters."

They have, in other words, within their mandate to 3 deal with policy questions relating to natural hazards.

DR. OKRENT: Well. thank you. Dr. Covello.

The next speaker is Dr. J. L. Von Thun.

MR. VON THUN: It is Larry Von Thun, and there is 5 1 no doctor.

DR. OKRENT: He is from the Bureau of Reclamation, 8 and he's going to give us two presentations. The first 9 discusses the mission progress of the seismic risk analysis 10 interagency committee on seismic safety. And then he will 11 discuss the Jackson Lake risk analysis. And if we are 12 fortunate. he may also provide some suggestions on what we 13 should do for nuclear power. 14

MR. VON THUN: I am with the Bureau of 15 Reclamationn. I don't know how many of you know what the 15 17 Bureau of Reclamation is.

DR. OKRENT: Why don't you tell us in 30 seconds. 18 MR. VON THUN: They just changed their name. I 17 will have to tell you that, as well. The Bureau of 20 Reclamation is a water resources agency dealing with the 17 21 western states. Most of the large dams in the western 22 U.S. were built by the Bureau of Reclamation between 1902 23 and the present: Glen Canyon, Hoover, Shasta, most of those 24 dams. As such, as an agency which is producing a product, 25

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we are more on the firing line in front of, say, states, pv HEE 1 even other federal agencies, with regard to risk assessment, 2 people asking us, "What are you doing about risk 3 assessment," rather than, say, being devoted to research. 4 So. what I will be discussing today is how we are ć 6 trying to apply our risk assessment methods with the information that we currently have. 6 DR. MARK: Could I ask. You said you have 17 8 western states? 7 MR. VON THUN: Yes. 10 DR. MARK: And the other states, you are not 11 active; but there, the Corps of Engineers might be doing 12 some things? 13 MR. VON THUN: That's right. The Corps of 14 15 Engineers is really applicable to the entire U.S. The Bureau of Reclamation, beginning with the Reclamation Act of 15 1902, only dealt with reclaiming or providing water, 11 essentially, for the arid west. That is the 18 differentiation. Whereas the Corps of Engineers works with 19 20 navigation, and that can be within any of the U.S. 21 The first presentation is with regards to a committee on seismic safety in federal construction. After 22 the San Fernando earthquake in 1971, a lot more attention 23 24 began being paid to the seismic safety of structures, both 25 dams, buildings, even nuclear power plants, although that

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was well along the way as far as seismic risk assessment. 1 And with the failure of a number of dams throughout the 2 U.S. and generally more an dmore attention being paid to 3 seismic safety, the President asked the Office of Science 4 and Technology Policy -- I believe that was where it was õ initiated - to form an interagency committee of all federal 6 agencies concerned with building structures to come together 1 and decide now the seismic safety could be improved. 8

And that committee has a number of subcommittees. IN They have committees on seismology, on site hazards, on II critical facilities. And one of their committees is on risk I2 analysis. And the question to this subcommittee is: how I3 should federal agencies be using risk analysis?

My personal background with regard to how I got on 14 this subcommittee stems largely from two events. One is the 15 Auburn Dam in California -- which is not a dam as yet, it is 15 just a proposed dam. It has been the subject of a great 11 amount of public interest with regard to seismic safety. 18 California has a Seismic Safety Commission which asked these 17 questions of the Bureau and of any other agency which is 20 planning on building a structure as to: can you verify its 21 seismic safety? And this gets into the question of what is 22 the true risk involved? 23

Carl Steinburge, who is the chairman of that Commission, asked me the question before a meeting similar

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to this with regard to acceptable risk to actually come up with a better definition for "acceptable risk," because, as he felt, "acceptable risk" is neither acceptable now nor accepted by anyone, it is just a term we all use. And in grilling before the Seismic Safety Commission, the Bureau began to think a lot about what and how to apply risk assessment in that work.

Then, following the Teton Dam failure, we were 8 reviwed by numerous agencies, and, without exception, the 7 advisement was given to develop risk assessments in our 10 work, both with existing dams and with ongoing dams. So, 11 some of the work that we have done has been in that regard 12 in trying to work with what is the seismic safety of our 13 existing dams and how do we determine what the probability 14 of risk of their failure is. 15

And it was through those types of efforts that I was involved in this committee or asked to be a part of this committee.

As far as the sccomplishments of our Subcommittee 5 on risk analysis, there have not been a great deal to date. I have provided you a three-page handout here which should not be considered the output of the committee, but rather my own personal input to the committee, because there have not been any decisions reached by the committee as yet as to how they are going to approach the problem of

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recommendations to other federal agencies on the use of risk assessment. But there are a few things which fit right into 2 3 what you are asking for as far as the purpose of this committee: what is being done and what might be done. 4

The first thing that I would discuss in this õ regard is a general framework for risk assessment. We have 6 three elements, as I see it, three elements with regard to 7 seismic safety: one is what is the propability of 3 occurrence of seismic events; the second is what is the 9 probability of failure of a facility given the seismic event 10 occurs; and the third is the estimation of the consequences 11 of failure of the facility. 12

In reading the literature, the terms "risk, 13 hazard, hazard potential, and exposure" are used 14 interchangeably; there is no consistency. And the first 15 thing I was recommending to this committee is that we 15 develop a framework where we consistently refer to these 11 different terms with regard to their application in decision 18 analysis by risk-based methods. 12

In this vein, then, I suggested the term 20 "exposure" is used in reference to the action or influence 21 to which a facility is subjected. In other words, what is 22 the exposure of a particular facility to an earthquake 23 either shaking or faulting. 24

The second term. "hazard," I suggest that that be

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used in reference to the damage potential. In other words,
 when we create a dam, a nuclear power plant, or a building,
 we have created a potential hazard that can fail and cause
 some damage. Without the facility there, the hazard doesn't
 exist.

The third term, "risk," has been used in all of ć the elements we talked about. The risk of the earthquake, 1 we talked about the risk of failure of the facility, and we 8 talked about the risk of loss of life to individuals. I 7 would suggest that, rather than use it in all those veins. 10 that we use the term "risk" to refer only to the probability 11 of failure occurring as the result of some exposure to some 12 action such as an earthquake and resulting in some damage. 13

The total framework which we deal with I called "risk-based decision analysis." With all the work that we do at the Bureau, that is the way we refer to it. So, this is the framework that I would suggest using.

As far as residual risk goes, the definition is supplied in your handout, and this is how I would look at residual risk and think that it should be advanced to the public and within all the different agencies.

22 "Residual risk" is the probability of occurrence 23 of a facility failure, the chance that a facility will fail, 24 and that loss of life or economic loss which remains in 25 existence. Some probability of that remains in existence.

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After the loading conditions, the earthquake 1 loading conditions or whatever loading conditions you have, 2 3 after those conditions have been specified, appropriate designs to take care of those conditions have been prepared 4 and additional safety precautions are established, what is 2 left after you do all of those things - after you have 6 assigned the facility, after you have specified what the 1 earthquake is for design or the other loading provisions for 3 design, after you have designed the facility to take that 9 loading and after you have established safety precautions -10 that is "residual risk." 11

And when somebody accepts that, when the owner of a facility or the U.S. Government or somebody says, "Okay, there is still this much chance that there could be a foulup or a problem," that becomes "accepted risk." And to date, that has not occurred, and that is really what I see you are talking about doing through this committee, is defining some number that becomes the "accepted risk."

We have talked about "acceptable risk," but I
think in very few cases, if any, has an agency or an owner
decided this is how much risk that I am willing to take.

22 With regard to what recommendations our 23 subcommittee might make, the next two pages provide my sort 24 of device or input to our subcommittee with regard to 25 recommendations. If you look at the middle of the second

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page of the handout, it says: "The question then is: considering the current level of knowledge, experience, and practice in risk analysis, what are the possible types of requirements of federal designers and regulators that could achieve the above results" -- meaning lowering the chance of seismic hazards.

These requirements and regulations would occur in
8 three different areas: One, the determination of seismic
9 loading. Under the determination of seismic loading, then,
10 there are three possible requirements that I have
11 suggested.

One is to specify the technique to determine the 12 level of loading to be used; the second is to establish a 13 requirement that to determine the risk level of loading 14 selected and compare it to other risks -- in other words, a 15 person designing a building or person designing a dam or a 16 nuclear reactor or whatever would be required under our 11 18 suggestions to determine what is the level, what is the risk of that particular level of loading. Then item 3 would be 19 20 just as -- or item C would be just as item B except we would specify what the methodology is that would require -- that 21 22 would allow that determination of risk.

If we got to the point of saying a risk level of loading at, say, 1 x 10 to the 4th was an acceptable or was the acceptable risk of loading, loading only, then one

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approach would be to say, to actually calculate the loading, given that an earthquake has an occurrence interval of a certain amount, that has a probability of not being ceded in so many years and that would specify that would meet that particular requirement of loading.

As of right now, my recommendation would be that 6 all we can require of federal agencies at this date is to 1 ask that in each analysis the risk level of loading be 8 selected, be determined, and that it be compared to the 4 rishs of other loadings so that we can get a handle on what 10 is the likelihood of all of the loadings and people actually 11 go through the process of seeing what the risk is. We are 12 not at a stage - I don't feel we are at a stage where we 13 can tell people building buildings or building dams that 14 this is the level of earthquake loading that should be used 15 and have that applied across the board. 16

17 Okay, the second area where we would require some 18 regulation is in determining the merit of design provisions 19 in the reduction of risk. This is to do with the question: 20 if we add such and such, a reinforcement, to our design, or 21 we add some additional safety precaution to our design, how 22 does that in fact lower the risk of failure?

And the requirements that we could impose there are: specify that the alternative designs to reflect the different degrees of resistance to seismic loads be

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identified; require that the reduction in risk as a result of various design measures be estimated along with the cost of the measure; and require an estimate in terms of the savings in potential damages be computed thus allowing a cost-benefit relation to be drawn.

This alternative A here is really nothing more
than what was suggested by Professor Whitman back in about
1971. He made a classical study of earthquake hazards in
Boston and went through an analysis showing a cost-benefit
for designing the buildings to various earthquake levels.
Right now I don't see that we are much farther along than
that.

And a possible requirement is that we just ask people designing buildings or any other structures to go through this process of looking to see what would we do to lower the risk of failure of this structure if we added this much reinforcement or if we made this particular change, look at the alternatives, and see what the benefits are.

In effect, this is very similar to the passage of the NEPA Act. There was no requirement other than -- or the basic requirement was that people look at the alternatives. And this is what we're talking about here: look at what the alternatives are, see and calculate what the reduction of risk is.

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A second possibility is that we would specify that

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the risk that is computed be no greater than a certain amount. And the third one -- which is in error here -- is that require that that requirement be determined by a specific methodology; in other words, we would say that the risk of failure of a facility can be no greater than a certain amount and we will tell you how you're going to calculate that certain amount.

Those would be the possible recommendations with regard to determining the benefit of alternative designs.

And the third item there is with regard to the 10 final product of determining what the risk of a loss of life 11 or economic loss is once the structure in in place and, 12 given that the event takes place, we could require that the 13 residual risk of various potential damage levels be 14 determined for certain structures. And then the second part 15 of that is that we would specify how much that residual risk 15 would be. 11

And as I say, these are not adopted by the committee. In fact, these have only been sent to them. But the timing of the meetings was such that they were going to meet yesterway and they didn't meet. They will be meeting next week. In fact, we have one member here from that subcommittee.

These are just suggestions to give you some idea of what is being thought about with regard to imposing some

31 493 02 13 sort of requirements or regulations or at least suggesting DV HEE 1 these for use by other federal agencies. 2 There is a member of the Nuclear Regulatory 3 Commission on this subcommittee. by the way. 4 So. I am open to questions on what our ó subcommittee is doing. 5 DR. OKRENT: Dr. Lowrance. 1 DR. LOWRANCE: Bill Lowrance, from the seismically 3 active area of Palo Alto, California. 9 How would item 2-8 be pursued? This says "specify 10 that the risk of failure given various seismic loadings 11 associated with the structure be determined and that it be 12 no greater than a given amount; that is, a risk ceiling be 13 14 prescribed." Where do you suggest that come from? MR. VON THUN: That's why I am saying that is 15 somewhere maybe in the future. Right now we are not to the 16 11 point that that can be done. When the committee was 18 formulated, that was one of the things that was sort of thought about, that this might occur. In fact, in the 17 directive we will get a little more to where that can come 20 from later. 21 22 But basically, the only place that I see that it 23 can come from is for people to begin applying the rules or begin applying the risk assessments, see what types of norms 24

or standards can be developed with regard to what is a good

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1 value to use as a risk level. If we don't make the studies 2 of actual applications, we won't have an idea whether 1 x 10 3 to the 6th or 1 x 10 to the 8th or to the -8th is a valid 4 number. So right now the number isn't available.

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DR. OKRENT: Dr. Lave.

DR. LAVE: What is the uncertainty level associated with either estimating the seismic risks or with estimating the probability of the failure of a structure in relation to a particular type of risk?

MR. VON THUN: It is very great. I would say that the first one is quite a bit less. What the loading is is less than that can be estimated better than can what the probability of a failure is given that loading occurs.

The reason for that is we have had as few 14 earthquakes as we have had. We have had a lot more 15 earthquakes than we have had failures due to earthquakes, 30 15 we don't have a very good statistical base on which to 17 decide how a dam or a structure is going to react to the 18 earthquake. Buildings may be a little different than dams, 12 but we don't have - we have, for instance, in the United 20 States only a couple of embankment dams that have suffered 21 damage due to earthquakes among the thousands and thousands 22 of embankment dams that we have. 23

24 DR. LAVE: Let me pursue this a little bit more.
25 How is the probability of a seismic event estimated? Is it

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simply historical frequency?

MR. VON THUN: No. The probability of a seismic 3 event has undergone -- the estimation has undergone a great 4 deal of work, and it is continuing to undergo a great deal of work.

6 But is based upon what is the geologic capability of a particular area, and that is referred to as the 1 8 "maximum credible earthquake," or in the nuclear reactor field as the "safe shutdown earthquake." This is the 9 largest earthquake that can be postulated to occur for a 10 particular seismic region. There we're talking about the 11 probability of an event that could vary from once in 100,000 12 years or once in 500,000 years down to where it could occur 13 once every three or four hundred years. For smaller-sized 14 earthquakes usually the historic frequency is the method 15 15 that is used.

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DR. LAVE: What steps have been taken or can be taken to try an quantify the level of uncertainty that is associated with each of the two events, either the seismic loading or the structure failure in case of a particular seismic loading?

6 MR. VON THUN: There have been a few studies. 7 There was recently a conference in Pasadena on earthquake 8 engineering, and at that conference there were some 9 suggestions made by Woodward, Clyde & Associates of how to 10 provide some constraints on the uncertainty. If one allows 11 the uncertainty to go unchecked, then at very low risk 12 levels it becomes a tremendously predominant factor.

So they were suggesting that certain modifications be applied to that uncertainty function as it approached the low risk levels. So other than a few attempts to look at this uncertainty question, there hasn't been a lot done.

DR. LAVE: Has there been any attempt at all to take a look at the uncertainty level with respect to the mean probability or the most frequent probability?

20 MR. VON THUN: Yes, there is.

21 DR. LAVE: And what kind of sub-numbers do you 22 come out with?

23 MR. VON THUN: I don't have them offhand. Do you 24 mean as far as, say, the mean level of acceleration is such 25 and such, and what is the bounds on that?

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DR. LAVE: No. I was thinking about -- you have here probabilities of seismic events of, for example, .003, and obviously there's a large uncertainty associated with that. Is the uncertainty equal to the mean or ten times the mean or a thousand times the mean?

MR. VON THUN: I think one of the best examples of 6 what that uncertainty is is in a paper that Dr. Okrent had a 7 lot to do with where the experts in seismology were asked 8 for a number of different nuclear reactors, nuclear reactor 9 sites, as to what the low level risk would be for this 10 maximum credible earthquake. Each of these investigators 11 postulated from available information what the risk of a 12 certain intensity earthquake was, and that gives an idea of 13 14 what the range is. And it was quite a range.

As far as a detailed assessment and application of uncertainty, I am certainly aware ci it, but I don't think it has been done. I am aware of its need to be done, but it really has not been done to the degrees which you are asking the question about.

20 DR. LAVE: Just one final one here. What could be 21 done to lower uncertainty levels?

22 MR. VON THUN: Well, with regard to the seismic 23 event, there isn't really anything that can be done except 24 do a good job of analysis of your site. We don't have any 25 othe information than the geologic record which we might be

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1 lucky and excavate through a fault and find that it has had 2 so many displacements in so many thousand years and be able 3 to estimate what the earthquake is on the basis of those 4 displacements.

At the Auburn site in California, we went through a tremendous study and really came up empty-handed as far as being able to definitively say what the recurrence interval of earthquakes in that area was. So it isn't a foolproof thing, but it is something that should be done.

We don't have any more historic records than we have, so we can't do any better on that. But my feeling is that the uncertainty in that is not so great.

With regard to performance under seismic loading, 13 we can make additional tests. We can do better studies. We 14 can develop dynamic analyses methods to try and predict the 15 response, but without prototype failures we really will 16 always have a certain amount of uncertainty. The approach 17 that we're taking at the Bureau is to try to make that 18 calculation on as many structures as possible in order to 19 assess the relative risks of these failures, and in that 20 way. get rid of the uncertainty. 21

If nobody makes any analyses, if we always keep it in the research mode, then we really will always have that uncertainty sitting there as far as the actual structures. I think once we start the studies on actual structures, we

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will reduce some of the uncertainty.

DR. OKRENT: Dr. Wilson?

DR. WILSON: I was just wondering -- I'm talking 3 abut the uncertainties -- one thing that worries me is one 4 tends to talk about the expected value of an earthquake or a 5 hazard and the uncertainty around that, whereas quite often 6 that is no what the decision-maker needs to know. He wants 7 to know the probability of exceeding a certain bound, and 8 hopefully he is going to set that bound so the probability 9 is very low. And since the distribution in which the 10 uncertainty is described and the width of that distribution 11 12 is certainly not very simple, are you addressing that specifically when you are discussing the uncertainty? 13

MR. VON THUN: Yes. Generally what is done is an 14 15 upper bound is taken, rather than the mean value, either in 16 all the steps or certain of the steps to assess the 17 loading. We don't take the upper bound at the first stage, 18 the upper bound at the second stage, and the upper bound at the third stage. We may take the upper bound in certain 19 regards, but that problem is being addressed. We do not 20 typically take the expected value in each case, and we look 21 at a number of possibilities. 22

23 In a later study, here you will see how that is
24 done.

DR. OKRENT: Dr. Castenberg?

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DR. CASTENBERG: Bill Castenberg from the ACRS. I'm curious about your definition of "hazard" and "risk." 2 If I understand correctly, risk is probability, and so you 3 could have a dam near a large city and a dam out in the 4 country that had the same risk where the probability failure 5 is the same, but they might have different hazards because 6 of population. And if I understand that correctly, most of 7 your work is geared toward risk reduction rather than hazard 8 reduction. Is that correct? 9

MR. VON THUN: Well, the work is with regard to risk-based decision analysis. Now we're not to the point where those types of decisions really have been made on the basis of risk analysis. But I think fundamentally the question is right. We would look at what the risk is at this site versus the risk at another site, and that is what we want to deduce.

DR. CASTENBERG: Do you mean, in the sense of thisdefinition, really probability?

19 MR. VON THUN: Yes.

20 DR. CASTENBERG: Or do you mean risk in a more 21 general sense where you include hazard as well as 22 probability?

23 MR. VON THUN: Hazard is always included. When 24 you talk about the resulting certain level of damage, that 25 would always be included, so that the risk of, say, 40

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lives would be the same, no matter where you were working,
 but the damage level, the risk of a certain damage level
 occurring, that is what we're talking about.

DR. OKRENT: Could I ask the following question? 4 Auburn dam which you mentioned was estimated by 5 Mr. Seidegren to have the potential for causing up to three 6 quarters of a million fatalities were it to fail suddenly, 7 which is indeed a large number. Is there, in your way of 8 thinking in regard to the evaluation of accepted risk or 9 acceptable risk or whatever way we do it, is there some 10 limitation that enters from the magnitude of the event, 11 independent of the probability, or should we always factor 12 in a probability times the maximum hazard and look only at 13 14 the product? Or how do you propose one deals with this 15 question?

MR. VON THUN: My proposal -- the way I would look 16 at that is, each case has got to be considered differently 17 with regard to what are the defined levels of damage in the 18 case of any dam, and Auburn is a good example. You would 19 look at what is the probability of damage level of \$2 20 billion for property damage, say, wiping out Sacramento, 21 doing damage to Sacramento, and the probability of so many 22 lives lost. And when one deals with that number, that 23 residual risk that was associated with that loss, he would 24 refer to that specific loss, so that it wouldn't be lost in 25

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front of the eyes of the public or in front of the eyes of 1 the Commission or anybody. He would say, this is the risk of that loss. And the decision might be made that no matter hat the risk was, even if it was -- as long as it was non-zero - that the hazard of putting the structure there 5 is so great that we won't accept any risk, and therefore the structure should not be sited there. 7

That would be on way to look at the problem. At 8 another site where you had very little potential damage 9 downstream, than a much higher risk would be maybe accepted. 10

I don't know whether that answers specifically 11 what your question is. 12

DR. OKRENT: I was just wondering if your 13 Interagency Committee was planning to come up with possible 14 numbers to put in such a thing or how the Bureau of 15 Reclamation. approaches the same question. They have a lot 16 17 of large dams which, let's say, don't have perhaps the three quarter million potential, but they certainly have hundreds 18 of thousands. I would guess. 19

MR. VON THUN: The Interagency Committee I don't 20 believe will come up with the numbers. We don't really have 21 the background on the Committee or even the diversity to 22 allow coming up with those numbers, nor have we the 23 studies. But I think that the report of the overall 24 Committee is going to be out within a few months. It is 25

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1 supposed to be out within a few months, and there is just no
2 way that those numbers could be developed and generated.
3 And I don't think it is right at this point to do it because
4 there isn't enough background to establish what those
5 numbers should be.

As far as what the Bureau's approach is, which by the way, their new name is the Water and Power Resources Service -- the Bureau's approach, which is really my approach or one that I think should be used, is that we can't establish the numbers until we have looked at a number of different sites and started getting some information.

The example, which I'll show you in a moment, on 12 Jackson Lake is currently the only real example where we 13 have some idea -- and maybe not even all that accurate an 14 idea -- but some idea of what the risk is on one structure. 15 Decision-makers need to have a whole background of what 16 these risks are in existing facilities and on other types of 17 risks, not only for seismic risks but for flood, for normal 18 resevoir loading, for any of the loadings. They have to get 19 an idea of what risk are we exposing the public to 20 involuntarily compared to what risk the public is exposing 21 them to voluntarily in order to come up with that number. 22

23 So to just pick the number right now is not 24 valid. What we feel is that we should go through this, look 25 at all of our existing dams or a large number of them, find

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1 out what the actual absolute risk of a failure is to a 2 number of events, and then we will be in a position to pick 3 that number.

DR. OKRENT: Dr. Shinozuka?

5 DR. SHINOZUKA: I am seriously concerned about the 6 uncertainty involved in the estimation of probability of 7 failure of a structure. This point has been raised, but 8 since I am more or less working in the structural analysis 9 and design area, I feel that the uncertainty involved in the 10 estimation of probability of failure of the structure would 11 be something we really have to address ourselves to.

I feel at this time that the methodology has not really been established. If you look at some of the papers dealing with this problem, the best you can see is the application of, shall we say, first order statistics involving just expansion of the first two times, evaluating variants, and apply certain subject judgments in estimating the uncertainty and crank out numbers.

It is even difficult to apply this to a relatively simple structure consisting of a number of elements. So my point here is that I think at all levels, federal levels and also university community research for example, I think we should take up this problem more seriously and look into it very carefully so that these risk assessment methodologies can become reliable.

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MR. VON THUN: I absolutely concur with you. I 1 think that the weakest link in what I will be presenting 2 here and the weakest link that faces us is in predicting how 3 the structure is going to fail, if it is going to fail, and 4 what the likelihood of its failure is. That is the weakest 5 link, and it is not in risk assessment methodology. The 6 methodology for the risk assessment there. It is in 7 understanding the failure, being able to decide what its 8 response is, and what its likelihood of failure is. 9

Once somebody can tell you that, then the risk assessment can go ahead and be performed. And even maybe an add-on to that is the foundation, like on a dam structure. We might know quite a bit about the materials that go into the dam and quite a bit about how the dam is going to respond itself, but the uncertainty in the foundation is even greater.

DR. SHINOZUKA: My difficulty is that although you mentioned that methodologies have been established, but if these methodologies require the information that we may never be able to get, then we are in trouble.

21 MR. VON THUN: That's right. And our approach 22 really is not to say that this is going to work. It is to 23 try and see if it works and see where the loopholes are. 24 That is our approach, rather than feeling it is an absolute 25 foregone conclusion that it will work.

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DR. OKRENT: Maybe it would be good to go on to your next part, and then we can discuss both parts of your presentation.

(Slide.)

5 MR. VON THUN: What I would like to talk about is 6 the second handout. The top got cut off. It should say, 7 "Decision Analysis Model to Determine Resevoir Restriction 8 Level at Jackson Lake", and the situation at Jackson Lake 9 which happens to be in the Teton area -- the Grand Teton, 10 Jackson Hole country.

This was a dam that was built back when a method 11 called hydraulic fill was used where the dam was actually 12 placed by putting in wet material and letting the wet 13 material run out, so it was a very loosely placed dam. And 14 a dam placed like this is subject to what is called 15 liquefaction. When an earthquake takes place, the soil 10 shakes. The core pressure or water pressure within the 17 material builds up, and the material can actually flow. 18

Van Norman Dam in California, in response to the
San Fernando earthquake, had partial liquefaction, and
Sheffield Dam in 1926 had a complete failure due to
liquefaction.

23 So as part of the reanalysis of our existing dams, 24 which amounts to about 300, this was one of the dams that we 25 took a look at, and it was recognized that this site was

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near to where there were faults, and there could be strong shaking at this site, and it was subject to liquefaction.

Professor Seed and Professor Lee from the 3 Univeristy of California took a look at this site and made 4 the recommendation. So we had a resevoir there that was 5 quite important as far as the public was concerned. A 6 number of people go there for recreation benefits. The lake 7 also supplies irrigation benefits in the lower Snake Valley 8 below this dam, so as far as the Bureau was concerned, it 9 was important to maintain the resevoir as high as practical 10 but also to reduce the risk. 11

12 So what I'm going to go through here is the decision-based risk analysis that we used in order to Jecide 13 what the level of the lake should be kept at. To do this, 14 the first point was to look at what the hazard was as a 15 function of resevoir level for the potential failure modes, 16 and we had a failure mode where the entire dam went out at 17 its base, height, and one way it went out at the top of the 18 zone where it had been placed by hydraulic fill. So we 19 looked at two different modes of failure, and we showed that 20 as the resevoir load lowered what the potential damage 21 downstream would be, given that a failure occurred. 22

I'm going to go through these in a little more
depth. I just want to go through the steps first.
The second thing was to estimate the probability

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of various levels of earthquakes causing liquefaction at the 1 dam. We had several source areas that could produce 2 earthquakes, and they could produce earthquakes of different 3 sizes with a different probability. Given that that 4 probability occurred or that that earthquake occurred, there 5 was some probability based again on our evidence from around 6 the world with regard to liquefaction that an earthquake of 7 this magnitude might and it might not produce liquefaction 8 in the dam. 9

A stronger earthquake would have much more 10 likelihood of producing liquefaction, so we had a 11 probability that the earthquake would occur, a probability 12 that the dam would liquefy from this earthquake given a 13 probability that liquefaction would occur at the dam site. 14 If liquefaction occurred at the dam site and the dam had 15 several probable failure modes. it might completely level 16 out. It might level out only a few feet or something in 17 18 between.

So we had to estimate the probability of damage as a function of resevoir level, because if we said that it could go through these different steps of failure and we put the resevoir at different levels, then there were different probabilities that the dam would fail for each of these failure modes.

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If there are any questions as I go through this,

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	2	MR. ETHERINGTON: Yes. Why does a magnitude seven						
	3	have different liquefaction probabilities in A. B. and C?						
	4	MR. VON THUN: Because of distance.						
	5	MR. ETHERINGTON: Oh, I see. It is distance.						
	6	MR. VON THUN: One source may be closer to the						
	7	site than another. I will have one up there in a little						
	8	more detail that shows that.						
	9	DR. CASTENBERG: On the column, "Earthquake						
	10	Probability", is that probability per year? How do we						
	11	interpret that?						
	12	MR. VON THUN: That is annual probability. Those						
	13	are hypothetical numbers.						
	14	DR. CASTENBERG: Right.						
	15	MR. VON THUN: But this is how we did it with						
	16	regard to annual probability, and then over the lifetime of						
	17	the structure. We typically work either with annual						
3	18	probability or probability in 100 years one of those two						
	19	modes.						
	20	(Slide.)						
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The next thing to do is to compute the probability 1 2 of overtopping as a function of reservoir restriction level 3 for each failure mode. So, we would take the probability that the earthquake could occur times the probability that 4 it would cause liquefaction times the probability that there S would be a certain failure mode on the dam, and then look at 6 the reservoir level and see whether that caused overtopping 1 or not. 3

And that gave us an absolute probability of overtopping as a function of the reservoir level, and we were able to work out this probability for the mode 1 type failure, which was in the upper part of the dam, and the mode 2 type failure. You see the mode 2 type failure was not -- in this particular case does not show much sensitivity to a drop in reservoir level.

16 Then the fifth step is to examine the likelihood 17 of overtopping and downstream hazard potential for the 18 current criteria versus any proposed revised criteria and 19 then evaluate the total reduction in the risk of each mode, 20 the acceptability of risk for each mode, and consider the 21 benefits of reservoir elevation, operating procedures for 22 maximum benefits within the range of acceptable risks.

23 Now I will go through those steps in a little more 24 detail.

(Slide.)

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This is - what I am showing now is sort of a PV HEE 1 fundamental approach that we would use with regard to 2 seismic probability consideration in any of the studies that 3 we do. We have a site here, and we have several sources 4 that could affect this site with regard to earthquakes. õ Here is a fairly large - this is where the Hebgen Lake ó. event occurred. We said a maximum earthquake of 7.5 could 1 occur at this site. This is quite some distance away. 3 Anything less than the seven to 7-1/2 range would not 9 produce a problem at the site. 10 We had -- there is another source here, the 11 intermountain seismic belt. It could produce an earthquake 12 of 7.5 which might affect the site. And then there are two 13 sources near the site that could produce earthquakes from 14 15 6.0 to 7.25. 16 (Slide.) Now, each of those sites could produce earthquakes 11 18 with this probability. The question was asked earlier about

> 19 how we make the determination with regard to the probability 20 of the event. This is based on historic record. There is 21 no earthquake of 7-1/2. There is an extrapolation to get to 22 7-1/2, to get the probability of that magnitude of event. 23 There happens to be geologic evidence in the area that shows 24 Us how much offset has occurred over the last 10,000 years, 25 and putting that into magnitude 7-1/4 earthquakes down to

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six earthquakes to account for that displacement, we are able to come up with a recurrence relation based upon geologic evidence, and then that is correlated with the historic evidence of seismicity in that area. We have a fairly good correlation.

5 So this type of relationship was used to get the 7 annual probability of earthquakes of a certain range, and we 8 have to talk about a range -- seven to 7-1/2, six to 6-1/2, 9 like that -- in order to encompass the total probability of 10 earthquakes.

And the other question about uncertainty that was 11 asked -- this is how we take care of -- the gentleman asked 12 about the range of expected value and so forth -- this is 13 how that is taken care of: by looking at the bigger 14 15 earthquakes. They have a higher probability of causing 15 damage, but they have a lower probability of occurring. But by taking them into groups like that, you can look at that 17 18 fairly realistically.

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(Slide.)

20 The next thing to do is to say, "Okay, now, from 21 all of these earthquakes we've looked at" — I think I got 22 that out of order, but the idea is the same: we need to 23 look at which earthquakes can cause liquefaction and which 24 cannot cause liquefaction. These, we say that any 25 earthquake within any of the zones at a certain distance and

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a certain magnitude that falls in this range, we will say that the probability of that causing liquefaction is zero and it no longer needs to be considered in the risk analysis.

5 This has to be low enough so that we encompass 6 even a minor amount of liquefaction. To get that, we use 7 the worldwide data and the advice of our consulants on what 8 might cause liquefaction.

(Slide.)

These Xs are examples of where liquefaction was 10 caused at various distances, and you can see from this that 11 where we have historical examples of liquefaction, we are up 12 in here with fairly large magnitude earthquakes, but there 13 have been some cases where we had small magnitude 14 earthquakes. This lower-bound curve then encompasses all-15 possible liquefaction-producing events. But if we did have 15 an earthquake up in this level, the chance of there being 11 liquefaction has got to be considered greater than if we had 18 an earthquake at this level, say, at this distance. And 19 that is one of the reasons for those probabilities varying. 20 DR. OKRENT: The Sheffield Dam you mentioned, 21

22 which failed and liquefaction occurred, what was the 23 magnitude of the event or the intensity at the site? 24 MR. VON THUN: I can't remember offhand. I think 25 it was on the order of a magnitude seven, but I don't

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remember offhand.

(Slide.)

This is just a reproduction of the little pox that 3 we saw earlier except these are the actual numbers that were 4 used in the assessment. The A-1 source and the A-2 source ć each had the same probability of earthquake, but because the 5 1 A-1 source was closer it had a higher probability of liquifying the dam. We only considered earthquakes from the 8 other two sources in the range 7.25 to 7.5. The one at a 4 greater distance had a lesser probability of liquifying the 10 11 site.

Then, by summing all of these, all areas combined -- because we can't just look at one of the areas, we have to take the total probability of liquefaction and combining all of the areas -- this said that there was essentially one chance, annually, one chance in 100 of there being some liquefaction at the site.

18 This was a lot greater than I would have guessed, than I guess even right now, but this is the way, when we 19 went through the analysis, these are the subjective numbers 20 21 that were applied. I think we would make actually -- this 22 probably should be maybe more on the order of one in 1000 because the dam has been there for 50 years thus far and 23 24 there hasn't been any indication of liquefaction. But if one had to make it an assessment of putting a dam there had 25

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I there never been one, I think there isn't anything basically wrong with these estimates from the data that we have worldwide and from the estimates that were made on the condition of the structure.

But this is exactly the problem that you raised. It is our estimate of what the structure would do is whether there would be liquefaction of the structure or not is pretty tough, but we tend to be conservative in all our estimates.

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(Slide.)

Engineers in general tend to take the conservative approach.

Now, the part that is not here in any detail is the next phase, where we say -- but it is in the report which was handed out -- which again is saying what the structure will do given that liquefaction occurs.

Now, when Sheffield Dam failed, it failed down to 20 percent of its height. When Van Norman Dam failed, it only failed about to 70 percent of its height; in fact, the reservoir was not lost when Van Norman failed. Those are the only two examples that we have.

And what we did was: we said there are three possible failure modes - 90 percent of height -- I can't remember the others -- 10 percent of height, and maybe 50 percent of height. It is in the report. We said there are

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three different possible failure modes of the structure, and three different possible earthquake levels: the strong earthquake, the medium earthquake, and the small earthquake. The small earthquake had some probability of causing a full failure down to 90 percent, but it had a lesser probability.

So, by taking each of those conditions of the 7 structure and each of the probabilities of earthquakes at 8 different levels, we made an estimate of what the 4 performance of the dam would be under the strong shaking. 10 And this is by far the weakest part of the analysis. In any 11 case, making that analysis, we were able to look at what the 12 risk level would be due to lowering the reservoir 13 elevation. And we found that if we lowered the reservoir 14 elevation to 6756 we were cutting the risk by 50 percent, 15 what we consider to be our apsolute risk. 16

17 It wouldn't make a lot of difference that these 18 numbers are probably not all that accurate, but we feel that 19 they are relatively accurate. This might be a couple of 20 other zeros on here or maybe one other zero. But the shape 21 of the curve, we feel, is fairly accurate.

So, from this we saw that we could reduce the risk from this mode I type failure which we thought was the most likely mode. We thought we could reduce the risk considerably.

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The other element after looking at how the risk of overtopping could be reduced, the next question is: as we lower the reservoir, the more we lower the reservoir the less damage even if we had overtopping.

(Slide.)

5 So, those two things work for you: you keep 7 reducing your damage as you go down, and you reduce your 8 likelihood of damage. So, this relationship that showed the 9 damage cost, right here, versus reservoir elevation, we can 10 then look at what is a good combination between lowering the 11 probability of there being overtopping and lowering the 12 damage with a new reservoir level.

And it turned out that if we went to any flow 13 greater than 50,000 second-feet, then we felt that we were 14 getting to fairly high damages: \$500 million in property 15 damage and associated loss of life, risk of loss of life. 15 It turned out that any flood less than 30,000 cfs would stay 14 within levees provided downstream by the Corps of 13 Engineers. So, it turned out that that happened to coincide 12 quite well with this risk-reduction level of 6756. 20 Actually, 6756-1/2, which hit about right here, would keep 21 us within 25,000 second-feet as being the maximum flood that 22 could be produced downstream. 23

24 So, the decision was fairly obvious: to stay 25 below this level and reduce the risk of overtopping by about

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half of what it was if we did not change the criteria.

We then proposed the -- the way our agency works 2 is we have regional offices that deal with the public and 3 deal with actually making the designs. Our office in Denver 4 does all of the analyses. So, we proposed this to the ċ people who are in charge of operating the plant. They said, 6 "Let us propose an alternative rather than just leaving the 1 reservoir at one fixed level all year. Let's look at how we 8 9 might operate the reservoir so that we can get maximum utilization for irrigation and for recreation and keep the 10 11 risk within a level that you've supplied."

So, they proposed a different operating criteria, which in fact kept the risk level just as we had specified, although they did raise the height of the dam during one month of the year.

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(Slide.)

So, the hazard during one month of the year is a
 little higher.

I didn't mention in this total probability
formulation we also took into condition the operating
criteria which showed the reservoir up and down during the
year. The probability that the reservoir was at a certain
height was taken into account in the total risk assessment.
That is the overview of that study.
DR. OKRENT: What did you do about the mode 2

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failure? That was the more serious one.

MR. VON THUN: The mode 2 failure, we essentially said that its risk was lower. This was in an area that was essentially not as subject to liquefaction. We said that the mode 2 failure had a much less likelihood of occurring, and so its total risk was less. But we did absolutely nothing about changing it.

The only way it is affected is that when we lower the reservoir to this level, its chance of failure if it did occur would be less flow out of the reservoir. But there wasn't anything specifically done or any decision based on the mode 2 failure.

The same results occurred as far as lowering the reservoir, but the chance of a mode 2 failure wasn't really a factor.

DR. OKRENT: I agree. But the mode 2 failure probability is only a factor of 10 smaller on your figure. MR. VON THUN: That's right.

DR. OKRENT: I gather the mode 2 failure leads to larger amounts of water.

21 MR. VON THUN: Yes.

DR. OKRENT: Greater damage, greater loss of life. I don't know. You didn't mention what kinds of loss of life could be associated with a mode 2 failure. What would it be in the summer?

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MR. VON THUN: In the summer there is recreation pv HEE 1 downstream where there are poaters. The chance of the mode 2 2 failure actually producing overtopping - I mean, 3 producing a worse flood wave isn't really known. It just 4 means that the failure would occur lower in the structure. õ Actually, the chance of overtopping is similar. 5 DR. OKRENT: So you have no basis for assuming 1 that a mode 2 failure means more water or greater flooding? 3 MR. VON THUN: That's right. The difference being 9 -- well. the total risk of its flooding is the same as the 10 mode | failure. 11 DR. OKRENT: I guess I don't understand. I would 12 13 have assumed, if you are failing down to a lower level, unless you assume once overtopping occurs you lose the whole 14 dam anyway -- what is your assumption? 15 MR. VON THUN: We made several different 16 assumptions about how that would fail. We had a 200-foot 11 18 breach, a 400-voot breach, and an 800-foot breach. So, it was the same under both conditions. 19 20 But really, the answer is we essentially ignored 21 the mode 2 failure as far as making any decisions on what to 22 do about the reservoir and whatever risks are remaining, 23 whatever residual risk is there for mode 2. Since it was 24 not essentially impacted by lowering the reservoir, we did not do anything. We did not make a decision on that basis. 25

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PV HEE	1	Now, this is not - just for information, this is
•	2	not the final answer. At Jackson these were interim
	3	criteria while we decide what to do about the structure in
•	4	terms of reinforcing it or rehabilitating it. But in the
	č	meantime we wanted to come up with a restriction level that
	ó	would be meaningful. And the analysis actually said we
	1	can't do much about the mode 2 failure.
	8	DR. OKRENI: I understand that. But what I am
	9	getting at is the probability of overtopping from a mode 2
	10	failure, if I read the graph, roughly is about 2 x 10 to the
	11	-4 per year.
	12	MR. VON THUN: That's right.
	13	DR. OKRENT: And the only thing you can do is take
•	14	the water out of the dam to some level where there would be
•	15	no flooding, in order to avoid it, I guess is what you are
	15	saying.
	17	MR. VON THUN: That's right.
	18	DR. OKRENT: So you are accepting some such risk
	17	here.
	20	MR. VON THUN: That's right.
	21	DR. OKRENT: That doesn't surprise me that it is
	22	this sort of magnitude. I think it is probably larger at
	23	various other dams.
	24	MR. VON THUN: And that is what we intend to find
•	25	out. The approach that we're doing is that this is the

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first; we actually made a decision on this basis; there were other analyses that were companion to this, but the decision 2 was made all the way to the commissioners' offices on the basis of this. But it is the first example where the decisionmakers have actually seen any numbers like this on which they are making a decision.

Now, the program that we have right now is a 1 reevaluation of existing structures, and we are taking two 3 dams -- one in a concrete dam and one in an earthen 9 embankment -- and trying to go through the total risk 10 situation -- this is just seismic risk -- and get a 11 comparison of what is the risk under just normal reservoir 12 loading, what is the risk under earthquake loading, what is 13 the risk from overtopping due to a flood, that we have 14 15 allowed some probability, what is the risk due to a landslide - all of these different risks - and put them 16 17 all in one package.

The University of Utah is doing exactly the same 18 thing for us at another dam, and there are several other 19 universities that are making these sort of studies, trying 20 to move into the more practical application. 21

I think MIT has a grant -- I am not sure -- I 22 think it is an NSF grant to make a study of total risk 23 24 assessment.

DR. OKRENT: They do have one, I believe, some

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sort of risk-benefit methodology.

MR. VON THUN: My feeling is that that is where we need to go in any of these things, is to try and generate these numbers. If we find out that we have serious deficiencies -- which I believe we will -- then that is the area that we ought to look into as far as risk assessment.

I think that we have spent plenty of time to date in looking at some of the minor ramifications, like the statistical analysis of peak acceleration; we have done all kinds of refinements on peak acceleration. It isn't even a particularly good parameter to use in judging the performance of the structure, and yet we have had study after study that looks at that particular parameter.

14 We need to go and find out the areas where we don't know very much and see if anything can be done. 15 Another example would be, say, looking at a concrete dam. 16 We do make hundreds of tests on the cylinders that go into 11 the concrete that goes into a concrete dam, and we can make 18 a good statistical evaluation on the chance of that being 19 less than the 4000 psi which we planned for it to be in 20 21 there.

But there isn't a concrete dam around that's going to fail compression due to that mode of failure. A foundation failure which we have very little assessment on is the way that it would fail, and that is the type thing

where we have to do this total risk assessment and see where PV HEE 1 we really have the weak areas and at that point decide 2 whether the method is usable or not usable. 3 DR. GRIESMEYER: You said you had an option of 4 raising the level for one month so that you can use it for ō recreation or better irrigation. And presumably, you kept ó the expected risk of overtopping constant; you lowered it a 1 little bit during your low time and raised it a little bit. 8 MR. VON THUN: That's right. 9 DR. GRIESMEYER: And this is good if the expected 10 value of risk is a good thing to limit. Now, if the 11 uncertainties are large, it may be really during that one 12 month you have an unacceptable risk. 13 MR. VON THUN: That's right. 14 DR. GRIESMEYER: Even though the expected value 15 over time is constant. 15 MR. VON THUN: That's right. And if it was 11 18 regarded - if we had regarded that it was unacceptable, then that's what we would have done. We said, "No, you 19

20 can't do it because we still have a large enough hazard here
21 that we will not accept the chance, the one in 12 annual
22 chance, of there being an earthquake during that period of
23 time."

24 DR. GRIESMEYER: And then you also have
25 uncertainties in these estimates. If you're lucky, you've

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got a couple more zeros there in front of it; if you're unlucky, you have a few less zeros and then it becomes a more serious event.

MR. VON THUN: And we did not, in this study, go into uncertainties. We intend to try and put in uncertainties in a meaningful manner on the work that we're doing now. We have a team composed of some people who are expert in risk analysis; the rest of the team is composed of people who work in dam safety and design. We feel that it is good to have those people in as a coordinated group.

And we intend to have the whole process reviewed by university people working in risk analysis, when we are through, to try and get an accurate assessment on an accurate use of the uncertainty. If we allowed uncertainty to go unchecked, I am sure that it would completely-dominate our studies because there is so much uncertainty.

What we are to try and band - the question was 11 asked about how do we deal with structure performance -- to 18 try and get some control on this number over here, we took 19 all of the data developed by the Corps of Engineers under 20 21 the National Dam Safety Act, when they went and got iformation from the 49,000 dams that are in the U.S. Ne 22 have information on all dam failures. We are going to - we 23 have a program where we have all of that information on a 24 data base - we are going to put dams in categories of 25

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height, type, location in the country, so that we know what their exposure is and develop an exposure function and then look at what their performance has been.

And that will give us some idea here, as an 4 empirical value, than, on the other hand, we're going S strictly on what I call the "calculated approach," where 5 we're trying to have engineers actually compute, given that 1 this is the loading, whether it be reservoir loading, 8 maximum reservoir loading, or earthquake or flood, what is 7 10 the probability that that dam will fail. And then we will 11 have that calculated number to compare against the 12 performance number and see whether there is any correlation at all. 13

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DR. OKRENT: Dr. Shinozuka?

DR. SHINOZUKA: I would like to know your assumption about liquefaction. When you say liquefaction has occurred, does that mean liquefaction has occurred throughout the dam or 4 at a certain location of the dam? 5

MR. VON THUN: We assume that it occurred at a certain location of the dam.

DR. SHINOZUKA: And you have a procedure from which 8 you can then evaluate probability of the dam failure? 9

MR. VON THUN: Yes, and also probability of damages. 10 Each of these types of cases, as I mentioned earlier -- every 11 one has to be considered on a case by case basis. There was 12 a certain zone, many of the dams that are built are built in 13 parts. First one agency builds this part, and then the 14 farmers add this part, and somebody else adds another part. 15 And so, at this particular site we had a certain area that 16 was subject, more subject to liquefaction than other areas. 17 And so that was taken into consideration. 18

DR. SHINOZUKA: Another question. This probability 19 of dam liquefaction under certain adverse conditions, these 20 probabilities will be given by some experts, or there are 21 ways in which you can compute these probabilities? 22

MR. VON THUN: There are ways in which you can compute it. This particular analysis was not done, you will note when you read the paper. Did you make adequate copies?

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There are dynamic analysis methods that can predict the performance of the structure. These are plagued by not having enough real life examples to compare with. But they can give you an estimate of what the performance has been on the basis of what we've seen in those analyses, plus what we saw at Sheffield Dam.

7 That is how the analysis was made. All you have 8 here is the summary report. The total report has all of the 9 appendices, the comments of Professors Seed and Lee, the 10 studies on the hazard that the USGS made and others. I just 11 brought the summary report along, and I don't know whether it 12 has the Sheffield earthquake magnitude in it or not.

13 If there are no more questinos on Jackson Lake --14 are there?

DR. OKRENT: I think Dr. Wilson has a question on something.

DR. WILSON: Yes. I would like to ask a general question. I have a colleague who has been connected with dams for some years, Arthur Cassagrande, with whom I've discussed these matters. And I know he has always been -- he maintains, of course, that a properly designed dam will just not fail.

And there, of course, the question is on the
adjective "properly." And when we try and get around to that,
it turns out that there's a difference of opinion of himself

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and some other people in the business. And of course, all the 1 dams he designed he feels are properly designed, and so on. 2 Is there any way of taking account of what appear 3 to be or what certainly, on some of the older people in the 4 business, are major differences of opinion in how one should 5 go about some of these dams? 6 MR. VON THUN: On how they should be designed? 7 DR. WILSON: Yes. As far as I can make out, if 8 perhaps they don't persist in the younger people who are 9 designing dams now, know about it; but they persist certainly 10 in the people of Arthur Cassagrande's age, the difference of 11 12 opinion as to whether some dams are well-designed or not 13 well-designed. 14 And if you picked two consultants working on this 15 from one group of opinion, you might completely not get the 16 proper spread of the uncertainty. 17 MR. VON THUN: I don't know. There are certainly 18 ways to crank that in. When we are dealing with remote 19 problems, we start with, say, an earthquake that has a maximum credible earthquake, I mentioned earlier, might have 20 a likelihood of one times 10^{-5} , the likelihood that the dam 21 failed if it is designed well. If you have someone like 22

Arthur Cassagrande and he would say, gooh, I'm sure my dam isn't going to fail.

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And then you're talking and you say: Well, how

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sure are you? Is there one chance in a hundred that it will fail? And so you then talk about one chance in a hundred times one chance in 10,000 that there would be a failure event. And then you talk about, well, how much failure is failure. And so a total failure -- there might only be one chance in 100 that, given that there is some failure, there might be a total failure.

8 So now you're talking about something like one times 10⁻⁹. To crank in a difference of opinion on how one person 9 10 thinks of a design versus how another thinks of a design may 11 not be all that meaningful in generating that total number. 12 But there are certainly ways to do it, because you could then 13 say: Well, if he says this is the way, and he says this is 14 the way, and you really think there is serious concern, then 15 you would just lower that factor in of one to 100 which the 16 person said could occur maybe to one in 10, to account for 17 the fact that there is a dispute over how it should really be 18 designed.

19 So I think that that is about as responsive as I 20 can be to that question. We have tried in the Corps of 21 Engineers data, which records whether or not the structure is 22 engineered or not engineered, because a number of the 45,000 23 dams in the U.S. were not actually engineered at all -- and 24 also, some of them are inspected regularly and some are not Inc 25 inspected regularly. 1573 069

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In our function of deciding which ones are more likely to fail or not to fail, we are going to crank in that sort of information to make that judgment.

Okay, the very last sheet of your handout on the
Jackson Lake paper doesn't have anything to do with the
Jackson Lake paper, but it was just included in this handout.
This is from another study that we made, again only to do with
seismicity. This was more of a study to decide what number
we would assign as being an acceptable number for seismic
risk.

11 And our problem here is that in certain areas of the 12 country, rather than having a specific fault to deal with, 13 we might have earthquakes at random location. This is more 14 prevalent in the areas such as Nebraska, Wyoming, North and 15 South Dakota, Kansas, and those areas. Here an earthquake 16 could occur right under the dam site, with some probability. 17 Or it could occur at a certain distance from the dam site with 18 some probability.

The likelihood of occurring right under the dam site is extremely remote. And the question here was: What type of probability should be assigned in deciding the distance from the site that one should assume the design earthquake? And in making this study which was handed out, which I believe Mr. Quittschreiber delivered to the members of the Committee, I took a look at what some of the probability factors that

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were used for seismic design throughout the country. And 1 this table is a presentation of what those are, at least the ones that I found.

Just for reference, the 100 year flood shows a 4 probability of annual occurrence at .01. A number of struc-5 tures throughout the country are designed to handle the 6 100 year flood. But the probability of exceeding the 100 year 7 flood is actually guite great over a 100 year period. And 8 the probability of a 200 year flood is even greater. 9

10 The California legislature developed a criteria 11 that said that any fault that has shown movement within the 12 last 10,000 years is to be considered an active fault for 13 purposes of locating residential structures. . In other words, 14 if a fault had moved, theoretically, 10,001 years ago, then 15 you could site your house on top of that fault. So the 16 accepted probability there is an annual occurrence of .0001, 17 and in a 100 year period it's probability of, say, reactivation, is .01. 18

19 The probability of not reactivation or not exceeding this in a 100 year period is .99. 20

The seismic risk map, which is now, I believe -has to be considered a misnomer. We don't talk about the seismic risk, because we really should talk about risk as being the total picture. I would rather refer to that as the seismic exposure.

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In any case, that shows a probability or gives the probability of a particular level of acceleration occurring without being exceeded, a 90 percent probability of not being exceeded in 50 years, which boils down to a once in 475 year event. And that probability of nonexceedence in a 100 year period is .81.

7 There was a study done, reported at, I think I said 8 earlier, the conference that I was referring to. I think that 9 report was in Pasadena. Actually, it was at Stanford. This 10 report, the case history, is for an MCE; was reported two 11 years ago at Pasadena. And this was an example used by an 12 investigator, and his probability for the MCE was .00004, and 13 that gives a probability of occurrence in a 100 year period 14 of .0004, and nonexceedence in a 100 year period of .996.

The NRC criteria of an earthquake, an active fault, now called a capable fault, of one movement in 35,000 years, or multiple movements in 500,000 years, I have interpreted those to mean -- just for this illustration, that would mean that if a fault had occurred -- a fault had last moved 35,001 years ago, then it would be considered inactive. So anything that is an accepted probability for seismic loading.

And the occurrence of multiple movements, I said more than two in 500,000 years. That boils down to .000006 of that type of event being exceeded, and so that would give a nonexceedence in a 100 year period of .997 and .9994.

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2 quantitative numbers for just the seismic risk -- I mean the 3 seismic exposure. 4 DR. OKRENT: With regard to the NRC criteria, I 5 think if you were to look at the return period for what is 6 called the safe shutdown earthquake, you would have a higher 7 probability of occurrence than the 100 year period by quite 8 a bit. In other words, I think the numbers you are extracting 9 from the criteria used for an inactive fault, a lower proba-10 bility of occurrence than one gets for the design against 11 seismic shaking. 12 MR. VON THUN: This is the only quantitative numbers 13 that I had. 14 DR. OKRENT: I realize that. I'm just mentioning 15 this in passing. 16 MR. VON THUN: You're saying that the number would 17 be like less? 18 DR. OKRENT: The exposure to shaking is larger than 19 this by quite a bit. 20 MR. VON THUN: But there isn't anything quantitative. 21 DR. OKRENT: Not in the criteria. You have to 22 evaluate it on a site by site basis. 23 MR. VON THUN: Yes. It would absolutely have to be, 24 because there isn't anyplace, I think, that you can put it Inc 25 aside where you would not have some shaking. But as far as

Those are just some examples of what could be interpreted as

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deciding whether the fault is inactive or active-- but the Bureau criteria which we used for the Auburn site was movement once in 100,000 years was active. Anything greater than that was inactive. And that gives you the number .999.

So what we said in this study was that, as far as an order of magnitude estimate, that it was certainly conservative enough. And so, in making a determination, where what really was involved here is that, here is our site, there are random earthquakes occurring, and we had to come up with a distance from the site where we would say a design earthquake would occur or a maximum credible earthquake would occur.

12 And so, if this distance was based on the probability 13 of that number right there, if there was a .999 chance that 14 there would be no earthquake within this zone during a 100 year 15 period, then that distance was specified. And in this case, 16 it happened to be something like, I think, 22 miles. There 17 were very few earthquakes around the area, but that gave a 18 quantitative way of assessing where we would place the design 19 earthquake.

On a completely arbitrary basis, we would have had to say, say if we had ignored the risk assessment, we would have had to say that the earthquake could occur right under the dam. So this is the only attempt that we have made to do a quantitative number like what you are talking about. And I really think that it is great that people are struggling

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mte 10 with putting quantitative numbers on just to find out whether 1 2 it can or cannot be done. 3 It would be nice to do it and nice to be able to tell the public, this is what we're thinking of in terms of a 4 5 total risk. Whether we can actually do it or not is another 6 question. MR. RUBINSTEIN: Was there any physical basis 7 associated with that distance? 8 9 DR. OKRENT: Would you please give your name? 10 MR. RUBINSTEIN: David Rubinstein, NRC. 11 Was there any physical basis? MR. VON THUN: The actual faults are handled as 12 13 actual faults. In other words, we have more than one earth-14 guake for which we would design if we had an actual fault, say, located here, that we knew the distance to, then that 15 16 would be used in the analysis, as well as the random earth-17 quake. 18 But in this case there was no structure. This 19 distance was not based on any structure. It was just based 20 on a seismotectonic zone. 21 MR. HARBER: Gerry Harber, NRC. Is that not based on a continuation of the relation-22 23 ship? 24 MR. VON THUN: No, not at this point. A continuation ce-Federal Reporters 25 relationship would then -- would occur here. Once you decided 1573 075

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where the earthquake was, then you would say: All right, we will consider a magnitude six or seven or whatever the earthquake is at 22 miles. And there would be a certain amount of attenuation to the site.

5 But the differential in acceleration was not 6 considered. We tend to specify the earthquake distance, 7 focal depth, and then look at what its effect on the dam is. 8 In most critical facilities, I think that is the way that 9 most of the people that I am familiar with -- the geologic 10 assessment is made first of when and where the earthquakes 11 will occur, and then we take that earthquake and specifically 12 work with it, rather than developing what might be considered 13 isoacceleration maps and working with just an acceleration.

MR. HARBER: But your circle there is based on the seismicity. How did you get the value of the radius of the circle? Based on the seismicity of that area around the earthquake within that area?

MR. VON THUN: Yes. In other words, you take a large area like this, and here's your site here, and throughout this large area you say that there is a random distribution of earthquakes, with some distribution, like I showed earlier, for a certain probability.

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If you take one little spot on that within this large area, that little spot has a certain probability of there being an earthquake of certain magnitude in that area

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1 out of the total area. So if you think about now, what we're 2 really saying is that within the site area there are a number 3 of these little unit areas that have a certain probability of producing an earthquake of a certain level. When you sum 4 5 those and they equal or exceed the .999 probability of nonexceedence, then you define the area of limitation, where 6 7 you say that there is .999 probability that there won't be 8 an earthquake within this zone.

9 MR. HARBER: But what happens if the isoseismal 10 area of maximum intensity is larger in diameter than your 11 circle?

MR. VON THUN: I would say if that were the situation, it would have to be handled in a different manner. That would move you clear out, and you would say there wouldn't be any earthquake considered at all. I don't think that can happen.

DR. OKRENT: I'm going to have to interrupt this
discussion, because we are about 11 minutes behind the agenda.
It's not your fault.

19 Thank you very much. It was a very interesting 20 presentation.

> Why don't we take ten minutes and then resume. (Brief recess.)

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DR. OKRENT: Our next speaker will be Michael McGee, who I am advised is an environmental scientist with the Office of Environmental Quality at HUD. He has a background in geophysics and geology as well as in public health, and worked with the Corps of Engineers before joining HUD. Mr. McGee?

MR. MC GEE: Thank you. My name is Mike McGee. 7 As was said, I am with the Department of Housing and Urban 8 Development. I am also a member of the subcommittee that 9 Larry has referred to on the earthquake hazard assessment. 10 I would heartily concur with many of the observations which 11 he has made on his specialty, and in particular emphasize 12 the need for recognizing the distinctness of the terms 13 "hazard" versus the term "risk," and how many people 14 IE interchange the two.

I think the question most often asked of me or of 16 people in my office is, namely, what the Sam Hill Housing 17 and Urban Development is doing in the process of risk 18 assessment, hazard analysis, because very few people think 19 of the Department as having any interest at all in such. I 20 have been in this particular specialty area now for about 21 2-1/2 years, and the Department for the past five years. We 22 have been concerned about the aspect of hazardous materials 23 from the standpoint of community safety, the safety of 24 HUD-supported projects, whether they be housing projects or 25

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community development projects, community growth.

Our basic issue is land use and the 2 incompatibility thereof with regards to hazardous materials 3 operations of facilities versus dense popluation centers and 4 how community growth is being tailored. We have found, from 5 our experience over the past, let's say five years, that the 6 definition of risk assessment or namely answering the 7 question of what is an acceptable risk, is really a problem 8 in human nature. And it seems to be directly proportional 9 to the public's awareness of that particular hazard. 10

The simplest case where the public is largely 11 ignorant of a danger, they will accept almost any definition 12 of what an acceptable risk is. Where the public's awareness 13 of that hazard may be, let's say, equal to the actual extent 14 of the hazard as known by scientists, engineers, given the 15 state of the art limitations, the public is amenable, 16 reasonably amenable, to some sort of reasonable definition 17 of acceptable risk. 18

The most profound situation seems to be where the public's awareness is, shall we say, magnified of what the actual hazard or danger seems to be, and here the definition of an acceptable risk becomes a very sensitive issue, and very site-specific for that portion of the public's awareness.

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We have been tending toward an education type

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approach, or an answer to try and address this problem, the idea being to make the public aware of all pertinent facts of the problem, trying to assure them that whoever the decision-maker is defining that acceptable risk, he has all essential elements well in hand.

The case history, if you will, which made us aware 6 that the problem existed, was in South Carolina. Columbia. 7 South Carolina, to be specific. It was a bulk storage 8 facility of a utility company which contained 40 9 60,000-gallon propane tanks, arranged in two rows. These 10 11 tanks were of such a construction that they were horizontal, much like an elongated frankfurter, in their design, and 12 such tanks, when they are involved in an incident, tend to 13 14 rupture quite violently, with the ends proceeding almost like a missile and in roughly parallel alignment to the long 15 axis of the tank. 16

In this case, the proposed housing project was located right directly near the ends of those tanks, the nearest house being 82 feet away from a 40,000-gallon -- or a 60,000-gallon container of propane. And the community had absolutely no idea why any of the engineers in the Department were somewhat concerned about the residents of the project which might move into that housing.

24 Our engineering analysis, which we had to proceed
 25 upon - because, after all, the Department hadn't been aware

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of the problem, didn't have any criteria to apply, was that an explosion involving one tank would have wiped out 60 percent of the residents of that total project, and we were talking about a project involving 1100 units of public housing.

The significance of Columbia, South Carolina, 6 then, began to get us thinking as to how to define the 7 problem, what sort of criteria we might need to prevent this 8 type of thing from occurring again. And we began to 9 question it: well, don't the local communities have codes 10 or safety conditions? Because, after all, in recent years 11 there has been a public trend away from federal regulation, 12 an over excess amount of red tape, forms, et cetera, just 13 for the sake of regulation. 14

We found that there wasn't, in fact, any, that the local communities didn't have safety standards, weren't aware of the problem as we had not been aware of the problem, or did not enforce whatever codes they did have. So we then recognized a need for safety provisions at a community level regarding hazardous materials facilities.

The principle involved two fundamental concepts which we defined. One is a safety separation distance. This is no 100 percent guarantee that — it would be defined by an environmental safety standard giving an acceptable degree of risk from some adverse effect. In crude English,

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putting enough distance between that hazardous material container and, let's say, a public housing site or some occupied community facility, so that an incident at the hazardous material site would not adversely impact or seriously impact the residents or occupants of that facility.

The other fundamental point was to define a 7 recognized danger zone. This danger zone would be that area 8 physically impacted by that hazardous material, when an 9 incident occurred with whatever conditions were operative at 10 the time the incident occurred. And our principle was that 11 safety separation distance, which we would prescribe by some 12 means. would at least equal the worst case danger zone from 13 that bazardous material container or installation or 14 15 facility.

We then funded research, awarded a contract, and I 16 have the several results garnered from that contract. One 17 was a departmental guidebook with procedures to analyze 18 hazards, namely, hazards from fire, hazards from blast or 19 explosion and hazards from toxic substances, and some 20 environmental safety standards. These environmental safety 21 standards addressed thermal radiation and blast 22 23 overpressure.

The safety standards which resulted were, one,
designed to achieve safety for buildings, occupied

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buildings. The precise safety standard was 10,000 BTUs per square foot per hour of time interval, and this was to prevent self-ignition of the structure which might be in close proximity to an intense source of thermal radiation for a period of time.

6 The thermal radiation standard for the protection 7 of people was 450 BTUs per square foot over an hour time 8 interval, and it was designed to prevent the occurrence of a 9 second degree skin burn on a person who might be in close 10 proximity to that intense source of thermal radiation.

The blast overpressure standard was 0.5 psi and it was designed for the safety of the building structure to prevent the failure of that structure or the failure of a major component thereof, which might adversely impact anybody inside that building, from the blast energy.

Now, a little bit about the nature of the 16 exposure. Now, note, I have been talking in terms of risk, 17 hazard, but I haven't really talked about exposure. With 18 respect to duration, we were saying the thermal radiation 19 mgiht be expected to last for as long as five minutes in 20 that particular building. The thermal radiation might be 21 expected to last as long as two minutes, to a person caught 22 in an exposed area at the time of an incident. And of 23 course, with respect to blast overpressure, the exposure 24 would be instantaneous. 25

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The assumptions were predicated that the local fire department could respond within a certain set period of 2 time and act effectively to reduce the amount of thermal radiation incident upon that building's surface. The ability of a person to react and take protective cover predicated the definition in two minutes.

Now, a lot of people would say that if somebody 7 was threatened by a fire. it would certainly take drastic 8 action long before two minutes occurred. Well, we as 9 engineers, we were looking for a safety margin, and with 10 respect to the statutory dictate of housing and urban 11 development, we were looking for rather large safety margins 12 in our result. for this reason, and that is the nature of 13 the exposed population at whatever time that incident might 14 15 occur.

HUD had to be concerned about low and moderate 16 17 income families. These families, it was felt, would have a high probability of large numbers of small children. A 18 small child in a crib would not be able to take the same 19 action as, say, one of your average human beings in the 20 sample population, your normal statistical average, i.e. the 21 child would not be able to run away effectively. 22

23 Point number two: HUD was concerned with elderly citizens, people with restricted mobility. So once again, a 24 25 10 or 15-second reaction time to a disaster might not be

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appropriate, especially if the project was designed for elderly citizens.

And point number three: handicapped citizens might actually necessitate a rescue or physical removal by someone else in order to ensure that they reached safety from such an incident.

So these were the concerns that we had when we built in our safety margins, and asked the research consultant to come up with environmental standards. The present status of our regulation now, or our policy now, if you will, is that we have produced an advance notice of proposed rulemaking which was published on the 10th of September in the Federal Register.

We are presently finalizing a departmental 14 regulation addressing the hazards of thermal radiation and 15 blast overpressure, and we are taking the position of 16 attempting to accurately recognize hazard scenarios in the 17 worst case and attempting to come as close as we can in 18 practical terms to achieving a zero risk. By that, I mean 19 if somebody defines a potential danger, no matter how safely 20 that tank might be designed, no matter how safe you might 21 call for certain housing design elements or blast wall 22 protection or some shielding, there is always the human 23 element involved, and we are talking about more sensitive 24 portions, if you will, of the total national population --25

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namely, elderly citizens and handicapped people and so on.

The duration of exposure and the exposed population caused us to get into risk assessment, which we have emphasized analyzing the hazard to achieve a low level assessment of risk. As a case in point, fire analysis, for us, we found was basically asking the question of: what is the worst fire hazard for a facility?

Some of the facilities we have come in contact 8 with, chemical plants, large refineries, various sources 9 which have had a large array of chemicals and/or fuels in a 10 large number of various designed containers. Our answer, 11 which we found, was you basically had to ask: what is the 12 most flammable material present on that installation? What 13 is the largest container containing a dangerously flammable 14 material on that installation, and finally, what is the 15 nearest container to your proposed housing site? 16

The largest safety separation distance which would 17 be calculated with resepct to that specific facility 18 ultimately came from one of those three which had previously 19 asked the questions, and this was the one which would be 20 employed with respect to the whole facility, for that site 21 or that project which was being evaluated as to its 22 suitability for housing or community development or what 23 have you. 24

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Our search through records for data and

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information pertinent to aid us in this -- we have found that there is almost no information which is directly applicable. We had to take into account a worst fire hazard, and nobody really asked people the question of where they were standing whenever they received, like, a second degree skin burn from an incident, or how many buildings were involved, radius-wise, from the source of the fire.

8 So we were immediately faced with a limitation, a 9 state of the art limitation on the amount of data that we 10 had.

We found we also had to take into account additive 11 factors. namely, what conditions, particularly with regard 12 to weather or just the human situation, might be additive, 13 might make a disasterous incident even worse yet --14 environmentally speaking, a worst case condition. Such 15 additive factors with regard to fire would be high wind 16 conditions, prolonged drought conditions and a delayed 17 response by the community or the local fire department to 18 enact safety measures and appropriate protective measures. 19

Interestingly enough, we did identify one actual occurrence of such an event. It occurred in Chelsea, Massachusetts, where approximately one-quarter to one-third of the entire urban community burned down and the same hazard scenario, interestingly enough, repeated itself within a 70-year time span, namely, an industrial source,

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actually a rag shop, caught fire during high gusting wind conditions. The community, used to fires in the industrial sector, attempted a delayed response. The water conditions or the fire-fighting resources were at a low ebb because of prolonged drought conditions and the same script repeated itself, I think in 1908 and again in 1973.

7 The third incident which hit the community 8 occurred one year later, in 1974. So what we have found is, 9 in attempting risk assessment or hazard analysis on these 10 type of disasters, you have to be confronted with a very 11 large absence of pertinent data that you might want. And we 12 have had to go the route of research to answer a lot of the 13 questions which we have had pressing us.

We have had very little tangible that has come forward and we have tried to expose our problem and our need for information in as many different directions as we could go. This has been educational not only in the aspect of us to the public, but in many cases of ourselves in attempting to refine hazard analysis.

With respect to explosion analysis, our approach was the same. What is the worst case hazard? Are there any additive factors which might make that a worst worst condition? And I think the most spectacular explosion, short of a nuclear weapon, is the BLEVE, the Boiling Liquid Expanding Vapor Exposion. Most people think of the incident

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1 which occurred in Crescent City, Illinois. If you are 2 familiar with the National Safety Transportation Board, they 3 have some spectacular photos of a fireball which is coming 4 close to engulfing a small midwestern community, and it 5 involved a relatively small container, 30,000-gallon liquid 6 propane tanker.

7 The spectacular point about it was it is one of 8 the only photos available of its kind. The photographer 9 happened to be right there at the right instant, and he said 10 that he had terrific problems trying to hold down the light 11 exposure in order that he wouldn't lose the photograph.

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These two hazards, thermal radiation and blast overpressure, we treat in our proposed regulation. Now, we say blast overpressure because we do not get into fragmentation or missile effects, which we have become aware are associated with catastrophic explosions of fuel or chemical facilities.

7 These, the statistical probabilities that would be 8 associated with trying to pin down acceptable risk and an 9 appropriate safety separation distance, are literally too 10 large to try and encompass with information as it exists right 11 now or as we are aware of it right now. I can give you one 12 example later of such an improbable incident.

The third hazard which we have chosen not to treat at this time, but to subject to future research, is that of toxic substances. Many of these have hit the headlines from time to time in the newspapers and usually involve mobile sources.

Now, once again, this has brought us to an interesting dilemma. By the nature of our responsibilities, we are treating stationary sources only. This is as opposed to most of what you hear, involving a railroad tank car or a truck tanker. These are the purview of the Department of Transportation, and as such we are limited in what standards we can apply to railroad rolling stock or truck traffic.

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The policy limitation which would hit us were we

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to treat mobile sources would be that we would have to restrict or apply safety separation distances and restrict housing from major highways and the rail lines, which have a large occurrence of chemical tanker traffic.

Toxic substarces. These we have found are asso-5 ciated with a large number of elements of uncertainty: wind 6 direction, wind speed, surface wind flow, like wallye wind 7 flow, atmospheric stability, and just the question of an 8 acute toxi limit of threshold brings into play all sorts of 9 questions about exotic research regarding human health effects, 10 what would be a safe dosage for a sudden, intense burst of a 11 chlorine gas cloud or an ammonia gas cloud. That in itself 12 would be a fertile field for research. 13

14 We have found two limits or two constraints, even attempting to refine ourselves to the more concrete aspects 15 16 of the problem, basically fire and blast. One is the flashback, where you have a flammable vapor cloud; and the 17 other is combustion products. Here what I'm talking about, 18 if you had a chemical container, like perhaps vinyl chloride, 19 which became involved in a fire, one of the considerations 20 would be that vinyl chloride is considered a hazardous vapor. 21 And yet, a combustion product, if you submit vinyl chloride 22 to fire, is phosgene, which is a military poison gas and 23 24 something altogether different, as opposed to defining a safe exposure level or an acceptable risk. 25

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1 As I say, we have only had about five years experience 2 at this. We are right willing to admit we are still learning 3 the trade, if you will. The more we compare notes with other 4 people, the more we attempt to educate the public as to differ-5 ent aspects of the hazard, the more we become aware of certain 6 factors that we have to consider and certain elements which 7 have to be incorporated in any risk assessment technique. 8 Our other areas of interest have included the 9 formation of an environmental hazards task force at the 10 secretarial level, which is attempting to address these issues 11 at a policy level for our department; chemical landfills as 12 a separate issue, and this being necessitated by the results 13 coming out of the Love Canal incident; radiation, namely 14 indoor exposure to radiation over reclaimed phosphate areas, 15 and radiation exposure due to either mining tailings or 16

17 All these have been hazardous aspects that we have 18 had to address or we have found a need to address in terms 19 of community safety and public housing. The constraints that 20 we now have have either surfaced as a result of people calling 21 to attention various cases and asking for an analysis from 22 our field offices or from our assembling of a case history 23 file of incidents.

radioactive impurities in construction materials.

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And one that struck me as intriguing relates to the question about why we are treating blast overpressure and

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1 vet ignoring considerations about fragmentation or missile effects. This involved an incident of a refueling facility 2 3 in Port Newark, New Jersey, and one of the results was that a section of a propane tank was propelled into the air as it 4 5 ruptured from a series of explosions at the facility, and upon returning to earth it penetrated the ground and ruptured 6 the underground water main which was supplying water for the 7 fire fighters who were fighting that particular fire. 8

9 So an assumption that we might have made as to the 10 duration of such a fire at a certain facility would have been 11 shot to pieces by such an unusual occurrence such as this.

As I say, we've only been at it five years and we're still learning the trade ourselves.

Thank you.

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DR. OKRENT: Dr. Lave?

DR. LAVE: I'm curious about two things. First of all, how is it that you protect severely handicapped people in the event of a fire, especially if it's a multi-story building and you're not on the bottom floor?

MR. MC GEE: We have had a case occurrence in Pennsylvania where they asked for an addition to an existing elderly facility. The hazard was two propane tanks which were located about 50 feet away. The community was totally in support of the project. And our answer, once somebody arrived on the scene and negotiated with the officials 1573 093

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¹ concerned, we took advantage of natural shielding of the land ² and we specifically asked that a blast wall be put into the ³ interim space between the wing which was to be added and the ⁴ propane tanks.

5 The thermal radiation portion of the threat to the 6 elderly residents, we asked for optical shielding. They were 7 going to put porches on the one side of the building. We 8 haven't got the design parameters, because our limitation 9 there is we're in the Office of Environmental Quality, so we 10 have to interact with the architectural and design standards 11 in housing within our own establishment.

We are in the process of negotiating such considerations.

DR. LAVE: Is it fair to interpret your answer that your answer is you don't expose them to the risk, and that's your way of protecting them?

MR. MC GEE: We try not to, yes, sir.

MR. LAVE: A second question is why is it that you're using the maximum crodible accident, somehow defined, as a design criteria? Here I would have thought that there is no justification for doing that, that you would want to design for the expected event and not the maximum credible event.

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MR. MC GEE: This came out of our research work with the consultant firm. For me to go beyond that, I would be speculating. 1573 094

1 DR. LAVE: Okay. Then let me just say that I think 2 there is absolutely not justification for using that criteria, 3 rather than using the entire distribution and trying to take a look at some sort of average risk, particularly where you're 4 5 talking about cases of a small number of people being killed 6 as a result of the maximum credible accident. I just don't 7 see any reason whatsoever to use that. And the short-term 8 consequences of using that are to overdesign structures, so 9 that you have less adequate, less available public housing 10 for people who need it, and therefore they suffer from having 11 not as much housing as they need. 12

MR. MC GEE: Well, we have also tried to come to grips with the problem that the facility or the installation may grow at some future point in time. If I may, there seems to be two or three practical limitations which we have to consider, simply because of the current need for housing in the country, and the current need for more and more fuels being conveniently stored for energy reasons, and more and more chemicals being utilized by a fairly large number of industries.

If we were to assume this is the boundary between, let's say, an industrially zoned property with some need for hazardous materials, and our proposed project site, when we review the project we can't make things retroactive to things in the past, nor can we treat any change which might occur inc. in the future.

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So if some facility had a large container here, then our assessment, our distance which might be calculated -- we realize that the developers are prone to walk the fine line. If you tell them 999 feet away you may build structures and you can build those structures, ten structures to an acre, they will go 999 feet and build 10 or 10.1 to an acre, if they can do so.

8 The question was asked of us, instead of fuel A, 9 some time in the future fuel B is put into this container, 10 the implication being that fuel B carries a much larger 11 separation distance than fuel A; what to do then?

Another point was, suppose a container at some point in the future is put in on the industrial property, carrying the same chemical or fuel in this container as was in this present container, the same separation distance. The population here would now be in jeopardy. Once again, we have no control in practical terms over such occurrences.

And it was also pointed out that community facilities heing as they are, even though the separation distance might be here, the children of that community might just elect to play right here, in which case the safety design measure that we were trying to achieve would be totally aborted if an incident were to occur.

24 So we recognized some elements that, however well inc. 25 intended the policy might be, were just simply out of purview.

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1 DR. LAVE: But I don't understand what conclusion 2 you draw from that. You know, it's sort of like saying, if 3 my grandfather -- my grandmother had wheels, she would be a 4 trolleycar. If somebody were dumb enough to put a facility, 5 a storage tank, right next to where your property was before, 6 then there's no design criteria you could have used which would 7 have protected you. 8 What else do you say after having said that? 9 MR. MC GEE: Well, all I'm trying to do there was 10 to reconcile the maximum credible, as opposed to an average, 11 occurrence, if you will. 12 MR. RICHARDSON: Jim Richardson, NRC. 13 There are certainly some societal benefits to be ' 14 gained occasionally by taking a certain amount of risk. Has 15 the HUD arrived at an agency policy on acceptable risk, what 16 level of risk is acceptable to the public? 17 MR. MC GEE: Not at this time. 18 MR. RICHARDSON: Is there a goal to establish any 19 such standard? 20 MR. MC GEE: We are looking to interacting with 21 other agencies to try to define such, or to achieve something 22 consistent with what other agencies may be arriving at on the 23 basis of their research. But not at this time; there is nothing 24 in existence. And we have this not as a specific goal, but as Inc el Reporte 25 a general principle.

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DR. OKRENT: Dr. Castenberg?

DR. CASTENBERG: I thought you said at the beginning
of your talk that you were surprised that local communities,
local regions, had not developed criteria of their own?

MR. MC GEE: We found no uniformity.

DR. CASTENBERG: Have you thought at all about withholding a project until that local government or local agency came up with some acceptable standards that they developed as a community, rather than you developing the criteria here in Washington?

MR. MC GEE: This again would have been before I joined the Department, and I can't really say what concerns were existing at the time of the research contract. Our experience started in hazard analysis and risk assessment after the research contract was turned back to us by the consultant, which was five years ago. So this would have been approximately seven or eight years ago.

I don't know, to be precise.

DR. OKRENT: With regard to the question by Mr. Richardson, a housing development poses other kinds of risks to its inhabitants besides those that arise from the storage of chemicals nearby. There can be fires that arise inside the building, crime inside the building. Earthquakes can cause damage to the building. And I'm sure we can think of one or two more.

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Is there some effort to look to see whether there are important, let's say, gains in safety that could be made in many of these areas; how the risk from such things would compare to the kinds of things you have been talking about; whether there is a more effective way to spend the money at some point; and also, what constitutes an acceptable level of risk in regard to things of this sort?

8 I have to assume if you spent more money in a 9 housing development, you could improve its fire resistance 10 against internally caused fires, and possibly reduce the 11 incidence of crime which threatens one's personal life, not 12 only his property.

MR. MC GEE: We are assessing other environmental hazards, things like what is an acceptable level of air pollution, what is the effect of noise on a community or the wellbeing of the community, what are the effects of ground water contamination on a community, particularly communities out West where ground water as a source may be important for their livelihood.

We are addressing socioeconomic factors in appropriate lighting, whether people may get hurt from the lack of such; traffic accessibility. There is an effort being made to address all environmental hazards, whether they be physical environmental hazards or socioeconomic hazards, by the Department before each and every project is funded. We had

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1 some involvement in the Love Canal incident. Some properties 2 were inherited back by the Department. Fortunately, someone 3 told me that the person looking over the project application 4 of Love Canal remembered that somewhere there had been a 5 chemical facility, and they had disposed of some sort of 6 chemicals way back when. And so he wrote in a precautionary 7 statement in the projects being applied for that the 8 Department should not consider anything except those homes 9 which were sited on original land, i.e., no landfill type of 10 sites.

And that thing in itself, I expect, saved the 12 Department a good deal of embarrassment when Love Canal did 13 surface when it did. And this was well before there was any such thing as environmental assessment or many of the terms 15 that we have today.

We don't have risk assessment in precise quantitative terms. In the absence thereof, we tend to approach it as close as we can to zero risk, the standpoint being, if there is a potential danger there, then it becomes a guestion of when this hazard actually will occur, as opposed to if it will occur.

DR. OKRENT: Dr. Shinozuka?

DR. SHINOZUKA: The fact that you intend to provide the people with zero risk, isn't that the basis for your 1573 100 choosing maximum credible situations?

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MR. MC GEE: In part, sir, in very large part.

DR. OKRENT: But isn't it a fiction that you are providing zero risk, since there are these other risks which in fact may be fairly substantial? You're trying to make it, I will call it, zero for purposes of discussion with regard to one specific area, let's say the storage of hazardous chemicals in the vicinity. But it is not a general goal that you are trying to achieve for all aspects.

9 MR. MC GEE: One constraint that we realized with 10 regard to blast overpressure is in the standard as specified 11 by the research consultant for what money that was available 12 at that time. There is some probability that someone could, 13 after all, be standing in front of a window, and although 14 the building itself might be secure from the blast wave 15 incident upon it, that person could just happen to be standing 16 there looking out of the window when such a blast would occur, 17 would most assuredly some adverse health effects.

Trying to pin precise numbers on what is the possibility of a person being impacted by shattered glass from a explosion which is, according to the industry, fairly negligible to start with, is very time-consuming to consultant and research firms, and very expensive and very iffy to pin down; and kind of like the example of what is the probability that a large section of propane tank will take out the water main which is being utilized to fight the fire.

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	1	There are too many "if's" in the problem, I guess,
•	2	is what I'm saying.
-	3	DR. OKRENT: Well, we are a few minutes behind the
-	4	agenda. Thank you very much for an interesting discussion.
	5	It is my first knowledge of some of the cases you mentioned,
	6	although I was aware that HUD had some kind of program of
	7	this sort.
	8	I'm going to propose that we break for lunch and
	9	reconvene, according to the agenda, at 1:30.
	10	(Whereupon, at 12:35 p.m., the meeting was recessed,
e-7	11	to reconvene at 1:30 p.m. the same day.)
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AFTERNOON SESSION

(1:35 p.m.)

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DR. OKRENT: We are going to have a shift in the printed agenda and the next speaker will be Mr. Snyder from American Nuclear Insurers.

MR. SNYDER: Thank you, Mr. Chairman.

7 My name is Phil Snyder. I am here -- I don't know if I can say representing the insurance industry, because that 8 9 is a rather broad term to say anyone is representing. But by 10 my experience in that area is why I'm here. I am a professional 11 engineer, started life as a chemist, spent eight years with 12 Reynold's Aluminum doing chemical and metallurgical research, 13 and then out of that, for some strange reason that I've never 14 quite figured out, I ended up in the insurance field and have 15 been working there for the last ten years, doing exactly what 16 we are discussing here today, and that is, assess risks, 17 translate these things to underwriters so they can make financial decisions, and work with the reduction of risks. 18

Now, the topic, of course, is use of risk assessment methodology, goals, and the criteria used by the insurance company. The initial draft that my boss wouldn't allow, I just said, well, we don't use any, and said that was simple, which isn't quite true. And he pointed out to me all the shortcomings in my statement.

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We do not as an industry sit down and perform

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esoteric mathematical studies of the risk, such as some of the things we have heard -- dam failure, aircraft crash, specific seismic probabilities at a specific location. But we do use historical facts concerning many events, and we use a branch of science called actuarial science, which is a little bit of mathematics and a little bit of waving a magic wand over a black pot, and put this result into our business.

Now, before we get too far along, I need to give you some brief idea of what insurance is. Insurance is not gambling. We don't sit down and play a poker game and shoot craps. Insurance is the transference of risk. The risk has to be known, identifiable, and already existing, before we in the insurance business can, for a financial fee, accept this risk, to take it off of someone else's shoulders.

In a poker game, two people sit down and actually create risk out of nothing, and that is a difference. And if you have something that is speculative or is in fact gambling, you'll find you cannot buy insurance on the outcome.

Now, back to this risk assessment. The simple way, of course, is for the people who are like Travellers', Mutual, Liberty, somebody that's in the homeowner's insurance, because they have got just the ideal situation. They are writing single family dwellings all across the United States, and you find that these are very easily categorized into similar things.

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Almost all of them, without doubt, have bathrooms, kitchens, bedrooms, living areas. A certain percentage have 2 garages. There are only certain broad categories of construc-3 tion. You have frame, you have masonry, you have masonry 4 veneer, and so forth. 5

Values also tend to lump together. You will find 6 that probably 99-1/2 percent of these will fit between 7 \$30,000 and \$200,000 in value. 8

So you have a tremendous, broad, and relatively 9 homogeneous population, and the actuaries can sit down with 10 these numbers and they can predict, at least on a nationwide 11 basis, right down to the seventh and eighth decimal place 12 what the loss experience in residences will be for the coming 13 year. 14

And the statistical base is so large that, say, 15 something like the conflagration in San Francisco after the 16 earthquake, which destroyed a very large segment of the city, 17 that doesn't affect the statistics at all. That is just way 18 down in the sixth and seventh decimal place. 19

Now, that is fine and dandy for us. Unfortunately, 20 in the business I'm in, American Nuclear Insurers, policy-21 writers on such places as Three Mile Island, we are not 22 working with a broad base of small-valued homogeneous items. 23 We have specific large-value nuclear power plants, fuel 24 inc. fabricating facilities, research institutions, and so forth 25

1 around the country.

2	And for those of you that do play with statistics
3	on occasion, there is nothing worse than the guy come running
4	in and say: Look at here, we've got a population of three and
5	an experience of X; now what's the frequency going to be over
6	the next ten years? Then he doesn't like the answer he gets.

So what do we do at American Nuclear Insurers, at
other insurance companies in this type business? I mean, let's
face it, General Motors has insurance, Ford Motor Company,
say Celanese Chemical, large papermills. They all carry
insurance. They're industries. Say U.S. Steel; you don't have
a large, homogeneous population of steel mills, either.

And the things you do statistically just don't apply. Yet we can profitably assess these risks and provide insurance for this type facility. And the way we do it is to sit down and hire a good engineering staff, which operates at many levels.

You start out with actually having engineers in the 18 19 field. Usually these are fairly young people. Most of them are either fresh out of college or -- often we find that they 20 are just either retired or have come off a hitch of, say, Navy 21 duty. In mechanical areas, a machinist's mate makes a good 22 starting point for certain types of engineering inspections. 23 24 These report to supervisors with more experience and training, Inc 1573 106 25 and right on up the line.

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And pretty soon in any industry, be it automotive, 1 steel, heavy chemical, primary metals production, you have 2 a large body of experience of looking in detail at very 3 small, discrete things, which funnels in like tributaries into 4 a river. Finally, somewhere at the top, you can make industry-5 wide assessments for broad rating purposes, and you can make, 6 to some degree, pretty good individual facility assessments 7 that this place is going to blow up or it's not, or it is a 8 9 good risk or it's not.

Let's get back to some of this. And I will do a little horn-tooting specifically in nuclear power plants. There is no experience. The first one didn't go into commercial operation until either the late 50s or early 60s. If forget when Dresden started up. We haven't had, thank goodness, a large history of big accidents to play with. So statistically we just have a broad range of confidence.

17 But what we in the insurance area find is two things: One, in any industry, in any area of insurable loss, even the 18 19 homeowners, it is not the big total 100 percent loss of something that we look at, that costs us the most money and so 20 forth. It is the incremental loss. It is when you burn out 21 your kitchen because the grease caught the curtains on fire. 22 That is not the total value of the dwelling. There are very 23 24 few of those in the country each year. But you have an Inc entirely different situation when you look at how many kitchen 25

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fires were there. And these, of course, are less than the policy value.

We carry the same thing in nuclear power plants. You find you have turbines, valves, motors, pipes, structures, electrical circuitry, control boards, pressure vessels, piping. And we, at least, say to some extent that the pipe carrying steam is a pipe carrying steam. An instrument cable is an instrument cable, whether it happens to be sensing the temperature of molten metal in a steel mill or whether it 10 happens to be carrying a signal for a containment pressure sensor.

12 And we look then at this. It is an instrument cable. 13 In the case of fire protection, which is my area of greatest experience, we know that cables burn. And the insurance 15 industry knows that cables burn. In fact, in 1956 -- not '66 or '76, but in '56 -- the Factory Insurance Asociation, which 17 is now called the Industrial Risk Insurers, published a book 18 which covered cable fires, switch gear installation and 19 proper installation and protection to prevent this.

Now, in the nuclear industry we sometimes tend to reinvent the wheel and things that may happen in a steel mill or a paper mill obviously can happen to us, and we sit down and write new regulations in a vaccum and they get enforced. Bright young design engineers sit down and design things out of existence. 1573 108

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At this point, as I usually do some place in every one of my talks, I will throw out Snyder's law again. Number one, it is that everything that can burn, will. Number two is, ignition sources are free. And, number three, Murphy was an optimist.

And the insurance organizations around the world that participate in writing nuclear facilities -- and this is a great, tightly knit fraternity that brings all of the insurance money available together, so that the plants in the United States, the plants in Germany, the plants in England, Switzerland, Sweden, are afforded the maximum insurance coverage that they can get.

We participate in all of them in the free world. 13 14 But they look -- the insurance business' greatest experience 15 in large facilities is with fire insurance. They look at the nuclear industry worldwide. They determined that the risk 16 from a large fire was too great. So, starting in 1972, there 17 were several international meetings which resulted in the 18 publication of international guidelines for fire protection 19 20 in nuclear power plants.

This was issued prior to the Brown's Ferry fire, and we like to toot our horn again and say, if Brown's Ferry had been constructed and operated in accordance with those guidelines, they would not have had their disastrous fire.

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We didn't insure Brown's Ferry and we didn't expect

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Brown's Ferry. But I will go so far as to say that if we had, 1 we would have prevented it, because you just never know. Again, Murphy was an optimist.

4 There are lots of other cases where our practices 5 in the insurance industry for reducing risk, at least to our dollars and the policyholder dollars, just doesn't quite track 6 7 with the regulatory atmosphere we see today. Piping is a 8 good example.

We know that you have pipes in paper mills, chemical 9 10 plants, fossil-fired coal plants. You name it, everything has 11 got pipes. You pipe water, steam, what have you. We also 12 know that these things are subject to failure. There are 13 quite a few piping failures throughout the country each year. And our way to ensure the least risk to us is to insist on 14 15 full compliance with the ASME Boiler and Pressure Vessel Code, 16 and that goes for the design, the construction, and the 17 maintenance and testing.

18 And if you closely read the federal regulations in 19 this area in the nuclear business, you will find only equiva-20 lency is required. And we sit back and say: Well, we don't 21 know what equivalent is. We don't have the staffs available to decree or study that something is equivalent. So we just 22 23 fall back and say: Fine, you meet the ASME Code. When you 24 have the certified stamp by all the authorized inspectors and Inc the operating certificates are in line, we will insure it. 25

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Of course, next year, when it's time to test it, you 1 2 have to keep that up, too.

3 Now, back to the actual, I guess more in-depth of risk analysis. As I said, we don't really do a rigorous 4 mathematical analysis of our risks, except in those areas that 5 are subject to good statistical work, such as homeowners 6 insurance, life insurance, where the risk is of early death 7 and you have a tremendous population to calculate for. 8

9 When you write a billion dollar chemical facility 10 and you are writing a policy that covers not only the actual 11 physical value of property at that location, but also the 12 continued operation of it, which we call business interruption 13 insurance -- and say, a large refinery could purchase a policy 14 that, in the event of loss by fire, storm, explosion, lightning, 15 whatever, it is covered; that the insurance company will pay 16 for their loss of profits until that production is restored.

17 And if you look at the production values of some 18 of the refineries and chemical plants these days, you defi-19 nitely get the attention of the underwriters, who immediately 20 come over to the engineers and say: Hey, what's going on? 21 Can I write this? Is it going to blow up tomorrow? And we 22 always very carefully weasel it around and say: No, it is 23 not likely to.

But he is the guy that signs the policy, but he always has a memo from the engineering side that told him it

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2	But we divide our loss studies in this high-risk,
3	high-severity, low-frequency situation, into sort of three
4	levels. We have what is called a probable loss. This is the
J	case where, back to Snyder's law, where it says ignition
6	sources are free. We assume some accident occurs. But then
7	we assume a reasonably adequate performance by the plant
8	personnel, by designed-in, built-in safety features and so
9	forth. These are your normal, nonconsequential industrial
10	accidents: a gas pipe fitting, a furmace breaks, the low
11	pressure sensor senses this and the valve goes shut. That is
12	an accident. Everything works like it should. And away we go.
13	We basically don't insure these. These are handled
14	by policy deductibles. We sort of consider them just normal
15	occurrences.
16	The second level we look at we call a maximum
17	probable loss, which goes a little further and assumes some

17 probable loss, which goes a little further and assumes some 18 adverse performance, either in the case of the operators or 19 on installed safety equipment or other such things. The 20 Brown's Ferry fire and the TMI incident we put in this category 21 of maximum probable loss.

And since we are in high limit, infrequent but high severity incidents, we have a third category which we call maximum catastrophic loss, which anticipates a serious failure of equipment and adverse performance of personnel.

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And we also anticipate that the loss will progress beyond those areas where you would normally expect it to bound itself by some passive means.

To get these concepts across, we usually use the example of a turbine. In the first case, that is a probable loss, we would assume that the turbine froze a blade, and this is held within the casing. The vibration sensors which they have sense the imbalance and the machine is safely shut down. As I said, we have deductibles and exclusions for that type thing. It is a normal operating occurrence. There is no problem and no insurance collection by the client.

12 At the second level -- in fact, we actually study 13 things like this to get estimates of the dollars involved .--14 we would make the assumption that this blade or several blades 15 actually penetrate the casing, do it in the worst possible 16 area, sever a lube oil line, and a fire starts. But to fit 17 in this category, we would then assume that the operators 18 took the correct actions to begin bringing the turbine down 19 to standstill, lubrication was maintained, and the fire 20 protection systems did activate and control the fire. These 21 are the type things that start getting headlines to be 22 written up in the paper. If it is a nuclear plant, it will 23 make national news.

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The third case, though, we also look at -- and very few people seem to go that far -- as we assume, without

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attaching any probabilities yet, that everything that we have talked about before happens. The blade goes up. It ruptures the oil line and the fire starts But in this case the fire, we would say, might progress such as it burns out the wiring which powers the lubrication oil pump for the turbine.

6 We heard about the propane tank breaking the water 7 main. We could make some assumption that the fire protection 8 system was impaired for one reason or another. The turbine 9 is sitting there burning, attempting to coast down without 10 lubrication. We seize a shaft, break the unit in two or 11 three pieces. The missiles progress out in sort of predictable 12 paths, hit a transformer in the switchyard, and that causes 13 an electrical failure here, there, and yonder.

And these things do happen, fortunately not very frequently, and we do look at them. And a fair amount of our engineering work is in trying to prevent this, such as relocation of equipment, redundant lubrication systems, protective control wiring, this type of thing.

We use, as I previously mentioned, a large staff -We use, as I previously mentioned, a large staff -"we" means the industry -- a well-trained and experienced
inspectors and engineers, and we inspect. And we consider
there's a big difference between inspect and audit. We
inspect all of the facilities which we insure on a rather
detailed basis.

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In just the mechanical equipment area, our inspectors

will average about 45 days per year per unit in a nuclear power plant. In doing this, he is physically checking motors, valves, piping, hangers, you name it, for their degree, how well are they maintained. He spends very little time, relatively speaking, reviewing compliance with maintenance criteria. Instead, he goes down and looks at the pump, or he looks at the motor.

And it is surprising how many times we will get a report in that the motor is fine, the pump is fine, but it's got no lubrication oil in it. And when we check, we find that the documentation is sufficient to show that this is properly maintained, but the end result doesn't agree with that.

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We use these engineers, and we use them subjectively and objectively. The subjective area is, in my opinion, the most important, and this is their personal opinion of the plant management, and these come from various different types of inspectors.

We have inspectors that are experienced in the fire Protection areas. One of the first things we ask of these inspectors is, what is your opinion of the management? Are they cooperative, and on and on and on? We send in mechanical equipment inspectors. We ask them the same question: What is your opinion of the management? Is it apod?

We will send in nuclear specialists, and this is 13 where we, of course, get into most of the auditing 14 procedures. But still one of the first questions we ask 15 them is: What is your, Mr. Inspector, your personal opinion 16 of management? And this subjective opinion, we feel, is the 17 18 most important item in assessing the risk at a particular facility. And although it may be extremely difficult and 19 impossible to quantify, it is our feeling that if you have 20 poor management, you have a definite increase in risk. 21

The next areas we look at, of course, get into the objective area where you can define and quantify such as we look at specific plant protection. Does it mean the appropriate building codes? Does it comply with the

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1 appropriate ASME codes? How many fire protection systems 2 are there? Of what quality are they? Are they build in 3 accordance with the applicable codes? What are your actual 4 demonstrated results of maintenance procedures? What type 5 of protection do you have against flood, tornado,

6 earthquake, lightning, and so forth? These, we look at and
7 can verify and do use in actually developing insurance rates
8 and so forth.

A third gross overall area that we look at is in 9 that area of specific hazards, such as rad waste handling 10 systems. You've got liquid, solid, gaseous, and so forth. 11 There are all sorts of ways to compress, compact, 12 concentrate, transport - you name it. We insure the 13 results of this, either if the equipment breaks or the 14 resultant contamination, so we have specialists who look at 15 15 these specific hazards.

For instance, if you are concentrating waste and using a medium that has known hazards of combustibility, we look at how is this combustible medium handled? Is it safely stored? Are the purchase orders written in such a manner that if you think your order of methyl-ethyl ketone, you don't get methyl-ethyl ketone peroxide. That's not too likely to happen anywhere, but it is just an example.

For instance, we ask, because of the known hazards of plastics, that you use certain grades of plastic film for

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your covering protector and so forth. At this point, we have a specialist who's checking to see that they are, in fact, ordering and are, in fact receiving the appropriate material.

In this area, we issue bulletins. You will find — I think we copy the NRC as well, but we have bulletins ranging from everything from how we want your cooling towers constructed to proper design for off-gas systems at BWRs. And we are most of the time proud of the fact that we don't have to follow these rather slow federal regulatory processes and can do things in a hurry.

12 Of course, doing them that way, we're not always 13 right, but at least we do something. As a for instance --14 and we can go back to Brown's Ferry again -- at the time of 15 the Brown's Ferry fire, the nuclear insurance industry had 16 identified that penetration seals, those caples through far 17 areas, were a problem and that the combustibility of caples 18 was a problem area.

We had started testing in several areas before the fire. In fact, our first cable fire tests were run several months before Brown's Ferry. And after the fire, we were able to get an area of penetration seals, a full-blown approval and testing program underway, and by fall -- that is between the fire being in March and either late September or early October -- was the first full-scale industry test,

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We had our program down, documented the approval 1 procedures on the way, and industry testing underway. We 2 continued testing cables, and we issued our own guidelines 3 for cable construction, cable installation, cable 4 separation, even though we had a lot of argument with the S IEEE and a few other organizations. And we did that, had 6 our own guidelines out by early 1976 in a final form, and 7 unless I have missed something drastic, the federal 8 government still does not have definitive regulations in 7 this area. They are still in draft. There are still 10 hearings going on. And there are only beginning to be 11 national concensus standards coming out in this area. 12

So we are proud of the fact that we can identify areas of hazard and areas of risk, and at least for our purposes of protecting our dollars, move promptly to do something about it.

Now, the purpose of this Subcommittee, as I 11 understand it -- and I may be wrong -- is to review the NRC 13 program on quantitative risk criteria and to possibly see if 19 there are methods, et cetera, that could be used to reduce 20 the risk to the public. And I say, fine. If we are looking 21 at a broad population, a statistical probability of 22 earthquake, that's the only way you can do it -- take a 23 large population. You know where the faults are. You make 24 25 assumptions, and so forth.

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But we are dealing with your licensing. We are 1 insuring specific nuclear power plants. We don't write an 2 insurance policy on a nuclear power generating industry of 3 4 the United States and have this big, broad, wonderful average to work with. We write specific facilities, and the ċ NRC licenses specific facilities, and it doesn't do us or 5 you too much good to know that some event has an entire 1 population probability of occurring only once every 10,000 3 years because no one stops to address the fact that that is 7 10 fine. but does it happen to be once in ten years at this particular location, and once in a million at all the rest? 11 Inat's what we have to deal with in the insurance 12

13 industry — is which one is the one that's going to get us, 14 not what is the industry-wide average. It is sort of a case 15 of figures don't lie, but liars figure.

If I can offer a suggestion — and I doubt very seriously if it can be implemented under the regulator systems — out that suggestion is that to reduce individual risks which will have the net result of reducing overall risks, you concentrate on the management of the facilities.

And the example I will give of that is the Dupont Corporation. They have, or they are well recognized at least in my business of being Mr. Safety — they don't blow up plants. They don't burn them down. They don't injurs employees — anything like the rest of American industry.

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Their personnel safety, fire and explosion safety, 1 transportation safety records are so good that they honestly 2 cannot afford to purchase insurance because the increased 3 cost to the corporation would just be prohibitive, because + no insurance company could afford to write those great of 5 values, even knowing the low risk, for a premium that 6 anywhere approaches their in-house cost for maintaining and 1 operating a safety program. 8

And the key to the Dupont program and quite a few other chemical people in the chemical industry is management responsibility from the Chairman of the Board to the President of the company to the individual plant manager. There is a real, deep belief and dedication to doing it safely.

When a Dupont plant puts up a sign that says, 15 "Safety first", they really mean it. They don't do it 15 11 because the National Safety Council sent them a box of them. In fact, they take it so seriously that a Dupont plant 18 manager who has too many accidents at his plant is in 17 jeopardy of losing his job, even if he happens to be setting 20 a productivity record for the whole corporation. They will 21 not tolerate managers who don't run a safe plant. 22

And by having this personal responsibility, knowing it is my job, we get something done. They believe in it. The foreman on the line who is supervising the

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people, he knows that he will get fired when the plant manager gets fired. So he is interested in being safe.

I think one of the best examples of that in the federal field and something that the Commission should definitely look at is the outstanding lack of success of the OSHA program. This was forced onto American industry as the great, wonderful thing that will make the workplace safe for the worker, and if you look at the statistics, there has been no improvement in accidents whatsoever.

10 The plants that were safe operations before OSHA 11 are still safe operations. The plants that weren't safe 12 operations before OSHA still aren't safe operations. And 13 there again is that management commitment.

14 OSHA requires compliance with regulations, and 15 there are two ways to comply with regulations. You can go 16 out and do only what you absolutely have to as a minimum to 17 meet the letter of the regulations and the auditor checks 18 you off, or you can really want a safe operation — find out 19 what the regulation means, where it came from, and go out 20 and do it on purpose, make it better in some cases.

In our own area, you can see this when we interview and discuss operators. You have operators in these plants. He's got a license. He's a licensed operator: he's been through the training program. And there is one guy -- he wanted to be a plant operator. That was

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1 one of his big goals. He wants to be a good one. He 2 studies extra time; he goes further than he has to; he 3 learns what makes a plant tick. He spends time talking to 4 other people in other departments -- what are you doing --5 and he's a darned good operator, and yet he may have had the 6 same score on the examination as the guy who only did what 7 he absolutely had to.

And I think from your own experience, you will know that that second guy is a much poorer operator than the first one I discussed.

And with that, I will answer any questions that I 12 can.

DR. LAVE: You made this interesting statement to begin with that there were small eventualities that wound up costing money. Is that only because of experience to date, or do you expect that that will be true in the future? If so, why do we need Price-Anderson?

18 MR. SNYDER: Well, I heard a similar question 19 earlier today. We need Price-Anderson because the insurance 20 industry does not have sufficient assets to provide all the 21 coverage necessary to the public.

22 DR. LAVE: Come on, now. What kind of accident 23 are you talking about?

24 MR. SNYDER: Well, what was the release at Three 25 Mile Island? I mean, offsite it is a minor accident, yet

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1 look at it from the insurance company's standpoint. For the 2 next 20 years, you're going to be battling lawsuits --3 possibly if the court climate is such, paying exorbitant 4 claims. There is no limit to what the courts may allow in a 5 very minor accident.

5 So we think - and we may be wrong, but the Congress somewhere made the decision that we do need nuclear power. Someone made the decision that the available private insurance wasn't enough to give the public a good feeling, so they added some on top.

DR. LAVE: Without getting to that, could I get back to the first part of my question? I understood you to say, it is the little things that have cost you money so far. And let me just ask again, do you expect that will continue to be true in the future, absent some really colossal occurrence?

MR. SNYDER: Okay. You may have misunderstood 11 that. You're right. Let's take a hypothetical plant of any 13 type that is worth \$100 million, and we write an insurance 19 policy for \$100 million. The probability of paying that 20 \$100 million is just vanishingly remote. What we pay are 21 the \$10,0000; \$30,000; \$50,000 every month, two months, 22 three months, type losses. And these add up over the entire 23 history of an insurance organization to be a much greater 24 sum than the individual, infrequent, what we call 25

macHEE | "shock loss."

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DR. LAVE: Would that also be true, for example, for supertankers carrying oil?

MR. SNYDER: I don't know. I'm not in the marine insurance business. But depending upon how the policies were written, which might cover contamination to cargo, late delivery, this type thing, it very possibly could. If there was only a catastrophe policy written that we're only going to pay you when the thing finally sinks, then, no, that Wouldn't be true.

DR. LAVE: That must be just a lovely kind of a case for an insurance company, if your claims are relatively small, much less than the face value of the policy -- lots of little tiny claims instead of a couple of really big ones.

MR. SNYDER: Well, no, it is not, because they won't buy the insurance if our premiums are exorbitant, so we have to sort of balance in there, if we are writing a \$100 million facility, they aren't going to pay \$50 million a year for insurance.

21 DR. WILSON: But I don't understand that one, 22 because the premiums that a utility company pays now are 23 such a small fraction of what the charges appear on my 24 electricity bill, I mean that it's after all -- the reason 25 they buy insurance is because they have to. If you multiply

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i it by ten, it still won't be on my electricity bill.

MR. SNYDER: That's true.

3 DR. WILSON: So that answer, I think, is just
4 wrong. It just can't be right.

MR. SNYDER: Let's back up a little. We are in the free market situation that, with the exception of what is required by Price-Anderson, the utilities can elect to buy or not to buy our insurance for damage to their property.

Now because Price-Anderson is mandated by law, and we are a monopoly, we feel somewhat bound to keep the rates as low as possible. In fact, if you look at the structure after ten years, we return all unexpended premiums to the policyholder. So what the utility paid in ten years ago, which wasn't used to pay for losses that resulted from operation during that year, is returned to nim this year.

DR. OKRENT: Can you say whether you have
 differentials in rates for insuring different nuclear power
 plant properties because of the management?

20 MR. SNYDER: No, not for management. 21 DR. OKRENT: So all of the managements have turned 22 out to be the same in your eyes from a dollar protection 23 point of view?

24 MR. SNYDER: From a legal rating point of view, by 25 being able to look at lots of things, if we have a plant

493 09 12 126 that we do feel the management is extremely poor, we can mgcHEE 1 find enough other things to complain about which are the 2 result of that poor management to actually get an increase 3 in rate. But it is not and cannot legally be the cause of 4 our judgment of their management capabilities. It has to be S based on physically verificable. Ś you-guys-don't-maintain-this-and-it-doesn't-work type 1 situations. 8 So it is the same result. 7 DR. OKRENT: Dr. Castenberg? 10 DR. CASTENBERG: Early in your talk in regard to 11 fires, you used the phrase: "The risk was too great, and 12 therefore we went and looked for some guidelines." When you 13 used the phrase "the risk was too great", was that a 14 qualitative judgment or a quantitative judgment made -- that 15 the risk was too great? How did you arrive at that phrase, 15 or how did you arrive at the decision that the risk was too 17 18 great? MR. SNYDER: It is almost like a multiplex. We 12 talked about rating. Obviously, if we could charge the full 20 Value of the plant, we wouldn't care what the risk was 21 because we could never pay out more than that for the rates 22 that we have to charge, and I'm talking general industry 23

now. They pay maybe an average of six cents per year per
hundred dollars of value of insurance, which is generally

about one tenth of the average homeowner's insurance. So MACHEE 1 when we look at a facility and then we find historically 2 here and there something new is cropping up like 3 concentrated cable fires, we transpose that to whatever 4 we're working with, and we say, worldwide we have 5 experienced a certain number of fires of values, dollar ó values at a certain level, can we afford at our present 1 rates to accept that risk of occurrence in our plants? 3 And when we find that we can't, because we are in 9 competition with other organizations who aren't going to 10 raise their rates because we do, we have to improve the 11 protection and the design. 12 DR. CASTENBERG: So you have some threshold limit 13 in dollars paid out which is a criterion? 14 MR. SNYDER: Yes, but it is not fixed. 15 DR. CASTENBERG: I see. 15 MR. SNYDER: It floats. 17 DR. OKRENT: Dr. Wilson? 13 DR. WILSON: The thing I'm not clear on, in some 19 other industries, certainly in for example gasoline tank 20 trucks and things of that sort, the insurance industry sets 21

standards. What is it? The Fire Protection Agency in Boston actually does it, and in fact they have got other standards for some of the industry even beyond that, and premiums for insurance are judged by the use of those

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standards.

So in a certain sense, the insurance industry did 2 a fair amount of the regulation of the industry through this 3 practice. Now I don't know of any example in the nuclear 4 industry. Is there any, for example, example where you 2 would set higher premiums for Three Mile Island-2 than Three 5 Mile Island-1 or anything whatsoever in the nuclear industry 1 where you were setting a criteria and force it on the 8 industry by adjustment of the premiums? Or is there any 9 contemplated? 10

MR. SNYDER: Yes. We do that for each individual facility. I am not an expert in the rating of the public liaoility insurance portion, but I know they have a published schedule that is public knowledge that they use to assess plants which cover such things as surrounding population density. And all of these factors go in, and different plants have different rates.

On the property side, the direct physical damage 18 to the utility company property that I work with, we have a 17 Rating Bureau which is an independent organization, Nuclear 20 Insurance Rating Bureau, that sits, I guess, quarterly in 21 New York City. We have to report to them a certain list of 22 facts about the individual plants. What is the size? What 23 is the value? What type of plant is it? Who built it? 24 Where is it? What kind of public fire department do they 25

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mgcHEE	1	have nearby, and on and on and on? Many reports. And they
•	2	establish, based on a lot of things including general
	3	published insurance rates for specific hazards, and they
•	4	come out with a rate. And that is what is charged to the
	ċ	plant.
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DR. WILSON: The second part of the question, is 1 there any feedback, and if I take the Pilgrim plant near 2 Boston, which happens to be a local one, it is a little 3 closer to Boston than. for example. Maine Yankee up in the 4 5 corner of Maine, and might, by your population density, therefore satisfy some different criteria. Is there any 6 known case in a siting decision to a utility company, say, 7 do they bill Pilgrim-2 or do they bill Maine Yankee 2? Is 8 there a choice of these things influencing what the industry 4 10 actually does?

MR. SNYDER: There should be, but the only time I we ever seen this effect occur is when we negotiated with the utility and said, what you propose is just not insurable. There will be no insurance available, period. Then the listen. Otherwise, as you previously mentioned, the cost of insurance is such a small part that it is generally ignored.

DR. OKRENT: Thank you, Mr. Snyder. This was an 18 interesting talk. I appreciate your coming here. I 19 understand that Mr. Ellett and Mr. Richardson are here now. 20 So we can revert back to the planned timing, albeit a little 21 delayed. Let me ask: would it intolerably inconvenience 22 Dr. Page, for example, if he is 40 minutes behind where he 23 is currently scheduled? Because we have slipped, is that 24 tolerable? 25

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DR. PAGE: That is okay.

DR. OKRENT: Then I would propose that we hear from either or both Mssrs. Ellett and Richardson from the Environmental Protection Agency.

5 MR. ELLETT: My understanding, you're going to 6 have other people from the EPA this afternoon -- I think you 7 will see similarities and differences between how each of 8 these offices factor risk analysis into their

9 decision-making process.

10 The Office of Radiation Programs uses a variety of 11 considerations in setting radiation protection standards and 12 guides. Risk is, of course, only one factor in the 13 decision-making process leading to regulation. I believe 14 you have copies of our policy statement of March 1975. It 15 has been published in the Federal Register and several other 16 places.

I would like to call your attention to the last 17 paragraph in that statement, where it says the linear 18 hypothesis by itself precludes the development of acceptable 19 levels of risk based solely on health considerations. 20 Therefore, in establishing radiation protection positions, 21 the agency will weigh not only the health impact but also 22 social, economic and other considerations associated with 23 the activities addressed. 24

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As is also stated in this policy statement, the

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1 Office of Radiation Programs believes it has an obligation 2 to make available to the public numerical estimates of the 3 risks to human health from radioactive contaminants. The 4 agency recognizes that these estimates are not precise and 5 that they are truly estimates and not predictions of 6 environmental impacts.

While such estimates are an important component of 7 the standard-setting process, they are not a substitute for 8 the current federal radiation protection guides, and I would 9 like to recall the first federal Radiation Protection 10 Council publication, where injunctions are given that any 11 radiation exposure must be both useful and necessary in the 12 first place, before there is any consideration of whether an 13 allowable risk is all right, an exposure must have an 14 expected benefit compared to the health risk imposed, and 15 finally, that all exposures be as low as practicable. 10

Moreover, to quote the Federal Radiation Council directly, they say there can be no single permissible or acceptable level of exposure without regard to the reason for permitting the exposure. I think our office has backed away from the idea that there is some kind of magic number applicable to all situations involving radiation exposure. And I believe this is reflected in the standards we've set.

24The Office of Radiation Programs has authored25several radiation protection standards and guides. None of

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these have identical risk estimates, although in some cases the estimated risks are not too different.

However, the basis for selecting the limits varied 3 quite strongly from one case to another. Now, one reason 4 for this is the legislative mandate for various types of 5 environmental regulations differ greatly depending upon what 6 is said in the enabling legislation. For example, the Safe 7 Drinking Water Act of 1974 specifies that the national 8 interim drinking water regulation shall protect health to 9 the extent feasible using technology and techniques that are 10 generally available, taking cost into consideration. 11

In contrast, under the Atomic Energy Act, the administrator has the authority to establish such standards as he may deem necessary or desirable to protect health or minimize danger to life or property. There is no reference to cost.

I would like to outline how the agencies establish 17 radiation standards under each of these differing 18 authorities. First, I would like to talk about the Safe 19 Drinking Water Act. Proposing limits for radioactive 20 contaminants of drinking water, the agency was faced with 21 two quite different situations. Man-made radioact.vity 22 usually enters the environment from controllable sources 23 already subject to a high degree of governmental 24 regulation. On the other hand, radioactivity is ubiquitous 25

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in ground water throughout the United States. Selecting the limits for man-made radioactivity correspond to a four milligram per year dose with an estimated risk of .4 to two deaths per year for each million persons exposed. That is, of course, exposed at that maximum limit, and we would expect most people not to be at the maximum limit.

This limit was not selected on the basis of a de 7 minimus risk. but rather. to quote the Federal Register 8 notice on these regulations, it was chosen on the basis of 9 current levels of radioactivity in community water systems 10 and to avoid undesirable future contamination of public 11 water supplies. The limit for radium was set a at a 12 concentration corresponding to an intake of 10 picacuries 13 per day. Estimated risk at this level of radioactivity is 14 15 .7 to three deaths per year for each million persons 16 exposed.

Selection of this limit was based on the cost of obtaining lower concentrations and agency's uncertainty on the number of community water systems that would be impacted. It was not selected on the basis that this was an acceptable or de minimus risk.

Indeed, the risk of the drinking water maximum contaminant limits are probably higher than allowed for any other drinking water contaminants.

25 Turning to the uranium fuel cycle standard, which

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was established under the Atomic Energy Act, a somewhat
 different approach was used. The agency examined the cost
 of risk prevention for different parts of the uranium fuel
 cycle and strove for some comparability in terms of cost per
 cancer death averted.

Mr. Richardson was very instrumental in developing the uranium fuel cycle standard and will talk a little bit more about the detail of how we developed our uranium fuel cycle limits.

MR. RICHARDSON: I would like to apologize for not 10 having any prepared statement for you. The rationale that 11 was used for the uranium fuel cycle standards -- I think 12 it's well known to most of the people here, and it is 13 documented to the extent that we were able to write it down 14 in the environmental impact statement that went along with 15 that standard when it was promulgated a couple of years 16 ago. And I am sure there are copies of that available. 17 We're about out, so I didn't bring 20 for everybody. 18

As Dr. Ellett pointed out, the standards for the uranium fuel cycle had a heavy base in cost as well as risk, because we are permitted to do that by the Atomic Energy Act, which doesn't really place any restrictions on the methodology that you use for setting standards.

24 We looked at, I think for the first time, the 25 question of long-term risks to large numbers of people

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spread over large distances.

That is to say we calculated the collective dose 2 commitments to the world's population in the case of 3 isotopes like crypton, and those standards reflect the risks 4 associated with those assessments as well as the risk 5 associated with doses to people close to facilities. And 6 that is probably the most significant difference between 7 previous standards and those standards for the uranium fuel 8 9 cycle.

10 The question of deciding at what point you had spent enough money to avoid risks was a central issue in the 11 12 standards, and it wasn't handled very cleanly because you 13 can't handle that kind of question very cleanly. What we 14 did was rank all of the major control methods by cost and by 15 the amount of risk that was avoided through their use. A 16 cost effectiveness ranking -- and we found that it was 17 convenient to divide all of those options, each of which had 18 its own dose level attached to it, into three broad 19 categories.

20 Quite arbitrarily, those that fell above a half 21 million dollars or so per life of lethal cancer, those 22 that fell less than \$100,000 for each of those types of 23 events, and then of course, a third class, which were those 24 that fell in between. That ranking implies an evaluation of 25 life that falls somewhere between \$100,000 and a half

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million dollars or so.

We purposely left it very vague. When we looked 2 at the options that were available to us for setting 3 standards based on that kind of a ranking, we discovered 4 that there were very, very few levels of control that fell 5 in the third or middle category and it became rather easy to 6 say, Yes, you should do all those things that cost more than 7 half a million dollars per life -- or you shouldn't do those 8 things, excuse me -- and that you obviously should do those 9 things that were down \$100,000 or less, because those value 10 judgments were, it appeared to us, generally acceptable 11 areas where there wasn't much dispute about whether you 12 should spend money at those levels. 13

There are always people who say you should spend 14 infinite amounts of money, but they weren't very reliable. 15 And there were very few people who said you shouldn't spend 16 money when the cost of life is less than \$100,000. We 17 published our proposals and if you read them carefully 18 enough -- we didn't make it terribly explicit, but if you 19 read it carefully, it is all in here. And out of the very 20 many comments that we received, not a single person, not one 21 person questioned this implied judgment that life - the 22 cutoff between when you should spend money to save lives and 23 when you shouldn't -- fell somewhere between \$100,000 and 24 half a million dollars. 25

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DR. WILSON: Do you have that case where it is kapHEE 1 published? 2

> MR. RICHARDSON: Yes, it's here. All of the 3 comments are in Volume 2. and the discussion of the cost 4 considerations is in Chapters 4 and 5 of Volume 1. 5

Well, that gave us some confidence that we were on 6 the right track, and we went ahead and I think that is 7 really all that I have to say about the question of criteria 8 9 for establishing standards.

We used a number which was directly related to 10 health effects, not to man rems or some other surrogate. We 11 used a range of values rather than a single number, and 12 nobody objected. I quess we are both open for questions. 13 DR. OKRENT: I will try one. Let me invent a 14 hypothetical situation that, from the fuel cycle 15 examination, you found the same kind of dispersion among 10 fixes -- in other words, that there were some cases where it 17 cost \$100.000 or less to defer premature death, or it was 18 over half a million dollars, but you estimated that the risk 19 to the individual that resulted when you used the cost of 20 life way of deciding what to implement -- where that risk 21 was 10 to the minus three per year to the individual, what 22 would you have done?

Would you have said it's okay, what we need to do 24 is meet this value of life criterion? If that wasn't okay, 25

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if it wasn't -- would 10 to the minus four have been okay. would 10 to the minus five?

MR. ELLETT: It happened in the uranium fuel cycle standard, but this is a hypothetical question. 4

MR. RICHARDSON: It happens all the time. And I 5 left out an important part of the discussion of those 0 standards. You have to have two things to worry about when 7 you establish standards, at least two things to protect 8 people, and one of them is what is the collective impact and 9 what is the maximum individual impact. And they are quite 10 different and independent things. 11

There you are faced with -- well, it is another 12 kind of a degree of arbitrariness. The range of evaluation 13 for human life is certainly arbitrary, but you can go to 14 society and say, Well, is it acceptable, what you've done? 15 I guess the same thing is true of individual risk. In the 16 case of the uranium fuel cycle, it was a fairly arbitrary 17 decision. 18

We had situations at milling operations where some 19 of the individual risks were fairly high, but the cost 20 effectiveness of eliminating them did not fall in the range 21 I just discussed. The situation for iodine emissions at 22 reactors sometimes falls into the same category. And there, 23 we got quite arbitrary. We looked at the level of risk that 24 had been attained in the industry in most of the components 25

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of the fuel cycle and we looked at the levels of risk that were attainable using cost effective methods, and they all fell at levels of dose which were below 25 millirems, and so we arbitrarily said, Well, for the sake of equity we will impose this kind of a limit.

Quite frankly, back in those days when we did 6 this, we did not look to see what the lifetime risk was to 7 an individual explicitly. It turns out now to be fairly 8 high compared to some other levels of acceptability used in 9 the agency for other standard-setting activities. 25 10 millirems per year is -- I've forgotten the number -- it's 11 on the order of 10 to the minus three or four per lifetime 12 of doses, certainly worse than 10 to the minus five or six, 13 which is what the agency strives for. 14

And we have to depend upon arguments that say, Well, that 25 millirems is really not the limit at which reactors and other facilities operate. It is the standard under which the regulations for ALARA sit -- as the framework in average exposures, for even common exposures to individuals are generally even much smaller than that.

I think if we were setting the standard today we would not be able to set a standard that was expected to be approached often at that type of level. But to answer your question, how do you arrive at the acceptability of a number 10 to the minus four or five, six or seven, I have no

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wisdom.

2 MR. LAVE: You made a statement that the agency 3 strives for 10 to the minus five or 10 to the minus six per 4 lifetime. Would you clarify that?

5 MR. RICHARDSON: Yes, the agency has recently 6 published the cancer policy proposal.

7 DR. OKRENT: If I take that 10 to the minus five 8 or 10 to the minus six per year in drinking water, for 9 example, is that for everything in the drinking water, or is 10 it for each item?

MR. ELLETT: Actually, it would be separate for man-made radioactivity and radium. That was just for administrative simplicity, we felt that anybody who was heavily impacted with man-made, for obvious reasons, surface water, so they would be subject to radium and vice versa. It isn't for each isotope; it is for all isotopes, sum.

DR. OKRENT: I thought that there was a goal that the agency had which was being applied more broadly than for radioactivity.

20 MR. ELLETT: That goal was articulated much later 21 than the drinking water regulations. The drinking water 22 regulation was the first regulation for radioactivity. All 23 other maximum contaminant levels for drinking water were set 24 on the basis of threshold that was obviously inapplicable to 25 radioactivity. I think at the time they were established,

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the agency considered the risk limits rather high for 1 radioactivity, but given the amount of radium contamination 2 and fallout contamination. there wasn't much that anybody could do about it.

DR. OKRENT: No. but I am just trying to 5 understand the answer to the question raised by Dr. Lave, 6 which I thought said that there was a goal by EPA recently 7 announced, that the lifetime risks from something -- I want 8 to find out what the "something" is, should be. I don't 9 know what you said. 10 to the minus five or 10 to the minus 10 11 six.

MR. ELLETT: I think the EPA speakers that will 12 come after me will be better qualified to speak on that than 13 myself. I can only tell you what we have done in the Office 14 of Radiation Programs. 15

The standards that I discuss with you were set 16 before that policy was ever articulated by the agency. It 17 doesn't become a retroactive truth. 18

19 DR. OKRENT: Somebody among the EPA speakers will be able to define the policy, and to what it applies? 20 IS Dr. Page saying yes? 21

22 DR. PAGE: Dr. Anderson is here, too. DR. ANDERSON: What was the question? 23 24 MR. ELLETT: I think it is a safe assumption. 25

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DR. OKRENT: Okay, I gather that it will gshHEE 1 automatically evolve. 2 DR. ELLETT: We will be here for further 3 4 discussion. DR. OKRENT: Are there other questions now for 5 Drs. Ellett or Richardson? 6 7 (No response.) DR. OKRENT: Thank you. I guess it will be useful 0 to hear the succeeding speakers. I gather that Dr. Anderson 9 is here, and she is also with the Environmental Protection 10 Agency, and if I recall correctly, very interested in 11 various aspects of toxic substances and so forth. 12 DR. ANDERSON: Are you ready for me? 13 DR. OKRENT: Yes, please. 14 15 (Pause.) DR. ANDERSON: I apologize for walking in just at 16 the last minute, so I don't know what I've missed. But I 17 looked at the part outlined on the program for me and I 18 represent the part of the PA that works in carcinogen risk 19 assessment. And recently, we are enlarging the office to 20 include the possibility of doing in informal ways risk 21 assessments for other health effects. 22 Can you hear me, or should I put this on? 23 DR. OKRENT: I guess that it is preferred if you 24 25 can.

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DR. ANDERSON: I notice specifically you said I would discuss case histories in the use of risk assessment and risk criteria in this office which is being formed around the carcinogen assessment group.

5 And I would make suggestions in appropriate goals and 6 risk criteria that might be used for nuclear power reactors.

7 The first order of business is something I feel
8 comfortable with. The second order of business, I certainly
9 will have to leave to this committee and to the Nuclear
10 Regulatory Commission.

I think that some of our experiences might perhaps be helpful in forming the basis for further thinking on your part.

The risk assessment activities in EPA have largely been involved with carcinogens and radiation, at least in formal ways of doing risk assessment, and having formally laid out risk assessment documents, become a part of the regulatory process.

So it is this area that I will discuss and I hope as a policy matter can provide some basis for your particular problems.

In 1976, the EPA did announce a policy for assessing risks associated with carcinogens and you can probably recall that the EPA was the first agency to do this. There are four major regulatory agencies involved in carcinogen

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regulation, including OSHA, Consumer Products Safety Commission, and the Food and Drug Administration.

But I think it is important to put risk assessment in an appropriate social context when we think about the use of risk assessment because it is within this context that we have found that risk assessment serves a particularly useful purpose in some case and in other cases, has really been able to provide very little for the regulatory

9 decision-maker.

So I would like to talk about three areas that have certainly affected recent risk assessment within EPA. The first is what I call social policy, which clearly is laid out by the Congress.

And I'm not going to get into details of regulatory authorities, but only to suggest the differences in measure where risk assessment may be plugged into regulating carcinogens.

The second is the approach that EPA has taken in a scientific way to lay out these risk assessments so that we have some uniform procedure agency-wide for assessing risk and presenting the information.

And finally, I'm going to give you on this overhead projector some examples of cases where the agency has used risk assessment as a part of the process and has actually taken an action which has either reached the final stages of

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regulation or is formally proposed.

In this area of social policy, suppose Congress decides right off the bat what is going to be regulated, how it shall be regulated. and who the regulator shall be? 4

Now there obviously are things that are not regulated, so 5 risk assessment in those areas becomes an academic exercise. 6 at least as far as regulators are concerned. Within the 7 establishment that I spoke of, the Occupational Safety and 8 Health Administration has an act which requires that it 4 protect worker health to take feasibility into account. 10

So feasibility becomes the primary focal point for 11 setting worker standards. 12

In the Food and Drug Administration, the Delaney clause, 13 of course, is the clause that comes to mind. That is the 14 15 only clause in the Federal Government that is an absolute ban clause. And clearly, the degree of risk assessment that 16 is appropriate here or useful here is very much less than a 17 risk benefit balancing situation, although there are other 18 provisions of the Food and Drug Act which certainly do use 19 risk benefit balancing approach such as in the drug 20 21 provisions.

Also, in food contamination risk assessment has begun to 22 play a role because of the importance of setting tolerance 23 levels and looking at risks associated with inadvertent 24 contaminants. 25

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Within EPA, we have almost the full range of legal requirements which permit us to use risk assessment in a widely varying number of instances and in many different ways.

And it also leads the scientist in the agency, and that certainly involves my group, to do risk assessments in more or less depth, depending upon what the practical framework is.

So EPA has seven major regulatory authorities under which we regulate carcinogens. And I'm using carcinogens, of course, as example because this is the one area where the agency has clearly stated a policy for using risk assessments and is doing risk assessments in a very consistent fashion.

15 These seven areas are covered under the Clean Air Act, 16 the Water Act, the Drinking Water, Pesticides, Toxic 17 Substances, Solid Waste and Radiation.

And you've already heard about radiation, so I don't have to talk about that. Nowhere in our provisions do we have an absolute ban clause, but we do have a number of different requirements in the FWPCA, or the Federal Water Pollution Control Act.

23 We have provisions or sections of the Act which are 24 technology-based alone. Therefore, risk assessment can play 25 very little role in actually regulating under that provision

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where we have a provision which requires that national water quality standards based on health alone, risk assessment is almost the only compelling force in setting that standard.

And I'll show you some examples of that.

5 Under the Clean Air Act, we do have a provision which 6 appears to be primarily health-based. So, again, risk 7 assessment becomes a very important tool.

8 And pesticides and toxic substances require overt risk 9 benefit balancing. And clearly, here is an opportunity for 10 the full use of whatever risk assessment can provide in a 11 risk benefit balancing approach.

So EPA now has this broad social authority or legal authority to regulate substances which are being subjected to risk assessment.

15 So the question then is how are we conducting these risk 16 assessments so that we are able to present some coherent 17 picture to the people making decisions under these various 18 acts.

EPA has adopted a process for doing this and insofar as possible, the agency has decided that regulation will take place in a two-step process to the extent that the statutes permit this.

The first step will be a step that lays out fully, as fully as possible, the risk assessment part of the regulatory consideration.

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The second step will lay out, insofar as is possible, the social and economic impacts. The two will be considered together as is appropriate under the Act.

Doing the first part, which is our part today, the risk assessment part, the agency decided that it would adopt a consistent approach. And I think, as with any risk, the idea is to define, first of all, how likely the risk is to occur.

9 With carcinogens, this is the qualitative part of the 10 risk assessment and we have decided to take a weight of 11 evidence approach, recognizing that only rarely do we know 12 for certain that something is a human carcinogen.

We express this qualitative part of the assessment in terms of the certainty of evidence, the weight of evidence, or the strength of the signal, taking everything into account.

17 The second part of the risk assessment is quite a 18 separate part of the process and that is on the assumption 19 that the risk exist, just how bad is it in terms of public 20 health.

Needless to say, in these two areas, in carcinogenesis, the tools aren't all that certain. We would like to have, for example, more human epidemiology data so that we can close the gap between the laboratory experience and predictions and what we are actually observing.

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In the few rare cases where we haven't, we regard this as precious data in our possession.

It is the basis for doing the risk assessment in 3 carcinogenesis and it certainly could stand strengthening. 4 Nevertheless, given the tools that we have now, we are 5 going about this risk assessment work expressing the 6 uncertainties, trying to clearly identify the gray areas 7 and, in short, trying to describe these risk assessments as 8 fully as we can to the regulator so that the uncertainties 9 do come through loud and clear. 10

The carcinogen assessment group in EPA, with which I have been affiliated for 3-1/2 years, has been largely responsible for this work. We have done most of these risk assessments that I'm speaking of, and we are charged with insuring the adequacy of risk assessment activities agency-wide.

We have now to date looked at about 100 or so cases, something over 100. We certainly have found that our information is most often not what we have liked to see. There is data missing and information largely incomplete, and so forth.

But given all of the deficiencies in the tools and the lack of data, we still are able to use risk assessment to a large extent within the agency in making our decisions. I have described the weight of evidence approach and the

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idea of expressing public health impacts in terms of magnitude and the public health problem.

I think the one tough area that the agency has not addressed, and it is the reason I can't help you with the second part of my assignment today, and that is exactly what level of the agency would be comfortable with accepting as an acceptable risk or as a safe risk, or at some level that we're even going to set as a target for regulatory action.

9 I think there are a number of reasons why this is 10 particularly difficult for the EPA, where there are 11 different legal requirements, as I described in the 12 beginning, where risk benefit comes into play.

13 Then, clearly, some assigned level of risk isn't going to 14 always apply because you are never going to duplicate or 15 very rarely duplicate exactly the balance between the risk 16 and the benefits.

So it makes sense in those areas for the risk level to
fluctuate, depending upon this balancing act.

In some areas, we have absolutely been driven to propose levels based on some target level of risk. And as I said, I will show you that example. But on the whole, I think these legal requirements cause particular problems for the EPA. We don't want to lock the agency into one target level and then find where there are absolutely no benefits at all, that we are really stuck with at least that level. And

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there are many other reasons that I won't go into.

I have a feeling that you probably heard a good deal about that. 3

I think one thing that has complemented the process in 4 EPA with regards to carcinogenesis is the inter-agency 5 activity. 6

The IRLG risk assessment doctrine has been adopted by 7 whole agencies and is titled, "The Basis for Risk 8 Assessment." 9

It was published in the Journal of the National Cancer 10 Institute in July of this year. I was on the panel that .11 wropte this document and we found it dovetails nicely with 12 the work that we've been doing inside the agency. 13

But I think of primarily importance to you would probably 14 be these case examples, which I do want to show you. These 15 are just some of many, many circumstances we have looked at 16 in EPA where risk assessment has been used. I had to be 17 careful in selecting these because I did not want to bring 18 you in some regulatory program where we really haven't 19 decided what to do yet. 20

21 So these are examples in the public forum already and where a decision has been made. And I have selected them to 22 demonstrate the different uses that risk assessment has that 23 24 have been put to within the agency.

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The Office of Air Programs is faced with a large number of possible carcinogens in the atmosphere to which people are being exposed both in high exposures around sub-population groups exposed to higher levels around point sources. and also nation-wide ambient exposure.

6 The office has a Section J12 that I mentioned that 7 appears to be largely a health-based section of the Act and 8 the question is: How can they implement a regulatory 9 policy? They have decided to use risk assessments in the 10 following ways.

They first have selected this list of organic chemicals. This list has been selected because they think they are the chemicals that they think that people are exposed to at the highest levels. They are very familiar organic solvents -chloroform bromide ethylene, dichloride ethylene oxide nitrosamines, tri-chlora ethylene, tri-chlora ethylene fina-iodine chloride, carbon tetrachloride.

So the idea was to present these to the carcinogensis group for risk assessment treatment.

20 We went through — we have been through many of these, 21 not all of them, but we have been able to present the Office 22 of Air Programs with, first of all, a qualitative statement 23 on how likely these agents are to be human carcinogens. 24 So we have a weight of evidence, or qualitative part of 25 the risk assessment which they can use.

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In addition, they asked us to do something called a unit calculation, and that is to assume that the standard individual is exposed to one microgram per cubic meter for a lifetime, and give them a related health risk number so that they can use this number in setting priorities.

So I have a few examples to show you.

(Slide.)

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8 They are using these unit calculations to make decisions 9 about which agents appear to be the most potent carcinogens 10 because they have to set some priority, they have to have 11 some way of approaching their particular problems.

They are expressed in increased individual lifetime risks. You will see that they fall into categories of one chance in 10,000, one chance in 100,000, one chance in a million, and so forth.

16 The office couples these with some knowledge of exposure 17 in order to set priorities based on human hazard.

DR. OKRENT: Those are lifetime risk, you said? DR. ANDERSON: Right, based on exposure to one microgram per cubic metter.

21 (Slide.)

This particular office then is faced often with looking at residual risks and also looking at relative risks in order to decide both what category should be regulated, as well as whether or not they have done an adequate job in

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regulating to some such standard.

This came up in the case of vinyl chloride. This table represents a comparison of risks associated with a variety of air pollutants.

5 In the case of vinyl chloride, Table 1 expresses the 6 lifetime probability of cancer death due to maximum exposure 7 and Table 2 expresses the lifetime probability of cancer due 8 to average exposure.

9 The second column is the number of exposed individuals 10 and the last column is the total cancer cases expected on an 11 annual basis.

DR. WILSON: When you say maximum exposure, you mean maximum exposure now taking place? I mean, some of these clearly, there were fantastic exposures in the past.

DR. ANDERSON: Right. This is from EPA's point of view based on an assessment of who's being exposed now in the environment over which we have some regulatory options. That is, people living in bands around these various

19 plants where vinyl chloride is an environmental pollutant.
20 DR. WILSON: So that would not include the work
21 place?

DR. ANDERSON: That's right, it does not include the work place. So we are looking at the possibility of regulatory exposure to those individuals living near these plants in the case of vinyl chloride.

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So the idea was to look at some population groups at high risk and here you see before regulation, these individuals living closest to these plants had a fairly high increased lifetime risk due to the vinyl chloride exposures.

5 And there were certainly not an insignificant number of 6 people being exposed at these high levels.

On the whole, we had then an average increased risk of 10 to the minus 4, which is still certainly a considerable risk, and 5 million people being exposed at this level. The agency took regulatory action. The resulting exposures reduced these risks by an order of magnitude. So then the question came up, in fact, it came up in an

13 impressive fashion -- we were sued to lower the 14 standard. And the question was, should we cash our chips 15 here? Should we make the companies involved in this 16 particular pollutant spend more money? Or did we think that 17 we had done an adequate job?

Our office of general counsel used a relative risk 18 concept in arguing that we had, for the time being, done an 19 adequate job in the vinyl chloride case. And they, in fact, 20 presented these two tables in their brief, demonstrating 21 that we had yet to regulate arsenic, benzene, cadmium coke 22 ovens whore we had fairly substantial risk to a fairly large 23 number of people, both in the maximum category as well as 24 the average category with the total impacts, in this last 25

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column obviously being fairly considerable.

In the case of coke ovens, 149 expected cancer deaths per 3 year.

So I think this is a good example of the use of risk assessment in looking at procedural risks as well as a very practical example of where risk assessment has been used in a relative fashion to make practical considerations and practical arguments for and against regulation.

By the way, these numbers are presented with decimal 9 points, not because of the precision of the numbers, but we 10 found if we take the decimal points away and round the 11 numbers off, people simply can't duplicate our exercise. 12 And so they don't know where the numbers came from. 13 So I meant to emphasize those uncertainties. Now in one 14 unique area in the agency, we have had to face the fact that 15 the law. as it is written --16

DR. OKRENT: Excuse me. Did your counsel win his case based on the position that it would be well to work on benzene and arsenic and so forth?

20 DR. ANDERSON: The case was won. And I don't know 21 to what extent in the final decision we agreed that we would 22 immediately work on benzene or arsenic because it was won 23 some time ago. And I think that we haven't really achieved 24 all that much yet, but we are working on it.

25 (Slide.)

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In this particular case -- I realize this is difficult to read -- but this is an area in one of our acts where we don't have the option of considering technology or feasibility or cost and benefits or social and economic impacts.

6 The Act clearly says that we have to set a 7 nationwide water quality criteria number, and it has to be a 8 number, and our general counsel's office told us that if the 9 number was zero it wouldn't be a practical matter that these 10 particular cases are tried at local district courts and that 11 the judge sitting out in the middle of someplace in the 12 midwest being presented with a zero level would simply throw

the thing out of court and never believe it for one minute.

So, in other words, the case has come up in EPA where we had to set some number, and the way we have gone about it is to use risk assessment as the basis for doing it.

These are proposed water quality criteria that 18 have been published in the Federal Register. Comment has 19 been invited. And they have not been finalized. I think 20 generally the comments have been reasonably favorable, at 21 least the methodology or the use of risk assessment has not 22 been - has not really been attacked all that heavily. Some 23 of the methodology, yes. And in some particular cases, the 24 data base for specific carcinogens. But as I said, these 25

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are not finalized.

The idea here was to take the list of water pollutants that we had agreed to consider in the court 3 consent decree to look at the dose response slope, the 4 incidence slope, choosing the most sensitive species, and to 5 come up with an associated water quality concentration that 6 is associated with an increased lifetime risk of 10-5. 7

Now, we assumed -- we had to make basic 8 assumptions about exposure, so we assumed here in the 9 footnote a lifetime daily consumption of two liters of water 10 per day and consumption of fish. And we took 11 bioaccumulation into account because that is one of the 12 driving factors in setting water quality criteria. So, for 13 14 these carcinogens, we came up with these numbers.

Then, our water office decided, "Well, why use 15 just 10-5? Why not propose a range?" So, they proposed the 16 number associated with 10-7, 10-6, and 10-5, and asked for 17 comment. So, they haven't really set one level yet, but you 18 can see what they are driving at. 19

DR. LOWRANCE: What does that 10-5 number mean? 20 DR. ANDERSON: It is the average increased 21 lifetime risk of getting cancer from exposure to these 22 particular chemicals based on an average daily intake of two 23 liters of water contaminated at that level per day for a 24 lifetime, over 70 years, and a consumption of .0187 25

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kilograms of fish per day with the appropriate bioaccumulation factor.

3 DR. OKRENT: For each one, so if four of them or 4 10 of them were in your water, you would have 10 times the 5 effect?

DR. ANDERSON: Right. And since these are 6 nationwide -- this point has been raised, you know, how do 7 you take into account multiple exposures from a single river 8 which happens to be very polluted? And the answer has to be 9 that, first of all, these are obviously very low 10 concentrations, and we simply haven't been able to take 11 co-carcinogenesis into account in setting these levels, 12 because where we have the information we have taken it into 13 account but we for the most part just don't have that kind 14 15 of information.

And also, since this is a nationwide number, it is 16 not a localized number. Localized circumstances can be 17 taken into account when state implementation plans are 18 approved by the agency. Since these are criteria levels 19 that are target levels, they are not enforceable levels. 20 And then a state presents a scheme for meeting these 21 standards. If they have some exceptional circumstance, the 22 agency can grant a variance. So if they have a particular 23 circumstance that can be taken into account at that stage of 24 the process. 25

493 12 04 DR. WILSON: I understand the numbers in the DV HEE 1 table, taking the two highest numbers -- the TTCD and the 2 DBNA -- I presume those are different because BCME 3 accumulates more: is that right? 4 DR. ANDERSON: Yes, that's right. And in this 5 case, where there is bioaccumulation or substantial 6 bioaccumulation, obviously the number was driver, by that 7 rather than the two liters of water per day. 8 This is a case where risk assessment has been 9 used, and it is unique in the area, as far as I know, where 10 it has been used as the only basis for proposing a number 11 that is saying that protecting public health. 12 DR. OKRENT: So. if I understand correctly, this 13 is a proposed goal and, in fact, it is proposed in terms of 14 10-5 and 10-6 and 10-7? 15 DR. ANDERSON: The level associated with that, 16 making certain assumptions about exposure into account. 17 DR. OKRENT: And if it were adopted, it would 18 still be a goal? 19 DR. ANDERSON: The way the Act is constructed, 20 these water quality criteria are criteria to be aimed for in 21 the state implementation plans, so these are not enforceable 22 levels, although our lawyers tell me they do take on a 23 fairly substantial significance. 24 DR. OKRENT: That is like the way you are fixing 25

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pv HEE 1 up the smog in Los Angeles.

2 DR. ANDERSON: Congress did this. Don't blame 3 us.

DR. OKRENT: I am not blaming you. I am only saying you can't always meet EPA's goals.

DR. ANDERSON: Yes. And the reason I started the discussion by mentioning the importance of the social constructs largely created by the Congress, the extent to which risk assessment is useful, at least in EPA, very much depends on the practical circumstance.

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(Slide.)

Finally, I wanted to show some examples of where risk assessment has been used in reaching benefit balance decisions. These are --

DR. OKRENT: Could I come back to the last point. Does EPA have any basis for measuring the cumulative risks from drinking water supplies with regard to carcinogenic effects as they exist now and, let's say, including radiation and without radiation for whatever it is — some very big city water supplies, not those fortunate enough to have the water they make beer out of?

DR. ANDERSON: I think that what you're driving at is something we would very much like to do. We haven't been able to do this, and, in fact, again, in a practical framework where we have, for example -- I know you're using

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1 this as an example -- I guess what you really want to know 2 is have we been able to take total body burden into account? 3 And I don't think we have. It would be ideal, but we 4 haven't been able to do it.

We would like to be able to say that we speak in terms of very low risk anyway and we hope that when they are all put together for an individual exposure we are doing reasonably well. But we really don't know. So, we aren't approaching it that way.

There are, in fact, some areas in EPA where risk 10 assessment is being left out of the process because it is so 11 hard to do. And in the case of drinking water there has 12 been a regulation to put charcoal filters in drinking water 13 supplies to simply take who knows what out, and they really 14 haven't been able to say what it is they're taking out. 15 Their regulation in 10 city public water supplies where 16 there are a lot of people taking drinking water from there 17 and where the water is dirty enough and they say, "We think 18 this makes sense. We can't spell it out in risk-assessment 19 terms." 20

21 DR. OKRENT: I vaguely recall seeing a paper by 22 Dr. Page when he was at Cal Tech on that area.

23 DR. ANDERSON: Perhaps he can shed more light on 24 this.

Now, this is an area where we certainly use risk

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I assessment probably for the longest period of time.
2 Pesticides certainly came into focus in the agency early
3 on. And risk assessment, the risk assessment process,
4 initially was written very much with the pesticide situation
5 in mind.

In short. the amendments to the Federal 6 Insecticide Act require a balancing of risk against 7 benefits. This permits an opportunity to squeeze risk 8 assessment for all its worth. And we would certainly like 4 to have better tools. In each of these cases there was a 10 part of the risk assessment which is not reflected on this 11 chart. and that is the qualitative assessment. This is very 12 important to EPA's process because the data can certainly 13 give more or less certainty to the signal that something is 14 in fact a human carcinogen. So, keep that in mind when we 15 look at these. 16

In the case of chlorobenzilate, the qualitative 17 data was not the strongest we'd ever seen. I think the 18 response was in the male liver, which some toxicologists 19 really don't regard as providing the strongest evidence at 20 all. Nevertheless, we regarded this as some evidence that 21 chlorobenzilate might pose a risk to humans. On the 22 assumption that it was a human carcinogen, we did some 23 qualitative risk assessment work. The primary use of 24 chlorobenzilate was for citrus fruits. The exposure 25

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assessment provided to us assumed a nationwide exposure of
 220 million people. The calculation provided these lifetime
 increased cancer risks due to the exposure on the citrus.

Now. the second is the lifetime risk to the 4 applicators because of their obviously higher exposure. The 5 first number. 10-6. is the lifetime risk to the people 6 eating the fruit because of some residues. In short, the 7 agency regarded this -- or the office of pesticide programs 8 and ultimately the administrator -- as a low risk. But in 9 the case of citrus. the benefits are exceedingly high. The 10 registration was retained, but in some moderate uses where 11 the benefits were regarded as very minimal -- such as I 12 think there was a minor use to control spiders around boat 13 docks, and that use was canceled -- it was decided that even 14 a low risk outweighs a very low benefit. 15

DR. LOWRANCE: Point of clarification. I don't quite understand how these numbers work. I think I am being simpleminded and just missing something. But would you just run across, say, the top line and tell how you got to the right-hand column?

21 DR. ANDERSON: Yes. I think this is important, 22 and I have left it out. In using quantitative risk 23 assessment in EPA, we try to emphasize that a two-pronged 24 approach is appropriate. First of all, with EPA's mission 25 it is very important to look at the increased individual

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1 risk because there can be pockets of high exposure; in this 2 case, the applicators, for example. So, it is important to 3 focus on the individual's increased lifetime risk.

In this case. I didn't, when I made up this slide, 4 I didn't have the number of applicators, so I couldn't fill 5 in the last column on total impact. But in other words, we 6 have an increased individual's risk, and then we have a 7 total nationwide impact. If we only look at the total 8 nationwide impact, we could have very few total cancer cases 9 nationwide, but we could have pockets of exposure where 10 individuals are suffering very high risks. So that is why 11 we emphasized both. 12

Alternatively, where we have, in this case, 220 million people exposed to very low levels with an increased risk of 10-6 with a nationwide number of expected cancer deaths per year of 1.5 or so, you can see that there could be circumstances where 220 million people would be exposed to a risk that would be considerable, and you would see that impact in those total numbers.

20 DR. WILSON: I think one thing that is troubling 21 us: if I take 220 million and multiply it by 2 x 10-6. I 22 get 440: I divide by seventy per life, and I get six 23 instead of 1-1/2.

DR. ANDERSON: It should come out to 1-1/2.
DR. WILSON: I multiplied 220 by 2 x 10-6, and

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that's 440. I divide by 70, and that is six. DV HEE 1 DR. ANDERSON: Okay, maybe I have made an error 2 3 here. DR. OKRENT: Well, in fact, if you look at the 4 first line under "amitraz," where the numbers are similar, 5 one gets eight, which is what Bill Lowrance said. 6 DR. ANDERSON: Yes. That evidently is an error. 7 I apologize. You should get the answer by multiplying the 8 first column by the second column and dividing by 70. 4 DR. LOWRANCE: I was just trying to be sure that I 10 understood. 11 DR. OKRENT: It is probably 7.47, if you want me 12 to quess. 13 DR. ANDERSON: Yes, that could be a typo. As long 14 as you understand what I am getting at. 15 Nevertheless, that was regarded, whether it's one 16 case or seven cases, as a low enough risk relative to the 17 benefits and the registration for citrus use was retained. 18 In the case of amitraz, there was an application 19 to the agency to consider this for registration. The 20 qualitative data was very weak, indeed. We had a signal 21 that it might cause cancer in one sex at one dose level of a 22 tumor which was very high in the historical controls. 23 Needless to say, blip of a signal was very uncertain, so we 24 said this could be regarded as suggestive evidence only and 25

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it would be very desirable to have another study.

But on the assumption that amitraz is a 2 carcinogen, we went ahead and looked at the dose response 3 curve we could construct from the data we had and said if it 4 is a carcinogen the impacts would look something like this 5 for consumption of apples for which the application was to 6 use amitraz on apples and pears. We looked at nationwide 7 impact on apple consumption eaters, and we came up with an 8 increased individual risk of around 10-6 and total impacts 9 in the case of apples and pears of eight and six. 10

For the applicators, you will see that the risk is somewhat higher.So this permits the program to look specifically at special labeling requirements for the applicators.

In this case, the risk-benefit balancing decision 15 came out -- I think it was pears -- that there were no good 16 substitutes for, so they decided to grant a three-year 17 temporary registration until more data could be generated. 18 In the other case it tipped the other way because there were 19 other pesticides available and the benefits were not thought 20 to be as considerable, and that registration was not 21 22 permitted.

23 So you can see how these things can teeter 24 depending upon just how strong that benefit side of the case 25 is.

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DR. OKRENT: What would you think are the uncertainties in your estimate of lifetime probability of cancer deaths due to exposure? Is it larger than a factor of 10?

DR. ANDERSON: This is something that we dont't 5 have the best information, and I think, as I said in the 6 beginning, we have very few cases where we can actually 7 close the gap between the predicted cancer cases and 8 observed cancer cases. In other words, there is great 4 debate on the shape of the dose response curve within 10 species extrapolation and even greater debate when you cross 11 species lines. 12

We are now doing something in the carcinogen 13 assessment group which I think will help. This whole 14 quantitative assessment business is based on essentially six 15 cases which were presented in 1975 as part of an NAS 16 17 pesticide report, where I think three of the cases came out 18 of the nose. Two of them were off by an order of magnitude lower. And one was off I think it was -- yes, it was off by 19 an order of two orders of magnitude. 20

In short, the basis for doing the qualitative assessment is not all that certain, but it is stronger than the quantitative and the qualitative. We have about 25 cases where we can compare the animal results with human results, and the correlation is pretty good. There is one

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case where it is not that good, where we don't have the animal data, on arsenic.

3 DR. OKRENT: Well, let me pose the question a 4 different way. We have been talking about several chemicals 5 here. Let me assume if we consider 100 of these, can one 6 rule out that for one of these that the lifetime risk turned 7 out to be 10-3 where you thought it was 10-6?

B DR. ANDERSON: No, we can't rule that out. What We have done in EPA is taken, as best we can, consistent assumptions and the same extrapolation model. Now, if you use a different extrapolation model, you get answers all over the place. So, the way the agency has been using this information is very much in a relative sense and not as an absolute correct number.

The other part that makes these numbers uncertain 15 aside from the uncertainties in the shape of the dose 16 response curve and across inter-species extrapolation, 17 certainly is the lack of good exposure information. 18 Exposure assessment is a very weak area indeed. So, when I 19 started out, I said these numbers are uncertain. I want to 20 emphasize again they are uncertain. But it is the best we 21 22 have.

DR. OKRENT: Now, I am not faulting you in any
way.
DR. ANDERSON: No. I just wanted to be sure, if I

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hadn't emphasized that.

DR. OKRENT: We face in the nuclear safety area 2 large uncertainties with regard to many predictions, and one 3 of the thorns in our side is what to do when you talk about 4 quantitative criteria in the face of these uncertainties. 5 And I am trying to ascertain a little bit what it is one 6 thinks could be the range of uncertainties here in the kinds 7 of things you are looking at and how EPA thinks it is 8 reasonable to, A, define the uncertainties and, B, to act in 9 the face of them. 10

DR. ANDERSON: What we have done is we certainly 11 know about the six cases that have been published. In 12 addition, we say that we take the linear model because we 13 want to -- we don't want to underestimate the risk because 14 if we are underestimating the risk we could have a national 15 disaster and not know it. But at the same time, if we are 16 way overestimating the risks, it is not being particularly 17 helpful to the process of setting regulatory actions. We 18 hope we are not vastly overestimating, and certainly we 19 don't want to underestimate. 20

What we are trying to do right now as an activity in the agency is to take the 30 or so possible cases where we have some human data and we have the animal data and we can compare the predicted human response with observed human response. Now, this doesn't mean we have the best

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epidemiology studies in all these cases, but we can at least 1 set an upper bound to see how close we are coming. And I 2 think in the near future we will be able to say a little 3 more about this. It looks like thus far -- and we're still 4 going through our calculations and we are adding more cases 5 -- that in about 90 percent of the cases we are coming out 6 within an order of magnitude, again taking very consistent 7 assumptions and the very same extrapolation model in every 8 case. 9

DR. WILSON: Arsenic would be way off; wouldn't it? I mean, there is no way you can predict the human taking the animal data from arsenic, you can get the human data.

DR. ANDERSON: Yes, in the case of arsenic we don't have the animal data.

DR. WILSON: Well, there is some animal data, but it doesn't give the right answer.

DR. ANDERSON: Yes, that is the one exception where we really don't have good animal backup data.

20 DR. WILSON: If there is another chemical out 21 there like arsenic and all you have is animal data, then 22 that might be the catastrophe.

23 DR. ANDERSON: Well, I am not sure I understand. 24 DR. WILSON: Well, we have some -- I know of about 25 60 different attempts to find carcinogenesis due to

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arsenic, and they basically either find very small carcinogenicity in animals or none at all. And then we know it does -- it is moderately potent for humans. In fact, it has been disputed over the years, but I think it is now generally agreed that it is.

But if only you had animal data and then you are trying to predict human data and make a plan, "Shall we use arsenic as a pesticide," the answer would clearly be "Yes." And you might well be wrong. And I am just worrying about that. These are the sort of things we are getting in the nuclear business, too.

DR. ANDERSON: But this is the qualitative side of the question. This is where we keep saying we are more certain than we are on the quantitative side, and that is: how likely are all of these animal bioassay tests to give us appropriate signals to indicate cancer risk where it exists? In the case of arsenic, that is the only really good exception in 26 cases.

DR. LAVE: Benzene?

DR. ANDERSON: Well, there are some indications if you pick the right model you might get leukemia. That is another good example.

23 DR. WILSON: It is also the numbers on benzene. 24 On benzene, what numbers we do have, if you put an upper 25 limit on animal data, it is not inconsistent with human

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1 data; whereas, the arsenic, the animal data is actually 2 inconsistent. It is not that it doesn't exist; it is 3 inconsistent.

DR. ANDERSON: Yes. In the case of aphlitoxin, of course, we only looked at responses in rats. We would have thought aphlitoxin was not a human carcinogenic. So, picking the right animal model certainly is important.

Just wandering through these quickly -- I think 8 you're getting the drift here of what we are trying to do --9 10 chlordane and heptachlor, which the agency canceled and 11 suspended, had substantial nationwide impacts mainly because the persistence and bioaccumulation in the range of the 12 hundreds. So, the agency did cancel and suspend those 13 14 uses. It retained only some underground uses for termite 15 control.

Finally, this is a case of kind of an after-the-fact risk assessment where the agency, before the guidelines were adopted for risk assessment, set an action level for kepone in fish in the James River. Most of you remember, I am sure, the James River incident. This was set largely on economic grounds: how much could we permit and still not kill the fishing industry down there.

23 When we did the risk assessment calculation after 24 the fact, we found indeed the risk was somewhat high 25 relative to other risks, where carcinogens had been

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1 regulated within the agency.

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I think the agency is not taking a risk benefit 2 approach to setting these action levels, and there have been 3 a series of --

4 DR. OKRENT: Excuse me. So there has been no 5 decision?

DR. ANDERSON: This was not changed, because the 6 fishing industry has largely -- they haven't had a lot to 7 fish down there, recently. They haven't changed this but 8 they have taken a different approach to setting action 9 levels, one where it is considered in the process of setting 10 the action level. This was before the agency really started 11 to do risk assessment work, that we were forced to use 12 safety factors and a crystal ball, and some knowledge of the 13 economic circumstances, in setting these levels. 14

DR. OKRENT: So, consumption was permitted, or was not?

DR. ANDERSON: Yes, with these levels. A few more 17 18 cases came to mind that I thought might be interesting for you all. We have some localized problems where it's very 19 hard to get something across to the public. Several 20 examples. One, we have a discharge of nitrosamines in our 21 Region 5 office in Indiana. There was sort of local panic, 22 you know, nitrosamines belonging to a family of well known 23 carcinogens, and the citizens were quite concerned. There 24 were two drinking water communities taking the water 25

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supplies downstream from this discharge, so the question
certainly wasn't a qualitative question of, are nitrosamines
cancerous or not, but rather, what kind of impacts are we
experiencing?

We had some exposure levels for these local 5 communities and we did this kind of risk extrapolation work 6 and we found that the levels to the people, the individual 7 increased lifetime risk levels to the individuals living in 8 these communities, was on the order of 10 to the minus 9 seven. It turned out that we emphasized that these numbers 10 are uncertain, that this is a relatively low risk estimate 11 and certainly doesn't indicate a public health emergency; 12 nevertheless, precautions seemed to be -- it seemed to be 13 reasonable to take precautions to reduce exposure. It 14 seemed to serve the regional office well. They were able to 15 get this across to the communities and the stir really did 16 17 die down fairly rapidly.

We had another similar discharge from a point 18 source into air in upper New York State. It was a 19 trichloroethylene discharge, and again we had some exposure 20 levels at monitored levels around the plant - in this case, 21 it looked like the public health risk was in the 22 neighborhood of 10 to the minus five, so what we're doing 23 with these numbers is we are comparing these now, but we 24 have kind of set up a scale and we're using the same model 25

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with sort of a scale of where regulatory actions with 1 regards to carcinogens have fallen. 2

And we can say this is somewhere on that scale, 3 it is somewhat higher, or it is the upper end or the lower 4 end of that scale. That is about as close as we have come 5 to really setting some target levels. But again, this was a 6 case where it seemed to emphasize that there was not an 7 enormous public health problem there, certainly not one 8 calling for immediate closure of the plant. EPA certainly 9 does have that authority. I think we recognized we have to 10 use it very carefully. 11

But if we thought that the circumstance was 12 certainly bad enough, we could simply shut the plant down. 13 DR. OKRENT: A 10 to the minus five number would 14 arise from continued exposure at that level? 15

DR. ANDERSON: Yes. Assuming the individual lives 10 there and is exposed for a lifetime of 70 years to the level 17 around the plant, yes, the lifetime average exposure. 18

DR. OKRENT: Okay. 19

DR. CASTENBERG: I noticed in some of the entries 20 in the last table -- used 220 million, the total population 21 of the U.S. If you had an extensive list of all the 22 chemicals used in the environment, how many of them would 23 the average person in the United States be exposed to? 1000 24 of them? 50 of them? 25

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DR. ANDERSON: I don't know. That list of 42 that I started out with, which is just the Office of Air Programs list of likely organic solvents to which people are exposed, certainly gives us a good start. And that is only their first cut. I really don't know the answer to that. I think o our Office of Toxic Substances could probably come closer to having information of that sort. I just don't have it.

DR. CASTENBERG: The reason I bring it up is I was 8 also concerned about this 10 to the five number -- not 4 concerned, but interested in the 10 to the minus five 10 number. Then the numbers on your last page are 10 to the 11 minus six numbers, for total U.S. population, the 220 12 13 million. The numbers on here are 10 to the minus six, and give you numbers like eight deaths, 10 deaths, six deaths, 14 and, at 10 to the minus five, then those numbers would be 80 15 and 60 instead of eight and six -- and if I am exposed, or 16 if you are exposing the population to 1000 of these things 17 on the list, or 10,000 of these, those numbers start to get 18 very large. 19

DR. ANDERSON: Yes, if in fact the exposures are to the same people at the same levels and so forth, although when we're talking about 10 to the minus five I think it is fair to keep in mind that everybody has a one-in-four chance of getting cancer, anyway, and a one-in-five chance of actually dying of it. So we're talking about a

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one-in-100,000 or one-in-a-million chance here. So, you could be exposed to quite a few things before you would have an incremental increased risk. That would be really outstanding; in fact, we sometimes look at some of these risks as levels that are below levels that would be detected by epidemiology. No detectable cancer when you get down ó this low. 7

So these are pretty low levels. But needless to 8 say, if an individual is exposed to enough different things 4 at low levels, presumably there is an accumulation of risk. 10 There is no question about it. 11

DR. LAVE: Could I ask you about the bioassay 12 data? In the case of aphilitoxins, as you mentioned, you 13 get very different numbers depending upon whether you're 14 extrapolating from mice or rats. How do you choose which 15 animal to extrapolate from? 16

DR. ANDERSON: We always pick the most 17 18 sensitive -

DR. LAVE: I thought that was your answer, because 19 that, then, means you don't have a consistent set of 20 methods. In some of the tables you've got human 21 epidemiology data; in some of these you have quite a number 22 of different animal species that were tested; in others, a 23 single animal species; and therefore the ones where there's 24 a single animal species, unless it happened to be the most 25

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sensitive one -- which is not very likely -- then you may be off by a factor of 1000 in the table.

3 DR. ANDERSON: There's a little bit of intimation 4 emerging that is somewhat helpful in this regard. Bruce 5 Ames and Ken Hooper and some of his people are putting 6 together -- they are computerizing all of the animal 7 bioassay work that has been done and I recently heard Ken 8 Hooper present a paper -- these results were not published. 9 They were alluded to in a Science Magazine article.

What they are saying they are finding is where you 10 have a positive response at all, and you threw out all of 11 your negative responses, that you are coming out with a 12 reasonable measure of potency; in other words, where you 13 have a positive response, you don't get potency measurements 14 all over the board. If your test model isn't going to pick 15 up the cancer signal at all, then you would just get a 16 negative response. 17

But this is certainly a problem. It is one of the 18 problems. When we started doing cancer risk assessment work 19 in EPA, we recognized it applies both to the qualitative 20 work as well as the quantitative. Chemicals have been 21 tested in very uneven fashions and not only that, some have 22 been tested in 30 systems and some in only one, and not 23 only that -- the quality and the design and conduct of the 24 study varies all over the place. 25

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DR. LAVE: But when I first asked somebody at the FDA that question, they said to me, Well, of course the animals you use are the ones that metabolize whatever it is that we are exposing it to, the same way that humans are exposed, and metabolize it the same way that humans do. You obviously don't use an animal that doesn't metabolize it the same way.

8 And that made a lot of sense to me, except then 9 when I talked to some of the people over on the other part 10 of FDA, they said, Well, of course we don't do it that way. 11 We use the most sensitive species.

DR. ANDERSON: Well, it would be nice if we could do what you first said: that is, be able to follow metabolic pathways and say, This test model has the same metabolic pathway as the human.

But most of the time we really have no earthly idea what the metabolic pathway is, so we couldn't possibly do it.

DR. WILSON: Wasn't part of the answer to it that all of the animals one uses are, in fact, mammals, so in that sense there is a metabolism? We're not using insects and they're not using ish.

23 DR. ANDERSON: Well, of course the reason we're 24 using rodents, again, goes back to the case of the 26 25 chemicals where we have some correlation information. If we

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had the same kind of data base for some other test model, I
 would think we could use it in the same way.

There is nothing particularly unique except for the amount of data, the data base.

DR. WILSON: Incidentally, we have a paper coming out which should be in press about now, comparing animal carcinogens in the different animals and it does have the results you described.

9 DR. ANDERSON: I think that's going to be very 10 helpful.

DR. WILSON: We agree almost exactly with Bruce Ames' output. I sat down with him and we went over the computer output.

DR. ANDERSON: We have talked to Ken about coming in and presenting some of this, because it goes right along with the work you are trying to do, that is, the correlation project of predicted and observed for every case we applied.

DR. LAVE: Can I just see if I can paraphrase what you and Dick just agreed to, to see whether I understand it? That is that where you find that a substance is a carcinogen across a number of species, that the potency across species will be quite similar; does that paraphrase it? DR. WILSON: Within a factor of 10, yes.

25 DR. LAVE: I would have thought some of the things

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we have been talking about earlier contradict that, but they
 may be the rare exceptions.

3 DR. WILSON: I think there may be three or four 4 exceptions. Arsenic is the big one.

DR. CACHERINI: Part of the answer to that question, in regard to the one part of FDA and the other part of FDA -- it depends upon whether one is looking for an estimate of quantification of the risk or whether they are trying to determine whether there is or is not a risk.

DR. OKRENT: Would you give your name?

In the first case, one would require a more appropriate model to the human than in the second case, where one's looking strictly to see if they can incite a risk in an animal model. So I think the appropriateness of the use for the actual number of quantification of the risk requires a model which is consistent with the human.

DR. OKRENT: Dr. Page?

DR. PAGE: There are two other points that go 18 along with what is coming out of Bruce Ames' laboratory. 19 One is that part of the exercise was to figure out whether 20 or not tests that came out negative were compatible with 21 tests that came out positive, in the sense that if you 22 looked at the potency that was applied by the positive test, 23 you could try to figure out what the power function was of 24 the negative one, to see whether or not it was likely that 25

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it would show up negative when that was given.

A lot of these inconsistencies between species turns out to be an inconsistency of the test design, where if you took into account the power of the test then you would see that these differences of potency aren't nearly as big as what would first appear if you looked at the test just sort of at face value.

The second point is that --

9 DR. WILSON: Isn't that just a statement that they 10 were seeing positive -- people were saying positive or 11 negative before and as soon as they put it in a number, 12 saying an upper limit, and saying, this is less than 13 something or other, then the inconsistency appeared? If you 14 just say positive or negative, you can get apparent 15 inconsistencies. But then you have to include the test.

DR. PAGE: That's correct. If you looked at the test and figured out what the power function was, and you graphed the tests -- that is what Hooper's people are doing -- then it looks like -- it looks much more compatible.

20 DR. ANDERSON: There's no question about it. You 21 do simply have some chemicals that the test model is 22 inappropriate — for whatever reasons, they can't give 23 enough dose to have the power to reach an adequate level.

I have just one other example I wanted to mention, and this is something that is plaguing EPA, and we are

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having to sit back and think hard about what to do - and that is the likely impacts of dieselization.

It is a case where risk assessment is undoubtedly going to play a large role, and I think the synfuels development also goes along the same pathway. The way we are looking at this is we need some answers fast, as usual, and so it is not possible to get all of the research 7 information we'd like to have. 8

So the way we are approaching this, from a risk 4 assessment point of view, is to attempt to get some 10 information to compare relative potencies with other 11 combustion products for which we have more experience, such 12 as coke ovens, cigarette smoke, coal tars -- and then get 13 some relative comparison with diesel exhaust, because the 14 question is not whether or not diesel exhausts are 15 carcinogenic -- we know they are, as are most combustion 16 products. But the question becomes: how much of a public 17 health hazard are we likely talking about as we go along 18 this dieselization pathway? 19

We very reluctantly did some very preliminary risk 20 estimates based on coke oven information. And no matter how 21 many caveats we put in and how much we emphasize we didn't 22 particularly want to do this, our Office of Air Programs 23 said they needed some information and something was better 24 than absolutely no idea, and that they were compelled to 25

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give at least some signal.

They wanted to know whether the dieselization was 2 likely to impose a large public health problem, so we did do 3 this. reluctantly. and we did find that it is conceivable 4 that diesel exhausts are as potent as coke oven emissions, 5 and if that data is at all applicable, and if their exposure 6 estimates are at all accurate. that we could be -- it raises 7 a warning signal. We could be dealing with a public health 8 9 problem of some magnitude.

But we now have some research in progress where we are trying to get some answers. We have been trying to compare these potencies using skin paintings and intratracheal data, and we hope to have a biological basis for doing this work. But I think this is an example of trying to use the best tools we have in a very uncertain circumstance.

17 But nevertheless, having some rough idea of -- or ballpark estimate --- is better than having simply no 10 information at all. So, in short, I think at EPA from the 19 experience that I've been talking about, the experiences 20 with carcinogens that I've been talking about, I have been 21 able to show you examples where we use risk assessments to 22 set priorities, to look at relative risk, when we are 23 considering further regulatory action. to look at residual 24 risk where we have taken an action and we want to know if 25

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that is good enough, in risk/benefit balancing decisions and in one unique case where we have actually proposed these criteria based on increased individual risk level.

This concludes, I think, my contribution to this. And as I said, I simply can't help you with the second part of my assignment.

DR. OKRENT: Dr. Leachman?

B DR. LEACHMAN: Yes, I am from the House Science and Technology Committee. I have a question with how much we have to know about -- the chemical carcinogens is something I know a little bit more about; namely, the radioactive or rather the radiation effects.

I think I understand correctly that the radiation 13 effects we know vastly more than we do about the chemical 14 carcinogens. and we also realize the difficulty that the 15 chemical carcinogens act in different ways, whereas 16 radiation generally acts the same way. But from a societal 17 or even a legal point of view, we are faced with the 18 realization that in the case of radiation we are now looking 19 back in a somewhat retrospective way, and realize that we 20 are very cautious, that most of the radiation we assumed in 21 a very pessimistic way that there is a linear dose effect 22 relationship. 23

24 We set up standards and we have the public very 25 concerned. Now, in retrospect, we realize that was overly

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stringent, and the concern was not properly placed. I
wonder whether there is a similar apprehension coming along
in the chemical work, in the sense that you do not -- I
sense that you do not now know the dose effect relationships
of small doses and maybe there is hardly any effect, and
maybe this is being overly stringent and overly cautious,
notwithstanding the fact that Congress has laid it on you.

BR. ANDERSON: A couple of things. In my ignorance, I guess I didn't realize that the dose response at very low doses of radiation had been all that thoroughly --

DR. LEACHMAN: Well, there are two types of radiation, the low linear energy transfer, low LET and the high LET. Most of the radiation that people encounter, except in buildings, is the low LET and there the dose effect relationship is generally believed to be much less at the very low levels, than previously expected. This is on the basis of current data.

DR. ANDERSON: From BEIR.

20 VOICE: You have only read a draft of that. I 21 think that is a limited interpretation by one group. 22 DR. LEACHMAN: Let's just say the majority, then.

23 DR. ANDERSON: I thought there was some debate, 24 and I don't want to talk about it except to say that in 25 general circumstances for chemical carcinogenesis that is

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less certain than the radiation area. That has a much more 1 solid foundation. When we talk about low dose exposures, 2 several of the models do approach the area of the low dose. 3 We are using, again, the best tools we have, as we can close 4 this gap I've talked about, between laboratory experiments 5 and some human observation, and I think it is possible, we 6 certainly have many things that are suspect carcinogens 7 which are in wide use --8

DR. LEACHMAN: Could I ask the fellow one
question? Do you use the Ames test at all? Do you always
have to use the animal test?

DR. ANDERSON: We have taken a position on that, 12 which is an official agency position and that is that in the 13 qualititative sense, we regard the Ames test and some other 14 short-term in vivo and in vitro test data as suggestive of 15 carcinogenesis in the present correlation, but we have not 16 yet been willing to use that information alone to form the 17 basis for saying that we really believe that the chemical is 18 19 likely to be a human carcinogen.

20 DR. LEACHMAN: But I was asking in a different 21 sense.

22 DR. ANDERSON: In the quantitative sense, no, we 23 don't use the data from the Ames test to do quantitative 24 extrapolations.

25 DR. LEACHMAN: That's not the sense I am asking.

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I I am asking: can you use the Ames test, which is so simple, cheap -- and you can get good statistics, to try to stablish a dose effect relationship?

DR. ANDERSON: That is what I was getting to, and we don't. We are not doing it for carcinogenesis at all. We don't think it is appropriate. However, the agency is attempting to write some guidelines for another health effect, mutagenesis, and looking at what, if anything, would appear to be appropriate for a risk extrapolation for an endpoint of mutagenesis, not carcinogenesis.

And that point has not yet been answered, and the agency has not taken an official position on it.

DR. OKRENT: Well, thank you, Dr. Anderson. I found that very interesting and informative. And I look forward to having someone keep us better informed in the future than we have been in the past.

17The next speaker is Dr. Page, also from EPA. But18first, why don't we take a short break?

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DR. OKRENT: If we can reconvene, I think our next speaker is Dr. Toby Page, who is also with EPA, indeed I 2 believe from Cal Tech. 3

(Pause.)

DR. PAGE: Let me just start with slightly more 5 than the usual disclaimer. Steve Jelenick was the one who 6 was invited to come here. He is the Assistant Administrator 7 for Toxic Chemicals, and since I have been working on the 8 concept of unreasonable risk, I was the one to fill his 9 shoes. However, I don't speak for EPA. I'm really a guest 10 scholar on a leave of absence from Cal Tech, so you can't 11 hold EPA responsible for anything I say. So that is a 12 13 strong disclaimer.

Now, having said that, I think what I would like 14 to do is just sort of talk a little in continuation of the 15 kinds of things that you were talking about with Betty 16 Anderson, and bring that into the approach that I sort of 17 18 see might be emerging from the toxic substances program and try to draw some parallels with the kinds of problems that 19 20 you people may be having with safety programs for nuclear 21 power.

And of course the last is what I know the least 22 about. so these will be sort of shots in the dark, but maybe 23 they'll be useful and maybe they won't be. 24

Okay, now. One of the things that emerged from 25

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1 the discussion with Betty Anderson is this number of 10 to 2 the minus 6 or 10 to the minus 5, and basically this is 3 looking at some sort of criterion for acceptable risk that 4 is focused on what is entirely on the risk side.

5 This is just not really in the cards for the toxic 6 chemicals control program, basically because the legislative 7 history requires balancing of cost, benefits, and risks. 8 That is quite clear. And so, what we are really directed to 9 do by the legislation is to develop a concept of 10 unreasonable risk that is up front about the balancing 11 process.

I think sort of as an aside there always is a 12 balancing process, even in the Delaney Amendment which 13 ostensibly says it does not have a balancing process. The 14 problem with the Delaney Amendment in my mind is not that it 15 precludes cost-benefit analysis. It is that it forces 16 cost-benefit analysis underground, so that we find people 17 unwilling to start the machinery to do appropriate tests 18 because they are scared of how they might come out. If they 19 came out positive, then they'd be forced to do something 20 that would lose control of the process. So what we find is 21 that in 19 years, only three chemicals falling under the 22 Delaney clause which seems a bit strange -- there are a lot 23 of carcinogens in the food supply. 24

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So this sort of gets to the end of what I wanted

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to say, which is basically, if we think of a cost-benefit analysis not just on the chemical at hand but on the whole structure of incentives and institutions, we may get much more power and use and guidance out of it that way.

And in a way what I'm saying is, if we are going 5 to try and set -- if we're going to try and make decisions 6 about how you're going to have street lamps, traffic lights, 7 or red and green, or whether you're going to have policemen 8 and stop signs or yield signs for a city that has got 40,000 9 intersections - it probably does not make too much sense to 10 do a thorough, year-long cost-benefit study on each one, 11 each intersection. 12

You could do a cost-benefit analysis on the cost 1of information, and you may need to develop some rules of 14 thumb that say we're going to be pretty crude, we're going 15 to set a green light for 20 seconds and a red light for 20 16 seconds, and then if there are problems, we may have to 17 18 readjust, but we want to get a lot of traffic lights out. And this may be a better technique than spending five years 19 or one year or whatever on a particular intersection. 20

Now the parallel I'm trying to draw here is that there are two levels to think about it. One is the level of the specific chemical, the specific problem at hand, and the other is the level of the entire institutional structure. And the latter forces you to be more qualitative in the

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analysis, less quantitative. But it allows lots of quantitative thinking.

And now I'm really sort of getting to the end of what I wanted to say, but I may as well say it right now, that it allows thinking in terms of trying to think through the principal agent problem, the cost of information. There are all of these disciplines that have a quantitative punch to them in the sense that they are rigorous.

On the other hand, their primary value I think is 9 in developing rules of thumb and guidance towards what kinds 10 of institutions make sense. And to sort of just say it 11 straight out, it appears to me that that is really what the 12 Three Mile Island report is trying to say -- that we focused 13 a great deal on the particular minor problem at hand, 14 whether or not a valve is going to fail, and we have left 15 out of consideration the institutional structure whereby we 16 worry about such questions as how operators are trained, 17 what kind of incentives are placed on the operators to learn 18 their material, to know what the regulations are, what kinds 19 of substitutes there are for the regulations, legal fee 20 applicants versus something else more decentralized, how we 21 look at design errors ex ante rather than ex post, which is 22 really a game of incentives. So I think it is that side 23 that needs stressing, and it is that side that comes out of 24 the Three Mile Island report, and I hope it is that side 25

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that will sort of clarify the rest of the remarks I want to make.

3 So having said that, the Toxic Substances Control 4 Act mentions the term "unreasonable risk" at least 43 5 times. It is hard to know how many more times it is in 6 there because it's very hard to count them. Your eyes glaze 7 over as you go through the Act. I am thankful to Harold 8 Greene, a law professor at Georgetown University who made 9 that comment before another session.

Now the term sometimes comes up "may present an 10 unreasonable risk", and this is a trigger for testing, and 11 sometimes it comes up with "presents an unreasonable risk", 12 and this is a trigger for precautionary action. It may also 13 14 come up in terms of "does not present an unreasonable risk", and this come out in terms of a responsibility to write 15 something in the Federal Register to show why you're not 16 17 regulating something in which you started a process. So whichever way you go, you have to worry about that. 18

19 There are some 43,000 chemicals on the list of 20 inventory of inorganic chemicals that are not being used as 21 pesticides. If they're used as pesticides and in commercial 22 list, they may be on the list as well. Cosmetics are not on 23 it. Tobacco is not on it. Things like that are exempted 24 from the Act. So we still have a residual very large number 25 of chemicals, being added to by about 400 per year, and you

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begin to see why I have this image of setting street lights in a city with 40,000 intersections.

If you decide you're going to regulate one at a 3 time and it takes five years to regulate one, then you're 4 talking about a large number of years. It sort of reminds 5 you of the kind of years we talk about for half-lives for 6 radioactive things that you have to worry about. There are 7 cheap tests like the Ames test that I think cost something 8 like \$200 to do a simple version, \$1000 to do a really good 9 version, to do the long term bioassay, the kind that Betty 10 Anderson would like to see before she comes out and says 11 that it really is a carcinogen - that may cost a half a 12 million dollars per shot -- so you're not going to be able 13 to require every chemical to be tested, every suspicious 14 chemical to be tested under a bioassay condition in order to 15 decide whether it is really worth regulating or not. 16

Some very crude guess, which I guess is just sort of drawn out of the air both has some sort of guidance to it, that perhaps one to five percent of the synthetic organic chemcials today that have been created since the Second World War may be carcinogens, mutagens, or teratogens and therefore subject to regulation.

23 One of the things I should mention, however, is I 24 think that it may be sort of an interesting point, is that 25 right now almost the entire focus of concern is on cancer.

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On the other hand, it may turn out that the mutagens and 1 teratogens pose greater harm socially than the carcinogens, 2 partially because they destroy the gene pool for many 3 generations as opposed to just kill one person today. This 4 may also be a concern to be considered with radiation. 5 because the same processes that cause cancer radioactively 6 may be able also to cause mutations you don't see for two or 7 three generations and then come up and have a larger impact. 8

Now the problem gets joined, I think, in a parallel way with the nuclear safeguards as it does with toxic chemicals, and that is that if we are trying to be remedial, the problem is sort of preidentified for us. We have an accident. Clean it up.

We find that asbestos insulation workers are -14 half of them are dying from lung cancer, so we know that :5 16 asbestos is a bad agent. But our problem is to be precautionary. And then we have to ask the question, how 17 18 much precaution is enough, and that becomes a very tough problem because the problems don't preidentify themselves 19 when you're trying to be precautionary, like trying to look 20 for a needle in a haystack, and until the needle announces 21 itself. it is very hard to find. 22

Now our problem in some ways, I think, may be a bit more structured than yours, and that is because we do have a formal test that we can do on chemicals to see

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whether or not they are carcinogens, mutagens, or what not, 1 and we know we have some testing protocols, and it is kind 2 of stylized. And the parallel problem for you, I think, is 3 how do you smoke out a design defect before it has actually 4 gone into an accident, and there is no sort of nice 5 methodology you can grind and come out with an answer that 6 tells you that, yes, indeed, this was a design defect, 7 although after the accident you very often can identify it. 8

So in our sort of stylized world, there are sort 9 of three basic ingredients that go into a concept of 10 unreasonable risk. One of them is the baseline information 11 that you have on hand before you make a decision whether or 12 not your're going to require testing. This involves what's 13 in the literature, what is in the premanufacturing notice, 14 what is know, what inferences you can make about it, this 15 16 sort of thing.

Then the second characteristic, the second 17 ingredient is the charateristics of the test. And for, I 18 think, all people who have enough of a sense of statistical :9 hypothesis testing to sort of realize that when you go into 20 a test, you can get hurt two ways. You can have a guilty 21 chemical come out innocent. or you can have an innocent 22 chemical come out guilty. You have false positives. You 23 can have false negatives. And you trade off the probability 24 of one against the other by setting the critical region of 25

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It just happens that for the kinds of effects we are trying to find, this trade-off is quite unfavorable, and just a sort of quick example of this -- the most used bioassay test is sort of the NCI test that requires 50 animals. It requires a five percent significance level, which means a five percent chance of a false positive, and for a medium level carcinogen, it offers very low power.

And example of this is, suppose that we have a ten 9 percent response rate, background response rate for the 10 animal, realizing that this does not mean that the animal is 11 super-sensitive because after all, we have a 25 percent 12 background response rate, so these mice are less sensitive 13 than we are, and suppose we're looking for something like 14 benzene, that might double this background rate under some 15 increase of dose below its maximally tolerated level. And 16 so, in other words, the background rate would jump from a 10 17 percent response rate to a 15 percent response rate. What 18 is the chance that the test is going to find this effect, 19 this 50 percent effect? 20

21 Well, the chance is less than one percent. So 22 here we are, we have an NCI type cancer test that has a five 23 percent chance of a false positive and a 99 percent chance 24 of a false negative, and in decision theory terms, this just 25 does not make much sense. The reason that it doesn't make

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much sense is, for many precautionary actions that we can 1 take, the cost of the precautionary action may be low compared to the cost of not taking the precautionary action 3 is the adverse hypothesis is true and this chemical really 4 is a carcinogen at the potency we're talking about. 5

So to say that again, if we have -- the third 6 ingredient is really the ratio of the cost of a false 7 negative to the cost of a false positive, and so that is 8 where sort of the economics comes in, and when we begin to 9 worry about what the costs of information are, that tells us 10 how much up front work we need to do to try to figure out 11 what this ratio might be before we begin to proceed in 12 requiring the test or requiring precautionary action. 13

Let me put the matter sort of the other way. 14 Suppose that the cost of information was zero, that we could 15 do these cost-benefit analyses at no cost and no time, then 16 it would make sense to do everything up front in the sense 17 that before we require tests, we would figure out what 18 regulation would be in order if the test came out positive, 19 at what level, and what the benefits foregone of the 20 chemical are once you regulate it, what the costs of the 21 chemical are in terms of not regulating it, and living with 22 the carcinogenic or mutagenic or teratogenic properties, to 23 do all that work up front. 24

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However, when we begin to worry about the cost of

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information in terms of both time and resource cost, because 1 these are expensive kinds of things to do, then we are 2 beginning to be in this traffic light setting problem where 3 it may not make sense to do as much up front work on the 4 cost-benefit side before we require the tests, as up front 5 work on the baseline information side to see whether or not 6 this hypothesis looks like there really is an adverse 7 hypothesis. 8

So what I'm saying is that, instead of worrying about your cost-benefit analysis only in terms of this chemical, if we worry about the cost-benefit analysis and the level of the entire decision-making process, we may make much better use out of it.

So that is the point. Let me just try to sort of draw this parallel a little more. It seems to me that in the big accidents that have happened and the inceresting near-accidents in nuclear power, we have a combination of three factors. We have the mechanical failure, the design error, and human error, and they sort of intermix. They come together.

And the problem is that one of these three is easy to study and the other two are real hard to study, and you can guess which one is the easy one to study. It is the mechanical failure. And that is what has gotten the lion's share of the attention.

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And this situation is a little bit like the old 1 joke of the man who lost a coin, and he's looking under a 2 streetlamp for it. A bystander comes along and says, "Can I 3 help you find this coin." And the man says, "Oh, yes, help 4 me find the coin." And the man says, "Where did you drop 5 it?" Then he said, "Oh, across the street." And he says, 6 "Well, why in God's name are you looking here?" And he 7 says, "That's where the light is." 8

So the problem is to think more systematically in a cautionary way of smoking out some of these design areas and some of these incentive systems that would make human error less likely. And I think that may be where the big payoff is. I think that is really the point I want to make.

Let me make just one other point and try to get 14 some reaction or discussion. I think when we take these 15 three ingredients into account that involve the toxics 16 17 problem, they also involve the nuclear safety problem with a 18 vengeance, in a sense. And that is that when we are dealing with the ratio of cost to mistakes, the downside costs of 19 being wrong and not finding some design error may be 20 thousands and billions of tons bigger than the downside cost 21 of being overly precautionary for some little tidbit. 22

23 So when we start looking at incremental cost of 24 safety and the whole potential on the downside, it is very 25 large. And so that sort of steers you to make all sorts of

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precautionary pile-ups, and the question is where do you stop.

DR. WILSON: On that, I'm not quite sure what 3 you're saying there, because -- excuse me -- I'm stopping 4 you there because it seems appropriate, because are you 5 trying to imply that the costs of not finding an error and 6 the actual cost of having to fix it up, or there is another 7 cost which we find very clear from Three Mile Island and 8 which is probably not the cost of fixing up Three Mile 9 Island, but the cost of the public concern that causes -10 which is an indirect cost, which is very much greater than 11 the actual direct cost? 12

DR. PAGE: Well, I mean both.

DR. WILSON: Are you meaning both?

DR. PAGE: Yes. Maybe it would be worth - I don't know, how do you want to do this? You want to open this up to discussion?

DR. OKRENT: Well, why don't you finish? We have time.

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DR. PAGE: Let me just give you a little stylized example of this to sort of pinpoint what I mean by these asymmetries.

Suppose that you're feeling a little poorly and you walk into your doctor's office and you say, I'm feeling a little poorly and so he gives you his check up and he says, don't worry too much. I think you're okay.

8 On the other hand, I've examined a lot of people like you 9 and I find that one out of 20 people like you has this rare 10 tumor.

And you begin to start shaking. So you have this 5 percent background level, and that's what I mean by the baseline information, a 5 percent chance that the adversa hypothesis is true.

And you say, well, what should I do? And he says, well, I think we should give you the test and the test is pretty good. It has only -- if you're due to have a tumor, there's a 90 percent chance that it will show up positive. If you don't have the tumor, there's a 90 percent chance that you will show up negative. Come back in two weeks and take the test.

22 So you take the test and you come back in two weeks and 23 he says, look, you'd better sit down. The test came out 24 positive. So you sit down and he says, but don't worry too 25 much. It is still unlikely you have the tumor. And you

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say what? How can this be? I thought it was a good test. And if you applied basis therom to the information I have

given you, it turns out that you really do only have a 30 percent chance of having this tumor, even after the test is true.

So then he says, well, should I have the operation or not?

Let's stop right here for a second. One point is that I think most people, when they are dealing with low probability events and things that require taking into account badly formed baseline information and new information, they do a real poor job. There's a whole history on this.

Kuhneman and Turfsky have an article in Science that show that people handle low probabilities very poorly in updating the situations, which is part of the problem that I think that you face as well as we face in toxic chemicals.

So you say, well, should I have this operation? It was only a 30 percent chance of having the turmor. And the doctor said, I think you should because the cost of dying of cancer is at least 10-fold times higher than the cost of the operation, as nasty as it is.

And you say, well, if I believe in subjective probabilities, and that's what the meaning of 10-fold means in the betting situation, then I'm willing to reject the bet

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and take the precautionary operation.

So then you take the operation and you come back and find 2 out that you were one of the lucky people that didn't have 3 the tumor after all. that it was a precautionary operation 4 and you sort of wonder how do you avoid malpractice suits? ó And he says, well, basically, I give all of my ó information up front. People know this is precautionary to 1 begin with. And you say, well, it is a mistake ratio of 2 8 to I to unnacessary operations, to unnecesary operation. 2 And he says, no, that's not true at all. My mistake ratio 10 was 19 to 1. 11

I have for every false, negative, I sustain 19 falsepositives.

Now if you grind through basis theorum again, you will find that is also true. And that's another place where people don't think very well about it.

So then the question becomes, when we look at toxic chemicals, we find lots of examples of false positives. You can quickly find 20 or 30 examples of false positives, but you can only find 2 or 3 examples of false negatives.

21 So the question is have we been fooling ourselves as to 22 the right balance of our mistake ratio? Have we not been 23 precautionary enough?

So that is a question of looking at expected values and seeing whether the numbers make sense or not.

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DR. WILSON: I did not catch the sign of that statement. Have we been too cautious, was that?

DR. PAGE: No. I'm saying have we been fooling 3 ourselves in the sense that we have paid a lot of attention 4 to false positives and we have protected ourselves a lot 3 against false positives. We have been unwilling to classify 5 something as a carcinogen until there is overwhelming 4 evidence that it is a carcinogen. And in doing so, we find 8 lots of classifications that go from safe to dangerous, 7 which is the sign that we have had a false negative -- I'm 10 sorry, which is a sign that we've had a false positive. 11

12 I'm sorry, this is a sign that we have had a previous 13 false negative when we take a chemical which we think is 14 safe and then we find it's dangerous.

Now there are a couple of cases where we take a chemical which we classify first as dangerous and then we loosen up and say, ah, maybe it's a little safer. The question is which way do these loosening and tightening operations go and what is the ratio of them?

So that becomes a way of calibrating what you think as to how precautionary you should be. And also, it gives you a way of approaching the problem of trying to decide what people are really implicitly judging as to the underlying likelihoods of that, of the hypotheses of the ratios of cost.

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Now when I said that you face this problem with a vengeance, what I meant was that two of these asymmetries can be summarized in terms of what used to be called the zero infinity dilemma, where the first half of the zero part is that the probability of the adverse hypothesis is considered to be many-fold times less than the probability of the benign hypothesis.

For chemicals, we may be dealing with the probability of 3 the adverse hypothesis being sort of one percent, five 2 percent. These are sort of the subjective estimations that 10 people will give you as to -- well, for example, if you ask 11 people - I hate to answer this people, but you ask them 12 anyway. You say, what do you think the probability is that 13 the cancer rates might double in the next 30 years due to 14 all these synthetic organics we've been pumping into the 15 environment in the next 20 years? 16

And they will hem and haw and you force them to have a median estimate from which they think it is just as likely to go more rather than less.

And I've done this a few times and it comes out somewhere from 1 to 5 percent, which is high considering the downside risks.

23 On the other hand, I have a feeling in the nuclear safety 24 area you are willing to push these priors way down many 25 orders of magnitude less than that.

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So we're talking about what kind of prior that you are willing to live with. So that is what I mean. These asymmetries may be more striking in the nuclear power field than they are in the toxic chemical field.

Let me just stop there and engage in a discussion.

DR. OKRENT: I have a question. You said that you were working on unreasonable risk, I think that that was the term. And I was wondering if you were going to quantify unreasonable risk for me in some way.

DR. PAGE: I think where this line of analysis goes is, first of all, it says it will be unlikely that we will come out with -- it is possible that we will come out with a rule of thumb that says we will live with chemicals that have risks less than I out of a million. But that is a rule of thumb.

That might be like setting the traffic lights in the 16 17 city. It is possible. It could come out that way. But I think it's unlikely that it's going to come out that way. I 13 think it's much more likely that it's going to come out to 17 be a statement that says that the standard of proof under 20 which you required this much evidence rather than that much 21 evidence in order to take a precautionary action is 22 dependent upon some sort of critical ratios which have to do 23 with your feeling on the ratio that the cost of a false 24 negative to the cost of a false positive, your feeling of 25

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the priors that has to do with the level of suspicion that you have on the chemical before you go into the process of gathering more information on it and how sensitive the test is, how favorable your trade-off curve is between false positives and negatives.

And that has something to do with whether or not you're going to require a half million test or a million dollar test or a \$2000 test.

30 that I think what is going to happen is that there are 10 going to be qualitative packages of what needs to be done in 11 what situations that are not going to be terribly 12 formalized. They are going to be judgment calls, but they 13 are going to be guided judgment calls.

14 DR. WILSON: Coming back to something that you are 15 saying, when Elizabeth Anderson was talking about this false 16 positive and false negative question, a thing which everyone 17 said where it is not found to be carcinogenic and people 18 suggested that they haven't looked carefully enough -- if 19 one looks through the data on this question of people just 20 saying, it is carcinogenic, it isn't.

And it is only just recently that this quantitative thing has been answered at all to actually get in there. Is that actually getting into the level of the unreasonable risk question? This risk is 10 to the minus 10. Even leaving yourself a factor of 100 or 1000, it really isn't worth

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bothering about. But this risk is 10 to the minus 1, and I have really got to move hand and earth to get it done. Is that sort of thinking likely to come about?

DR. PAGE: I think so, sure, and even more so. I mean it may turn out that if you are looking at -- here's an example of what we're talking about. Suppose that you're looking at a medium level carcinogen, maybe benzene as an example, which has an extraordinarily large exposure.

9 Then for that kind of carcinogen, you may want to not 10 live with a 5 percent significance level in the test. In 11 other words, you do a test and you find that it is 12 carcinogen of this potency with a P value of 10 percent, as 13 opposed 5 percent.

14 That may be enough for a precautionary regulatory action 15 because the exposure is so high and the power of the test is 16 low for the potency that you are concerned about for 17 regulatory purposes.

So in other words, this potential ratio of cost of wrong decisions either way helps guide the process of what kind of sensitivity makes sense in order to take the precautionary action.

22 DR. LAVE: That would say that you would not do a 23 50 rad test.

24 DR. PAGE: That's right. Let's say that you want 25 to have a more expensive test with a more favorable

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trade-off all along the line and then still adjust your
 fine-tuning the test between false positives and negatives.
 3 So instead of coming out with a single one rule of thumb,
 4 I think that we're going to get a number of rules of thumb.
 DR. OKRENT: It seems to me that what you've been

discussing is what level of information and what level of
uncertainty goes with what anticipated level of risk.
And I would argue in fact that in the nuclear reactor
game, the same thought processes are gone through, except
they are not so labelled.

There are some devices that you have to build and test and test and test to show that they are going to work. And there are others for which there exist general design criteria. And the designer says, yes, I designed it according to these criteria.

16 That is taken as probably good enough with a minor audit.
17 And in a sense, these are related to how important you think
18 the function is and what happens if the function fails.

So, what I'm still interested in is whether you see a
chance of defining unreasonable risk, unacceptable risk,
acceptable risk. I don't care which adjective you put in
front of the word, but is there some way you see of
quantifying one of these in the field in which you are
working, and with an uncertainty band, if you so wish?
DR. PAGE: I think instead of having an absolute

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number that says one out of a million, that's the sort of
thing that you're asking about, whether or not things might
tend toward a number like one out of a million is
acceptable, one out of 100,000 is not acceptable.

Is that right?

DR. OKRENT: That is being done implicitly by the actions that are taken anyway. I mean, we looked at a list of things that might be in water and so forth. And if you are accepting this in water, whether you say it or not, your best information is that this is what is going on.

DR. PAGE: Well, I think that in EPA, especially in the radiation program, there is an effort to try and develop a rule of thumb that is sort of absolute like that. But in the office of toxic chemicals and substances, this is less likely to happen because of a mandate to do upfront balancing of cost and benefits. That is written right into the legislative history.

So that the kinds of rules of thumb that are likely to 18 emerge when you put all of this together and you worry about 17 the cost of information I think are going to say something 20 about what standard of evidence is appropriate in this 21 situation and what kinds of mistakes we're willing to live 22 with in the aggregate, that kind of thing. And how long, if 23 you have to do a two-year cost and penefit analysis before 24 you come out with a regulation, this may be too long. So 25

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what else can you do?

I think what I am suggesting is that the path of this kind of approach which really is an application of worrying about incentive compatability and this sort of thing is to worry about what kinds of incentives need to be created sc that the system will work better sort of on its own.

And it seems to me that this is very much the spirit of 1 the Kemeny Report. It says that we spent much too long 3 worrying about will this valve fail, sort of without humans 7 around, and not enough time worrying about what kind of 10 incentive structure do we need to have so that utilities are 11 going to have trained operators, or so that they're going to 12 have the valves and alarm systems and have the alarm systems 13 as hierarchical so 100 alarms don't ring all at once, or so 14 that you can see the meters, they are not all hidden from 15 view, or all are not hidden from view. 15

DR. OKRENT: You see, I can find an equivalent analogy in the practice of medicine.

17 There was a time in the '20s when doctors were rather 20 careless about prescribing radioactive materials as health 21 improvements. And in the 1950s, they were rather careless 22 about giving children radiation treatments.

And they now, I think, many of them are more cautious, but not necessarily all because there are a certain number that give X-rays to protect against malpractice suits, and

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gshHEE I so forth.

I have little doubt there is a change in people's thinking after they know more. I assume that in the practice of, for example, looking at toxic chemicals, things have evolved and there are some things that, as you said, were thought to be negative or false negatives, and so forth.

And you could, I think, look at the nuclear reactor business and say, they had a false negative because they thought that by, in fact, putting in lots of equipment and not relying on the operator, they had protected themselves against something.

You can see parallels, I think, in each technology. And I guess I tend to expect them. I guess you would like to have perfection, but I haven't seen it, as I say, in the practice of medicine, and I've been in the middle of some of the errors that the practice of medicine has made.

DR. LAVE: May I paraphrase something that Tobysaid to make sure it is clear?

I think that in part of the agreement, or at least part of what he was answering was that if the general perception is that nuclear power is totally unnecessary, then the acceptable risk level is going to be enormously different than if the general perception is that nuclear power is really necessary for our existence.

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DR. OKRENT: I agree.

DR. LAVE: But then when you say what is the acceptable risk level, that is being postulated on some general view as to what contribution nuclear power will make toward our social well being.

Insofar as that changes rapidly, for example, and you can
 certainly expect the perception as to what the acceptable
 risk level will be will change rather rapidly.

DR. PAGE: That can be sort of added to, and I was 4 just reading through the Three Mile Island report this 10 morning. One of the things they say that struck me is that 11 the accident itself, even though it didn't go its full path 12 13 and people did not get heavily dosed, was clearly unacceptable from a social policy point of view. And 14 lõ another Three Mile Island accident in the next few years would also be unacceptable in the sense that it would have 15 11 enormous political ramifications and what would happen to the industry. 18

So I guess part of what I'm saying is that a notion of acceptable risk has to do with sort of the individuals that anay suffer because they are getting individually dosed with radiation because there has been some accident.

But another part of the notion of acceptable risk has to do with the entire energy program and what kinds of accidents are acceptable in a political sense of setting

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down the industry or keeping it going.

And sort of the flavor that I got from the Three Mile Island report was that we have to look at the latter.

DR. LEACHMAN: I'm curious about what Mr. Lave is saying and what you, the speaker, are saying. Are you talking about the headlines here or are you talking about some realities when you're talking about whether nuclear energy is needed and how people perceive these things? What are you going to do instead? What are the comparative risks? I don't know what your points are.

DR. PAGE: Well, the point is that if people l2 pelieve that --

DR. LEACHMAN: What is "people." I don't understand what you mean. Are you talking about a public opinion poll? Are you talking about the Union of Concerned Scientists? Are you talking about what the knowledgeable scientists believe?

What is "the people"?

DR. PAGE: I'm really talking about the entire legislative process in the sense of whether or not a moratorium gets voted in Congress or not.

DR. LEACHMAN: Well, that is decided. DR. PAGE: Well, it's not decided because there could be another Three Mile Island accident tomorrow. So the question is what is the level of safety that we're

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willing to live with in reference to the likelihoods of other partial accidents and what the likely public response to it is, as it is filtered through the political system? I mean, those are real. The attitudes are real. And if people get very upset and they close down the industry, that is a real decision.

DR. LEACHMAN: There is a real indication a couple
of years ago with a vote, and it was a legislative consensus
2 to 1 against shutdown.

Now I'm not sure what people you're talking about and what these opinions are that you're speaking about.

DR. PAGE: The impression that I got from reading 12 this Three Mile Island report is that the repercussions of 13 another Three Mile Island accident might reverse that vote. 14 So this becomes part of a calculus as to what is an 15 acceptable risk. And especially if you believe that nuclear 15 power is necessary because there are no good alternatives. 14 Then that puts a different flavor on what safety needs to 18 be done, so that there won't be these political 19

20 repercussions.

21 DR. LEACHMAN: I'm not sure what context you're 22 sayning that in. Are you saying in comparative risks or 23 something else?

24 DR. PAGE: What I'm saying is we tend to think in 25 terms of sort of the real risk of people getting hurt and

how many cancers there are going to be and that sort of gshHEE 1.1 thing. 2 But there's also a political risk that has to do with 3 Congress voting down the nuclear industry. 4 Five years ago that would be considered sort of ć inconceivable, but not it is conceivable. ó DR. WILSON: That is the standard, in a sense. 1 That distinction is not much different -- on the second 3 type of risk is the sort of decision analysis that has been 9 taught at Harvard Business School for some years. 10 I mean. that's the standard business risk. And the type 11 of risk that we're talking about, risk to life and limb, is 12 13 a different one. DR. PAGE: I should keep those separate. 14 DR. WILSON: Yours is an older type. Businessmen 15 are taught to face that type of risk. 15 DR. PAGE: Maybe I wasn't clear enough in 11 separating the two. 18 DR. LAVE: Toby, you were being a little slippery, 19 I think, talking about some of the asymmetries, particularly 20 about the path or what is the probability of a chemical that 21 was classified as a carcinogen now being exonerated versus a 22 chemical that was not classified as a carcinogen now being 23 classified. 24 And I think that your point is well taken. But one has 25

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to be careful in applying the point.

In particular, I think it is extremely unlikely that a 2 substance which was once classified as a carcinogen would be 3 subsequently exonerated. Takes cyclamates, just for a 4 couple of reasons. One, it is clearly an uphill battle to ő try and reverse it later on. That is the birden of proof is 6 clearly on you to prove that it is not a carcinogen, which 4 is probably an impossible task, as they are finding out with 8 cyclar es. 7

10 And so, in general, there's no additional testing that 11 happens.

Secondly, I think that there is always an natural path of some substance being not classified as a carcinogen. That is, if we have a new chemical come on the scene, of course it is not classified as a carcinogen until we get some ovidence on it.

So that as evidence begins to accumulate, things will be
 classified as carcinogens.

I think in general your point is well taken about looking at the decision calculus. But the asymmetries are much more difficult to account for.

22 DR. PAGE: That is a good point. Basically, what 23 you're saying is that not only do we have to worry about the 24 discovery of these false positives and false negatives, but 25 we also have to worry about the probability of discovering

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them and the means of discovering them.

And I think that this gets down to sort of what I wanted 2 to talk about, which is that when you start asking these 3 kinds of questions and you start asking how can I better 4 discover these previous past mistakes, and how can I better õ anticipate them in the future. And then we get into the ó. design question a little bit. I'm sort of looking at the 7 design question as sort of equivalent to trying to find out 3 whether a new chemical is a carcinogen ex ante, because it 2 is just hard to tell whether a chemical is a carcinogen ex 10 ante, just as it's hard to know in Three Mile Island or in 11 Brown's Ferry the cables were lined and they should have 12 been separated. 13

14 After the fact, it is easy to see. But before the fact, 15 it's real hard.

DR. WILSON: Isn't the problem there both in the 15 carcinogens and in the reactor questions a problem because 1. 13 you haven't specified properly your boundary line? Now I would like to take as a naive principle that 17 everything is carcinogenic as a starting point and that they 20 may be, even drinking water is probably carcinogenic, but 21 very low potency. And it's just a question of amount. 22 If you take that starting point and ask yourself, what is 23

24 the number by which you have potency or some such thing, the 25 slope which Elizabeth Anderson was talking about where you

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In reactor safety, the same thing comes up. If you are trying to say that something which appeared to be safe has now proved to be unsafe, do you always find that was the case? We would always find something starts by being safe, but it has never been in use. There's no experience with it. And then it automatically becomes unsafe the first time it fails.

7 So if you start again with the viewpoint, which I 8 think in reactor safety we tend to start with, that any 9 gadget is potentially unsafe, it is a question of the level 10 of the failure level at which you begin to start worrying about 11 it. And again, I think that particular problem disappears 12 because it is -- I am essentially arguing for always putting 13 upper limits on something when you don't know it, rather than 14 just saying it is not there.

Does that sound right?

16 DR. PAGE: I think there is a lot of sense in what 17 you are saying. I don't know -- I don't know whether -- I 18 mean, the impression -- you see, I guess I'm just trying --19 I'm sort of being swayed by this Three Mile Island report. 20 The sense that I got is that people in the industry had the 21 feeling that nuclear power plants were safe because there had 22 been no accidents that involved people for a long time. And 23 so there was a certain sort of complacency within the industry. 24 And when an outsider said, we have to make these plants safer, Ace-Federal Reporters, Inc. 25 then the reaction was, well, they're already safe and there's

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nothing that can be done.

But in reading the Three Mile Island report, it sounds like there are all kinds of ways they can be made safer. Some of these ways are at low cost, and they arise because we've been looking at just one aspect or we have been concentrating on one aspect of the problem and neglecting other aspects, which are sort of up for grabs.

8 There is a lot that can be done because it has 9 been relatively unexploited, and that is in the design side 10 and the training side. So I look upon that sort of as an 11 optimistic, hopeful --

12 MR. LAVE: Although there is another point. TOSCA was an attempt by the Congress to switch the burden of proof 13 14 of trying to correct bad situations that had occurred and 15 trying to prevent situations that did occur, as was OSHA. 16 And getting back into your basic framework, whether it makes 17 sense to go for prevention rather than early detection depends upon what is the cost of prevention versus the cost 18 19 of early detection.

And if it turns out that -- suppose it turns out that one chemical in 10,000 is a carcinogen. Then I think the judgment will have been wrong by the Congress and TOSCA would have been wrong from a social viewpoint. It would have been better to try and indulge in early detection, to count the few dead bodies that arise and say that's too bad, rather

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than to go through the elaborate steps you're going through.
And I think that part of what the nuclear people keep on saying
is that they have always felt under the burden of prevention
rather than early detection. So it is clearly cheaper and
easier to find faults when you are engaging in early detection,
rather than the prevention phase.

And it may be that part of what the Three Mile Island report does is to show that the nuclear people were searching under the light rather than looking at these other areas that they couldn't quite deal with, and may have been unaware that they were searching under the light.

DR. OKRENT: I wonder if I could turn the discussion 12 back to the kind of thing that Richard Wilson was bringing 13 up a little bit ago. Is there, in your opinion, some level 14 of risk that is small enough that if you know it with some 15 degree of uncertainty to be stated, this is acceptable for 16 sociecy to impose upon somebody who receives no direct 17 benefits, as may well be the case for various of the chemicals 18 19 that you are dealing with?

DR. PAGE: If we adopted an acceptable risk of one out of a million and everybody is dosed by this chemical, that means 220 cancers per yoar. It certainly seems to me that there are many kinds of chemicals for which this would be an unacceptably high number of dead bodies in order to get the benefit. 1573 227

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And I can think of formaldehyde and toothpaste as an example. If that raised the risk to one out of a million for the entire population, it just wouldn't be worth it to get that nice, stingy taste in toothpaste. There are other ways you can do it.

I think there are times when one out of a million
risk is far too high a risk. On the other hand, I think you
can probably easily think of situations where we as a society
have been willing to live and appear to be willing to live
with a risk of one out of a million or more than that, because
the benefits seek high in comparison.

12 DR. OKRENT: If I can paraphrase what you just said, 13 the one in a million multiplied times 200 million -- so this 14 is where everyone is exposed -- imposes a large enough 15 societal cost that there should be some benefit that 16 justifies this. If there were a limited number of individuals 17 exposed to the one in a million -- let me say a million 18 instead of 200 million -- would that change your conclusion? 19 Or 100,000? Or is there some -- would you be willing to say, 20 well, 100,000 have this exposure, but the rest of society is 21 much, much lower?

And then, would you still look strongly -- I'm just trying to see, is there some number that is low enough that, if the total societal burden isn't large, from an individual point of view you would think it was all right?

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1	DR. PAGE: Well, I think the total number exposed
2	is certainly an important consideration, and also whether or
3	not if the exposure is voluntarily assumed. I think that
4	is an important consideration. And if the market in which
5	the risk is assumed voluntarily, if it is a good market and
6	with well-informed people and people who are getting hazard
7	pay and that sort of thing, then that and the market is
8	really working and people aren't forced into it because they
9	happen to live in Appalachia.
10	DR. OKRENT: But generally speaking, we're talking
11	about places where people are ill-informed and it may not
12	even be well known.
13	DR. PAGE: Well, I think these are all parts of
14	what you mean as to whether something is acceptable or not.
15	I think a risk that is imposed from one generation to another
16	generation is different, because it has equity aspects to it,
17	from a risk that is imposed by one person to himself as he
18	drives his car down the highway.
19	Because of these things, I think it may be a mistake
20	to get a simple number, and it may make more sense to, first
21	of all, to try to figure out what the ingredients are and not
22	just a shopping list, but how they actually interact, one with
23	the other.

Ace-Federal Reporters, Inc. 25 I think where the real payoff is is in trying to make the

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incentive system work better, so that some of these choices aren't quite as imposed and nasty as they appear to be now. What I'm saying is that it appears that there is a lot of give in the system that could be exploited if we were to attend to the level of incentives and institutions, as opposed to accepting the menu as given and then deciding whether or not we're going to live with it, up or down.

DR. WILSON: The incentive system working better 8 is something which I think most of us feel very strongly about. 9 It is important. But there has been very little achievement 10 of that aim. When you set a standard, it tends to be set in 11 concrete, and then all incentive is just absolutely stifled. 12 So the real question is, how can you achieve that? I mean, 13 do you set a standard which can be moved up and down by some 14 sort of procedure every few months -- or every few years, I 15 mean -- if more data comes in, has a procedure for reviewing 16 17 it?

And, associated with that, should you set a standard, an extremely tight one if you have no information at all and we just don't use the chemical; and then gradually relaxing as you get more and more information? I mean, at the moment -- well, it's not quite true. But in many cases we have no regulations at all if we have no information.

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DR. PAGE: Well, I think these are the right kinds of questions to ask. And in the chemical field, for example, 1573 230

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we have some of the same problem as you have in the nuclear field, where a lot of the regulation is done by industry and reported back to the central government, and the central government accepts, is in the position where it almost has to accept the word of the industry that these things have been done, whatever they are.

The situation in testing, the industry does its own testing of chemicals and the validation of tests. The incentives to do a good test rather than a bad test right now are backwards, in the sense that you have a better chance of getting a chemical accepted if you do a bad test.

Now, how are you going to turn this around? Well, double-blind testing, validation of testing, strict liability for the tests, and such, like the SEC has rules that hold the officers of a company accountable for bad information submitted in the financial data.

You can begin to think about what kinds of institutional mechanisms might lead to better tests and validation of the tests. And we might get out of this awful position of going and finding that enormous numbers of tests on pesticides are worthless.

DR. WILSON: Well, the ones you have described to us are one which are in a regression of a never-ending sequence of checks and checks, and not automatic feedback inc. systems. I mean, I would like to have an automatic feedback

so you could connect the loop once, and then it automatically
 stabilizes. At present the loop is completely unstable, and
 we have to put stop points here just to stop the whole thing
 from going to pieces.

And you are just -- the list of things are just a bunch of stop points and not a system to make it basically stable.

8 DR. PAGE: Although a third part of the testing 9 scheme could have this feedback, where you end up paying people 10 off or being bountyhunters, essentially.

DR. WILSON: That is why I like the idea of something being automatically treated dangerous right from the beginning, and there is some level of risk which you can accept, and then you can go away from that level by doing more and more tests. And then you climb up to here. And you might then say, well, no matter how safe it is, we can't do it.

DR. PAGE: Another example of this is in the design of the tests. The safe dose may be coupled to essentially, to the confidence level, the error bar in the result. So you get rewarded for a sharper test. And that was one of the motivations for the technique back in the beginning.

> DR. OKRENT: Other questions for Dr. Page? We have been more than generous in posing questions. (No response.)

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DR. OKRENT: Well, thank you. You are welcome to

mte 9 sit down around the table. We are going to have some general 1 discussion, and you may join if you are so inclined. 2 The thing I would like for us to do at this point 3 is to get comments from our consultants in particular on what 4 would be fruitful things to do, assuming that we still have 5 a goal of trying to develop some kind of possible approach 6 to quantitative risk acceptance criteria that we could present

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to the full Committee, that they might buy, that they could 8 present to the NRC for consideration. 9

I think I have indicated that the Commissioners 10 themselves have now indicated that they feel a need to move 11 in this direction. And I think we heard from Mr. Von Thun 12 that there are others who are moving in this direction. We 13 see that, for its problems, EPA is developing approaches. 14

Who wants to start the discussion?

DR. WILSON: One hought to me is that the biggest 16 single gap at the moment -- and I don't know how to fill it --17 in thinking of how one might use -- there are some cases 18 where one can obviously, explicitly or implicitly, use risk 19 assessment, is -- and it is both a gap and a characterization, 20 and incentives -- is after you've thought about reactor 21 safety, how do you make sure? Because almost certainly, 22 somewhere in there there is something cheap you can do to 23 make reactors safer, and on any cost-benefit ratio it will be 24 Inc. cheaper. 25

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I don't know what it would be. If I knew what it would be, I would have told somebody what it would be, and it would be done.

And the question is -- the interesting question is --4 I was thinking of an analogy on the radiation things of the 5 20s, when all of the medical people were saying: Here are 6 medical X-rays. The diagnosis we can do with them is so 7 beneficial that it hardly matters to us what the risk is; and 8 the benefits are so huge, we should go ahead and do them. 9 And there were one or two people whispering from behind the 10 closed doors, where they had been pushed off to the side: Yes, 11 but you can probably get the same benefit with much less risk 12 by using sensitive film and not covering off the parts of the 13 body, and all of those things we know about now and we all 14 know of. 15

We've got the exposure factor. It took a long time, about 30 or 40 years, to get that point across. And I think the major thing we're talking, we're trying to get across, is how to get that aspect of looking at those unknown things.

21 DR. OKRENT: Well, I would suggest that you could 22 have an ALARA and I have said an AGARA, as good as reasonably 23 achievable, criteria. In other words, you may have to meet 24 some limit. Whether it's a non-acceptance limit or an 25 acceptance limit, I don't know. But after that, you could

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•	1	say you would still have to make such other improvements.
	2	DR. WILSON: But that is if you think of them. It
	3	is the forcing I mean, some of the improvements of Three
	4	Mile Island, for example, that the Kemeny Commission report
	5	comes out with are so obvious to us now. It is unclear to
	6	us I mean, if anybody really thought about them as clearly
	7	as we now think about them, they certainly would have got done.
	8	But nobody did.
	9	And I think that is the biggest single gap.
	10	DR. LAVE: Well, Dave, I think that the problem is
	11	or at least the problem as I see it is that asking the
	12	question of what is an acceptable risk criteria is not going
-	13	to be a fruitful way of proceeding; that part of what Dick
	14	was just saying and part of what Toby Page was telling us a
	15	little while ago, and part of what Skovic has, and I think
	16	that very nice piece that was included, is that there are a
	17	whole set of other concerns, that it is not quite as simple
	18	as deriving a single number.
	19	I mean, here in the last few minutes we've been
	20	talking about uncertainty and how it is that one could reduce
•	21	the uncertainties surrounding any risk. We've been talking
-	22	about feedback mechanisms. We talked at the first meeting
	23	about verification of risks, that is, if you have some
ederal Reporters,	24	estimate, what in the world does that really mean? Can anybody
Little rieporters,	25	really believe it?
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and the second	
• 1	We have been talking about benefits. And it seems
2	to me we have a whole nexus of problems that are just too
• 3	complicated to be expressed in what is a single risk number.
4	I guess if I were being a little bit playful, I would probably
5	answer the question you posed to Toby by saying: Well, I guess
6	that 10^{-20} is a risk that I would accept, even though it was
7	of no benefit to me, if I was absolutely sure that it was no
8	greater than 10^{-20} . Now, are you happy because I have given
9	you that number?
10	I mean, I think not. I think that the number is
11	surely going to be high enough so that the costs that are
12	associated with achieving it are going to be out of all bounds.
13	DR. OKRENT: Well, to answer your direct question,
14	I would say no, your proposed number I would find to be
15	unacceptable.
16	By the way, 1 did not say there should be a single
17	number. I don't think you heard me urge that there should
18	be criteria that involves a single number. And I am not
19	proposing that there be criteria that are independent of
20	benefits or whatever.
21	I am asking, though, if one is going to try to
22	develop risk acceptance criteria which are quantitative in
23	nature and which include whatever other aspects they should,
24 Ace-Federal Reporters, Inc	because char of part of the reasoners in more that
25	how should we go at it and what is a possible approach, or
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1 however you want to put it?

2 So I choose not to set up that straw man of a single 3 number and knock it down. I could, also.

DR. LOWRANCE: I gather when you say "risk ceptance criteria," what you mean is criteria that would be useful in managing the future of nuclear power, or at least the reactor side? Is that what you really mean by, quote, "risk acceptance criteria," close quote?

9 DR. OKRENT: Well, it obviously could mean different 10 things to different people. We heard Mr. Von Thun earlier 11 mention that they are beginning a process of trying to lay 12 out for top level of management in what was the Bureau of 13 Reclamation, which now has a new name I cannot remember, what 14 their best estimate is of the risks. And they also have 15 comparative risks of different approaches and so forth.

So when they make a decision, this is part of the information. But they clearly included the fact, at Jackson Lake, that this was not a body of water with no benefits. There clearly were benefits associated with this. And so, they in fact were buying risks under any of the approaches, even the one that was nominally not a risk for failure mode one, but there still was a failure mode two.

I think in fact one can argue from today 'til tomorrow, as it were, about how hard it is to develop risk acceptance criteria. The regulators, the people who build 1573 237

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things, are still going to build things that are imposing 1 2 risks, or standards that impose risks. And my own feeling is it is better to have them laid out as clearly as you can, 3 either as Von Thun said or as we are seeing the EPA is trying 4 to do, and, let me say, as the NRC should try to do. And they 5 can say: Look, this is what we're trying to achieve. And 6 they may have to say: This is what the best estimates are, 7 and these are the uncertainties, and here are the residual 8 risks that will exist if and when they meet the design criteria 9 the way we think they should be. And it is presented as the 10 total package of what we mean when we say these reactors can 11 be operated without undue risks to the health and safet . 12 And if you the Congress think that is wrong, tell us what 13 you think should be different; or if you the public, or however 14 15 it is.

It would seem to me that would be preferable. In fact, it might have averted a lot of the difficulties that exist today. Not all and not some of the technical issues, but you could still omit some of the technical factors.

I don't want to mix two different questions. How do you treat design errors, about which I've been worried for many years. It's not that I think they are unimportant, but I don't want to mix the two things.

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DR. WILSON: There are about two or three places where it seems to me that one should be able to develop over a period of time places in NRC where risk calculations should be useful. First, it is not clear to me, if you develop a standard for anything, that a risk calculation is necessarily explicitly, although it should be done implicitly.

I mean, we talked about these standards EPA is 8 developing. Elizabeth Anderson never mentioned that this 7 was calculated solely on the mathematical equation going 10 from a risk calculation to the standard. And in the same 11 sense, the radiation standards, of course, are the oldest 12 ones. And in a very real sense, all of the criteria which 13 the EPA has talked about have already been identified by 14 ICRP in setting the radiation standards, of compatibility 15 with the background, and a rough calculation of risk on the 15 linear hypothesis, and small increments -- all of those 11 13 things are in there.

So, although — and they are not explicitly mentioned in the standard-setting pieces of paper or — in fact, the only words on the application of them are these words "as low as reasonably achievable, economic and other factors taken into account," and all of those nice phrases that get added onto the standard.

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So, I think it is important to emphasize that a

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risk calculation procedure should be backing up a standard and sort of be implicit behind it even though it is not explicitly used in the standard.

The other places where some calculations of risk. 4 calculations of benefit, and maybe even comparison of risks õ and benefits might be important, are the continual tasks ć that the NRC gets on what it does when it suddenly gets a 1 new piece of information which is important for the question 3 of whether the present 72 reactors should stay on line or 2 maybe a subset of them, those General Electric boiling water 10 reactors or even those boiling water reactors which don't 11 have the special jet pumps. 12

Now, every now and again a piece of information 13 comes up which one hadn't expected. I was thinking, 14 particularly because it affected us locally and affected my 15 personal electricity bill, of the shutting down of reactors 15 this spring because of earthquake hazards. Now, earthquake 11. hazards are not something very amenable to risk assessment, 13 of course. Nonetheless, we could have made a sort of rough 14 estimate on it, and I am not sure one was done. 20

But I tried to think about it a little bit myself because while I was suffering the pain of increased electricity bills, the question came: should one, for example, shut down after two weeks, give them two weeks? I mean, what is the risk of - granted, it is a thing you

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really want to look at this question carefully, you want to put incentives to have someone look at it quickly, is shutting down the whole reactor too much of an incentive or just a "fix it and give us some information in two weeks" time or we shut down." Presumably, that could be addressed by risk calculation.

DR. OKRENT: I agree with you. In fact, there -8 in our letter of May 16, in its second sentence, said,
9 referring to quantitative safety goals, "This could be
10 helpful, for example, in developing criteria for NRC actions
11 concerning operating plants."

So, we are conscious of the possible use of such criteria. And I don't think the NRC staff now have a yardstick. So, even if they had a yardstick, it might encourage them to see are they able to measure against the yardstick, which you cannot always do. But in that particular case, they might have been able to.

DR. WILSON: Well, again, it is the uncertainties 18 in the calculation that have to be prought in. In 19 earthquakes, the uncertainties are huge. But nonetheless, 20 it was clearly a case that the retrofitting -- you know, it 21 is again - the retrofitting clearly is not because they 22 won't - couldn't stand an earthquake at all. It is because 23 if the calculations were wrong, they wouldn't stand quite 24 such a big earthquake as they were designed for. And things 25

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of this sort could all go into it.

So, I think those are quite important financially, 2 and the things I am most interested in, however, I think, we 3 ought to try to find methods of using a risk calculation to 4 simplify the regulatory process. And that, I think, is D. perhaps one of the most important things - not necessarily 5 major regulatory processes. but - and that then has to be 1 done in what one would, as scientists say, in a form where 3 there is a negative feedback so the incentive is automatic. 7

One of the problems with one place where it is brought in in the standard after the slowest practicable hearing was the statement that "if you can reduce the sxposure for" -- what is it -- "a million dollars a man-rem, then you should do so."

15 There are no particular incentives in there. It
16 didn't replace any of the other low-level radiation things.
17 It was added to.

13 One might, for example, talk about such criteria if on the following basis - I am not sure it was the right 19 one, but it was the one I thought about for that particular 20 -- it is going back on something which has been done in a 21 similar criteria one might say instead of setting 10 22 millirems per year at the site boundary for the criteria, 23 set an absolute maximum of 100 millirems combined with a 24 mandatory regulatory measurement of calculation of what the 25

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dosage is, a mandatory charge at the base of a million dollars per man rem to give automatically not only a demand that he reduce but a financial incentive -- something of that general approach.

But is a combination. It is placing the mandatory S standard which can produce a lot of work on that 5 regulation. If you go down to 10 millirems and forcing the 1 tech specs and you would reduce the amount of work, and we 3 would have a simple procedure, which is simpler for a 9 variety of reasons. One, it is the only regulatory -- part 10 of it is subsequent to the event and not before the event. 11 Those are the only general ideas that - I am not sure that 12 is workaple in that particular case. 13

DR. OKRENT: Well, I like the idea of a risk tax which, in effect, is what you are saying.

DR. WILSON: Right.

DR. OKRENT: I don't know whether that is part of a framework for risk acceptance criteria where there is a question of risk management. In my own mind, they are related, but in a slightly different box. But I am open-minded.

I am trying to encourage you all to think positively. I think the community or too long has been trying to point toward all the difficulties in developing an approach, and I think it is time to --

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DR. WILSON: Well, I think the important thing about any positive statement is this: that I am always worried when someone says this is too uncertain to do a risk analysis - because that is usually the case -- where I would like to see someone attempt a risk analysis more than any other case.

DR. OKRENT: I agree.

BR. WILSON: It's not because the number is going to be reliable or it's not going ' be extremely uncertain. But until someone has attempted a risk analysis, set the set out, I am not even sure he has thought about the problem.

12 DR. OKRENT: I agree.

13 Bill, do you have anything?

DR. LOWRANCE: I am concerned with knowing where 14 to take all of this. I have been troubled today as I was in 15 the previous session. It seems to me that the most 15 difficult aspect of all of this or one of the most difficult 17 13 parts is not at the early end of how one describes the physical risks and comes up with some probabilities and 19 consequences and one tries to bound the uncertainties and so 20 on, but the "so what" question -- how does that then imply 21 social action and management decisions or cutoffs or upper 22 limits or lower limits or whatever. 23

And you just heard Dick say that systematic approaches should be used more in developing and backing

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regulatory decisions, say, by the NRC. That sounds fine.

But then the question is: for any newly discovered hazard - let's say, within the reactor - at what point, at what marginal return, do we then ignore the new signal or at which point do we start taking action? We just danced around that question all day and, yes, the ó Bureau of Reclamation is doinng systematic risk analysis, i out it is not really looking at the "so what" point, at what 3 point you stop building those big dams. 7

And as I said in the last meeting, I think if 10 people really knew what the hazards of those big dams are 11 and when a big one finally goes -- I mean, a really big one 12 finally collapses and kills one of the expected communities, 13 100,000 people or so -- that whole complexion is going to 14 change. We're no longer going to be able to sit back and 15 say, "For years the Bureau of Reclamation and others have 15 been doing their analyses, and it is all working out well 11 and we ought to do that in the nuclear area." 13

I don't know if any major technological area has 17 ever done this and done it in an open way so there would be 20 scrutiny and fairly informed knowledge -- not by the general 21 public, whoever that is -- but by the decisionmaking 22 public. I am just not sure how we got onto that point. 23 DR. OKRENT: There is a member of our audience. 24 MS. HALLER: Agnes Haller, of Babcock & Wilcox. 25

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245 493 17 08 I came across this study not too long ago that was DV HEE 1 done by the Canadian Atomic Energy Commission. It is a 2 report - whose number I don't happen to have with me -3 regarding the comparisons of energy sources and their 4 risks. And it traces everything -- coal, nuclear, ć photovoltaic, any source that we might be considering for ó. major production use -- through the mining and source. 1 obtaining the source of the material to construction to 3 production. all the way to waste disposal. 9 And I would like to recommend the report to you as 10 a possibility for background information. 11 DR. OKRENT: Thank you. I think you are probably 12 referring to what is called the "INHAB Report," around which 13 I guess there is some controversy about the results. 14 MS. HALLER: I am sure there are questions, but it 15 is a methodology that I thought would be useful. 15 DR. OKRENT: Dr. Shinozuka. 11 DR. SHINOZUKA: If I may, I would like to talk 18 about problems associated with hardware in the nuclear 12 problem. This causes a discussion away from acceptable risk 20 criteria, but I think I would like to lead to that end of my 21 comments. 22 Could we -- the power plant consists of electrical 23 systems, structural systems, warehouses for the electrical 24 system and the control system. The mechanical-electrical 25

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system obviously might become an initiating event of a very many number of possible event trees. At the same time, it will induce in some cases structural failures.

Now, when we look at the structural system, it might fail due to natural hazard, notably by earthquake. And by doing so, that is structural failures and that in turn induces failures of mechanical systems.

8 If you look at control systems, including the
9 angineered emergency safety systems, if they fail,
10 definitely they will induce all kinds of problems.

11 To make a long story short, all of these will 12 definitely increase the possibility of radioactivity 13 release, if not definitely lead to it.

I see three basic problems which ha e not been really dealt with carefully, dealing with these systems:

Number one, the interactions of these failures are not well understood at this time. For instance, if an earthquake hits, what is the probability that the control system fails, which will in turn increase the probability of failure of certain mechanical and structural systems? These are not well -- this problem has not been very well addressed.

Number two, human factors, particularly human
errors in terms of design situation or operating
situation. This is an important aspect which we really have

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to systematically deal with. And I don't think I have seen really a systematic approach to deal with human factors.

Finally, uncertainties in evaluating particularly structural and mechanical system behaviors are really, really wise. I think we really should make an effort -- and when I say "we," I mean the general engineering profession -- should make an effort to, if not of course eliminate, to reduce the, let's say, confidence associated with such uncertainty.

I think all of these problems must be looked into systematically before we can really come up with estimates of probability of, let's say, radioactivity release of a specified amount, which are needed, I suppose, for the ultimate risk assessment we are talking about. These are some, I would say, practical implementable suggestions I can offer right away with the engineering community.

17 Of course, probably we will have to have some 18 research funding to receive these researches, to see that 19 they be implemented. But I think that that is really 20 important. That is what I would like to say.

21 DR. OKRENT: Well, let me not comment at the 22 moment. I agree with much of what you said.

23 Bill, you had your hand up.

24 DR. LOWRANCE: I would just like to raise my own 25 continuing concern, and that is the question: was the Three

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Mile Island accident a surprise to anybody who had been involved in the WASH-1400, Rasmussen study, and all of the modifications made since, the Lewis follow-up and so on? Was that accident fairly within the assessment fully at hand within the industry and the regulators? Or was it some sor of total surprise?

My guess, to answer the question a little bit, is that some subparts of it were surprises to lots of people and were not fully anticipated by the formal analysis; but overall as a huge machine most aspects of it seem to have been within the boundaries within the limits that had been drawn around the system before -- in the before-the-fact analyses.

So, then, I ask myself, "Well, so what? Do we need to do any more studies if we are getting better and better at the Rasmussen-type studies? That is, how will the machine behave and then adding operator error and better management of accidents and emergencies and evacuations and things of that sort? Or is there something else really fundamentally wrong with all of this?"

And it may be then that that is, when I am driven to sort of thinking about the effect of an accident in this case where no one was killed outright, is that what we ought to be worrying about? And how do we accommodate that balking effect, the fact that it is terribly disruptive

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because it started down a very serious branch of the fault tree? Is that effect something we ought to be worried about more? And how do we do that? How does formal analysis help 3 us with that?

This is just a large question I am just trying to ó raise that is somehow wandering around in my mind. 5

DR. WILSON: That brings up something that I did 1 not include in my list of issues. But I think it can help. 8 And that is: as a partial comment on that and also a 7 partial comment, I think certainly I was expecting something 10 the size of Three Mile Island to be coming up any time. I 11 12 was hoping I was wrong.

But I must say I have read Rasmussen's report. 13 and, of course, it wasn't exactly what was predicted by it 14 in any way, but many people in the industry had not expected 15 it. I mean, they really thought Rasmussen was rather 15 pessimistic. And so, in that sense, it was a shock. 17

The other thing is also true: that as I think 13 about it, what did the Rasmussen report do, and how could it 19 be used? It was used incorrectly by two sets of people: 20 incorrectly by the Commission and the industry in saying 21 reactors were safe; incorrectly by intervenors who were 22 saying it's a bunch of nonsense. But really, it was a rough 23 assessment of where the industry was at. 24

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But what it was not used as was a set of things

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which reactors are that safe if you follow these procedures. And you look at this very carefully.

So, there is one set of things where I hope something must have been done where the risk analysis is in fact being used and it should be used. It wasn't before Three Mile Island. And it was recommended by the Lewis committee and everybody.

And so I think we should continue to realize it 3 both in itself and all its ramifications, and that is if 7 Herbert Dekamp and his staff had read the 82 sequences of 10 the water reactors that Rasmussen went through and said, 11 "Well. I wonder how this Westinghouse sequence applies to 12 the Babcock & Wilcox reactors." it is inconceivable to me 13 that they wouldn't have realized that this particular 14 sequence is a thousand times more probable in the Babcock & 15 Wilcox reactors. It's not inconceivable to me that in that 16 case they'd do one of two things: certainly, alert people; 11 and. if not -- and badder still, it was not done until May, 18 which was just the set point of all of the things, so it 19 didn't happen so frequently. 20

Those aspects of risk analysis seem to me in management of industry, seem to me more important. That approaches the question I was saying that one of the points of doing risk analysis is to guarantee someone has thought through the problem. And in fact, one of the things that

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Three Mile Island showed is that the particular staff had not thought through the problem, and this I had hoped: that if you have a thing like the Rasmussen report, 82 sequences, it is not that much work to ask everyone of the trained operators in the simulator training to think in terms of

what do you do if that happens.

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DR. LAVE: That's a good point. But I think there is one thing there that might be unfortunate. Three Mile Island does not serve to disprove the Rasmussen calculation, but neither did they serve to prove them. That is, they are simply consistent with them, and one cannot say, aha, since Three Mile Island was consistent with them, therefore 6 Rasmussen was right and various other people were wrong. 7

But let me try and be positive. Using that and 8 what the other people have said to try and be positive --9 and Dave, I'm sorry. I was reacting to some of the questions 10 you were posing to speakers, which is why I was trying to ask 11 you whether you had stopped beating your wife. 12

DR. OKRENT: Well, I did not feel it fair to push 13 any of the speakers except Toby Page on the question of 14 quantitative risk acceptance criteria. But I feel it is fair 15 16 to push you all.

17 DR. LAVE: Well, let me try and do that. Trying 18 to react in the spirit that you posed the question, I think that we know enough now to know that the framework in which 19 that question has to be posed is more complicated perhaps 20 than had been realized by the NRC at the beginning of the 21 study. That is, it has several aspects about it which we now 22 know to be important. And let me just put a couple of them 23 24 down.

> That, first of all, estimating risks without being 1573 253

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able to verify the levels of those risks is almost a meaningless exercise; and that probably at this point the most important aspect of risk assessment for the nuclear reactors has to do with some attempt to verify what those probabilities are, and not simply to make them larger or smaller or whatever it is.

Secondly, we need to know much more about the residual uncertainty once the risks have been estimated and verified to the extent possible, and that magnitude of residual uncertainty has to do both with the unverified part of the risk, since most of the risk will necessarily be unverifiable -- but we're also looking beyond that part.

The third part is what Dick has just been stressing, 13 which is we need to worry about a different framework in 14 15 which nuclear reactors are operated, so that reactor operators 16 are motivated to think about whether it is worthwhile to go to the Rasmussen sequence or some other sequence, or worry 17 about whether the level of training is correct or whatever 18 19 it is; that is, that the incentives are properly placed so that somebody other than the NRC Commissioners are worrying 20 21 about all of this in detail.

However smart the NRC is, it can never approximate the amount of smartness represented by all of those people out there in the field operating reactors every day, who, if properly motivated to worry about the right kinds of 1573 254

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problems, are going to do a much better job than the NRC staff could ever possibly do.

So you want to get the incentives right. And then the last part of that is that any notion of acceptable risk 4 is necessarily tied to some notion of the benefit that you 5 are getting from looking at that risk, which not only has 6 to do with the distribution of the benefits and the distribu-7 tion of the risks, but also the overall benefit. And in this 8 case, that really comes down to what is the cost of a kilowatt-9 hour foregone or the cost of a kilowatt-hour generated by an 10 alternative to nuclear power, such as coal. 11

And I think only by getting estimates of all of 12 these things and by looking at the parts of those estimate; 13 that one can verify, can one begin to get this answer of what 14 then is acceptable, what should design or operational criteria 15 16 be.

DR. OKRENT: I must say I agree that the points you 17 raise are relevant. I think we discussed them before at 18 previous meetings, well before the ACRS got involved in this 19 specific activity. And we are very conscious of the problem 20 of uncertainties. In fact, to me the problem of the uncer-21 tainties and your inability to be confident of what we can 22 predict, unless you're willing to talk about relatively high 23 risk levels, is a big impediment in this whole thing. 24

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Maybe I'm wrong in trying to divorce what I will

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call risk management from risk acceptance, because obviously you all think it should be there. I am not opposed to it. Remember, Whipple and I wrote a paper in this area. I thought that maybe life would be simpler if we left it out. But what you tend to be saying is that you shouldn't be leaving it out, you should have it in there somewhere. And I am perfectly willing to be open-minded in that regard. 7

I should note, we started a little bit of our own 8 effort, although it is a small effort. In fact, 9 David Johnson and Bill Castenberg have been asked to try to 10 11 give their estimates as to what extent did they think we could produce estimates of the individual risk from a nuclear plant, 12 with what degree of uncertainty, or something that they would 13 be willing to defend, even subjectively. But that is a small 14 15 efiort.

16 So, having said that, I want to come back to you in 17 a minute and say, now what do we do. But let me call on 18 Toby Page.

19 DR. PAGE: I wonder if this would be an acceptable dichotomy, that when you are worried about assessment of risk 20 in sort of a descriptive sense, in trying to figure out what 21 the probabilities are -- that sounds sort of like what you 22 were pressing me on and other people, in terms of trying to 23 24 describe the nature of the risks as they are. But when we Inc. begin to ask questions about what is acceptable or what is a 25

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reasonable risk, what are the criteria for risk, then we're really beginning to get into the normative questions. And when we get into these questions, the amount that we can change the risk by having incentive systems and institutions this way rather than that way becomes an important part of calculus, to decide what we're going to live with.

So that's one of the reasons why some of us are sort of fighting the idea that what you're calling risk management can be divorced from acceptable risk. If you said, let's try to divorce risk management from an assessment of risk as it exists today, then maybe we could sort of go along with that sort of dichotomy.

DR. OKRENT: By the way, I favor what I called an ALARA criteria, and I also, as I indicated, really favor something that is the equivalent of a risk tax.

But let me note, there are different ways of trying to get to levels of risk. One is to say, well, I will try to give the licensee an incentive. But the NRC could say, we will try to build nuclear plants underground. Maybe that way we will reduce the risk. They might be changing the cost by 50 percent, and I think that should cover it. That is a lot of money.

Society has to ask itself, is that where it should spend that much money, because you multiple it times a billion times X times -- so it is not something that I think the NRC

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should do lightly, if it were to do it, or the Congress. 1 By the way, sometimes, to put myself in a little 2 bit of perspective, I do another kind of calculation about 3 effects of radiation, namely, what is the effect of nuclear 4 war. And I come up with the effect on the U.S. of 100 million 5 early casualties and 100 million delayed, in Rasmussen 6 parlance. And if you change the probability of such a war 7 by a thousandth of a percent, if you increase it, that is 8 still 10⁸ over 10⁻⁵. So it is 10³ people expected value per 9 year. 10

That is still a pretty big number, in fact. And who is there to argue that he knows what changes the probability of a nuclear war by one-thousandth of a percent? Certainly even oil supplies, you could argue, fall in that category readily. So it is a tricky bit when you start trying to put everything in perspective.

DR. WILSON: I always like + argue in terms of 17 bounds, because so much of the talk people have is -- can be 18 bounded. The comments that Dr. Lave had and criticisms I have 19 had on risk benefit analysis is no good, you're just kidding 20 us, and so on, but you can't do this, that and the other --21 and they put up straw men and destroy them, because they are 22 picking something which Lester Lave never said, and he never 23 said the numbers were highly reliable. They said -- he 24 Inc said the numbers are this sort of magnitude if you calculate 25

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them this way. I very much doubt whether that's zero and whether that's half a million.

And if you start putting bounds on it, you get things which people can't disagree with. I think when you do something of the same on acceptable risk -- I mean, you talked about 10^{-20} and whether that was acceptable. Well, if 6 I was being subjected to risk, it certainly is more acceptable 7 to me to accept 10⁻²⁰ than to pay for a 15-cent stamp to 8 complain to my Congressman. I mean, that is a very simple 9 risk-benefit calculation. I mean, much more -- \$100 million 10 per life is what I gain on that one, even with 15 cents per 11 12 stamp.

So if one puts it in that ridiculous form, it 13 becomes clear that some low level, like 10 to the minus --14 I don't know. In this case, I think probably 10-10 could be 15 argued in a fair form, in which everybody would agree, when 16 you put it in a ridiculous form. 17

I even got Samuel Epstein to agree on the risk of 18 carcinogens which is acceptable. But one goes by pointing 19 out that saccharin -- one shouldn't bound waitresses serving 20 in the cafes, because the risk is 10^{-10} . Well, 10^{-10} is what 21 a critical risk analyst calls absurd, because it is small. 22 But I think it is worth doing that, because that does give 23 you a boundary point which is non-zero, and it immediately puts some of the things where you can immediately start 25

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	1	thinking at a certain stage. And then you have to do your
	2	thinking between a range of 10^{-10} and 10^{-2} , And 10^{-2} , you
	3	say, look, if those reactors aren't safe at 10^{-2} , well, you
	4	certainly will not build them.
	5	DR. OKRENT: You know, society imposes risks of
	6	10^{-2} , knowing them. They are doing it in Los Angeles now.
	7	DR. WILSON: Per lifetime.
	8	DR. OKRENT: No, per year, on seismically substandard
	9	buildings, pre-1933 brick buildings with no seismic protection
	10	at all. I think the probability, even after allowing for you
	11	being there half of the time and so forth and the people
	12	don't know. They have not been notified.
	13	DR. WILSON: Well, we had 10 ⁻³ in Canberra Island,
	14	as we heard in the previous meeting, and that's a pretty
	15	reliable number.
	16	DR. GRIESMEYER: It is most likely not any smaller
	17	than 10^{-3} .
	18	DR. WILSON: I think it is in Everett, Massachusetts,
	19	where the LNG ships come in there, and the population density
	20	is bigger.
	21	DR. OKRENT: Well, in any event, we need somehow
	22	to decide in some relatively short time what would be fruitful
	23	steps to take next. Now, it may be that the National
Reporters,	24 Inc.	Academy of Sciences group will hold a workshop in this area.
	25	I don't know. We probably won't know until next year.
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1	DR. LAVE: Don't hold your breath.
2	DR. OKRENT: I'm not going to hold my breath in any
• 3	event.
4	So again, I urge you to think positive.
5	DR. LAVE: Well, without volunteering to do it, I
6	think one could set out a document which lists the structure
7	of what would be required to get some answers to risk regula-
8	tion and risk management, and then worry about how it is that
9	you could fill in that structure in order to then get some-
10	thing that was workable.
11	DR. MARK: I wonder, Lester, if you could say that
12	again? Are you thinking of trying to you spoke of a
13	structure make a pitch for plans you might make and the
14	ways in which risk could be estimated, made available to the
15	licensing or regulatory process, rather as Mr. Wilson was
16	saying?
17	DR. LAVE: Yes, I think one could specify a
18	structure which could wind up being a how to do it. Step
19	one is blind, step two is blind. We need to know exactly
20	these kinds of things, and these are how you go about knowing
21	them, and these are the steps you have to take as you get
22	from A to B.
23	DR. MARK: And these are the reasons why you should
24 ce-Federal Reporters, Inc.	do it?
25	DR. LAVE: Oh, yes. 1573 261

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DR. WILSON: This is sort of a manual for the people who are trying to do it?

DR. LAVE: Let me be careful in the reaction. I think the manual is the end product. I think for right now what one could do would be to set down perhaps three pages of what the outline of that framework looks like, and then from there start trying to figure out how it is that precisely 7 which pieces of information are needed for each part of the framework, and then precisely how is it that you go out and 9 10 get those pieces of infor ation.

11 So that I think it is not something that could be 12 written full-blown at this point, but I think one could put 13 down the structure and start asking the questions at this 14 point, which I take it is what the four of us are supposed to 15 be doing.

16 DR. WILSON: I think the one thing that I find --17 different people work differently. But I find I can't ask 18 the questions in any abstract way, without ever having tried to look at the specific problem. I always find me full of 19 crazy examples about this, that or the other. But this is 20 the only way I know how to think about it. And we could 21 certainly set up examples of how one might address the 22 question in certain specific examples that you have in the 23 24 past.

I mean, this earthquake hazard thing; how one might

•	1	have gone about that decision of whether to shut down imme-
-	2	diately, later, or something a little more logically than
•	3	it seemed. It may have been done, for all I know. I mean,
	4	I wasn't I have got good lines into the NRC, but they're
	5	not that good.
	6	DR. MARK: You haven't found any logic.
	7	DR. WILSON: Yes. In general principle, logic is
	8	not to be found anywhere in Washington.
	9	But the point is that one could presumably look at
	10	that and find some example and say that should apply to this,
	11	and try and build on that. That is the way I would go about
-	12	doing that.
•	13	DR. LAVE: I think that's fine.
	14	Let me say that I too like to have specific examples.
	15	But I like to see if I can put down a general framework first
	16	and then find out whether the general framework makes any
	17	sense by testing it with specific examples.
	18	DR. OKRENT: I will be happy to see an approach
	19	coming from each end.
	20	Let's see. Toby Page?
-	21	DR. PAGE: Well, just sort of picking up this thing
•	22	we said a little while ago, in this general framework it would
-	23	be nice to see a chapter on how you go about evaluating
Ann Endered Brown	24	previous risk assessment efforts. What has happened is that
Ace-Federal Reporters,	1nc. 25	a lot of probability assessments are made, and then I

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don't know. I mean, I am an outsider, so I don't know. But 1 my feeling is that they are not systematically evaluated and 2 have a reality test run upon them. Maybe I'm wrong, but it 3 seems to me that one very simple thing -- and maybe this 4 cannot be done, I don't know -- is that if you take a report 5 like the Rasmussen Report, which must have thousands of 6 specific probability estimates buried here and there -- would 7 this part fail and that part fail -- you go down this path 8 and that path. Each one of these by themselves can't be 9 tested. 10

However, if we have a bunch of these which are assumed to be independent, then we can add them up to a variable which you can observe. And by doing so, we can have two tests: One is whether or not the aggregate of these individual trials really adds up to what you would expect to see as an expected value of the binomial, because each binomial trial has a different probability to it.

And the other is, then you check the independence assumption, which is a critical assumption for a lot of these error trees. So you sort of get a feeling as to whether or not these independent assumptions make sense and whether or not these individual assessments are consistent with the observable kinds of variables.

DR. WILSON: If I may comment on the first thing, I would mention I put a thing on David's pile at lunchtime.

1	A research fellow and I are just writing a book on some of
2	these things and have a chapter on just that. But it is in
3	draft, and there is a copy on your pile there. And this is
4	the thing I was going to send to you in the mail. So in a
5	sense, that is an attempt at some of these questions. And
6	the conclusion is that most of the attempts in the past have
7	been full of problems, largely because I think they haven't
8	asked the questions, and they have not been complete as to
9	what they were aiming at in the end.
10	But I think that sort of thing, maybe we should
11	that was a rather general thing we were coping with. But for
12	the NRC, what we want to go through here is those aspects
13	which are particularly applicable to the NRC.
14	DR. OKRENT: By the way, let me know I have been
15	an advocate of the proof quality control under risk assessment.
16	So I have to support your general thesis.
17	I guess I don't want us to get into a position of
18	doing what NSF has asked the National Academy to do for
19	them. They have asked the National Academy to help them
20	out with a long-range research program. If that is all we
21	can do for the NRC, I would say we have been a failure.
22	Maybe that is the best we can do, but I would consider it a
23	failure.

Ace-Federal Reporters, Inc. 25 the problem that risk assessments, not only nuclear but on 1575 265 mte 14

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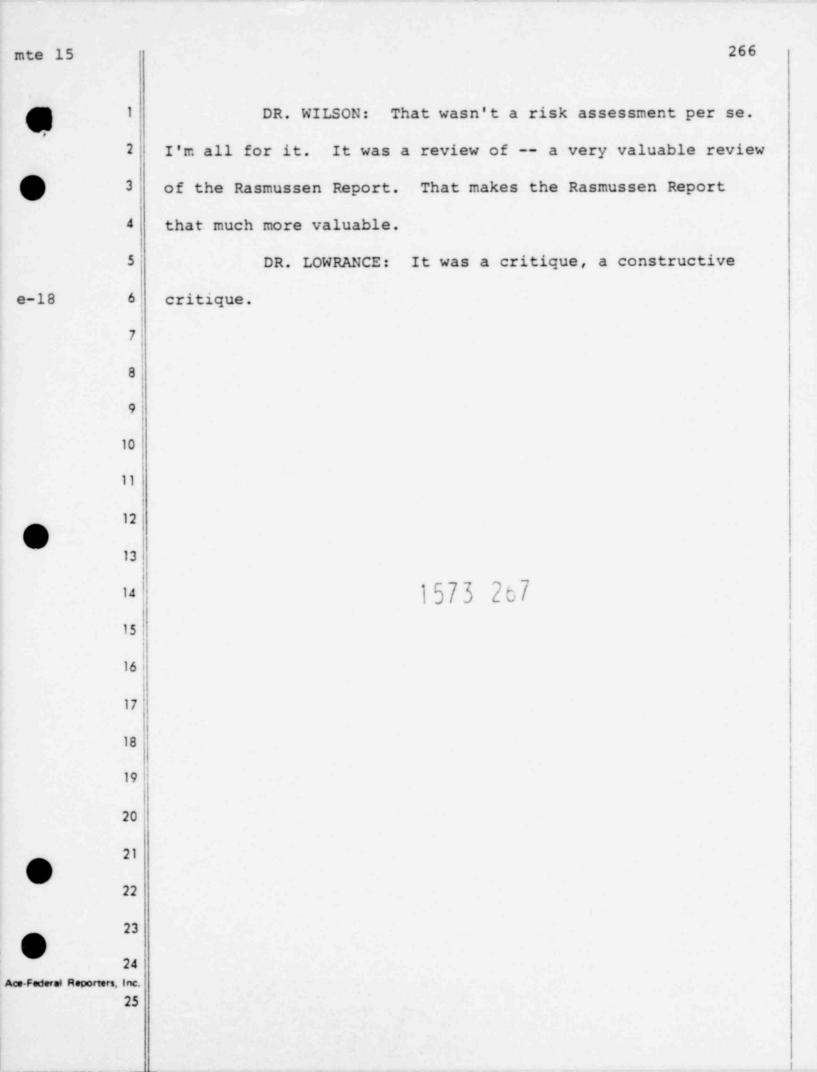
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whatever, have been subject to uncertainties, systematic and otherwise, generally in the past. And a few have received careful review in detail.

DR. LOWRANCE: I would just insert my feeling that 4 the NRC and some related agencies have really done more 5 apsessment than we seem to be giving them credit for. A lot 6 of what has been done in my mind is not all that good, but 7 8 there have been an enormous number of assessments, both in 9 specific site proposals for reactors, industry, Government 10 studies of all sorts on design problems and operator errors, 11 and siting, and philosophy of siting and design, and it goes 12 on and on.

Some of it has been done other places than NRC. I think we ought to give some credit and realize there is a lot of work to be drawn on; and then groups that have tried to pull it all together, have made some progress, and have come up with some kind of middle of the road assessments, as I understand it.

19 The Academy's CONIA study is coming out now with 20 its overall reports in 23 different pieces or something of 21 that sort. And maybe you want to speak to the basic assessment 22 problem on the nuclear side. But I think there is more work 23 that has been done than you are giving credit for. The Lewis 24 panel in examining the WASH-1400 study I think was a good Ace-Federal Reporters, Inc. 25 exercise. 1573 266



DR. WILSON: I was wondering: as a matter of HEE 1 mechanism, the several ideas that I have now, I think, are 2 things where NRC should and could be using risk assessment, 3 which they don't at least appear, from my perspective, to be 4 using, where they probably are on the back of Saul Levine's ć envelopes. 6 I could write down in a few pages those items and 1 send them to you, and you could circulate them to other 8 people. 7 DR. OKRENT: Well, I think that would be of 10 interest. I would say it is not directly attacking the 11 objective. I would like to see what these things are to see 12 whether in fact there are some places where perhaps they 13 should be that nobody has recommended to them. 14 DR. WILSON: What do you think is the objective? 15 16 DR. OKRENT: To try to develop some approach to 17 quantitative safety goals and improve management. DR. LOWRANCE: What are some examples, David? For 18 19 example, what are a couple of things that we could urge 20 someone to do? DR. OKRENT: Well, you heard what George Kinshen 21 22 proposed. He thinks he has proposed a set of quantitative safety goals for nuclear reactors. He has published this in 23 the Institution of Civil Engineers, or something like this. 24 There have been other proposals for quantitative safety 25

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goals. You may think, "Well, they can't be posed that way. They have to be posed in some other way." What is the way in which they should be posed?

DR. MARK: David, I think I have been a little 4 unclear. I am not sure if the rest of the group is. You ć have very frequently used the word "acceptable." That, of 5 course, throws everything off the track, because 1 "acceptable" -- is there such a thing? When you say 3 "quantitative safety goal," that is a rather different 9 kettle of fish. It is acceptable to Kinshen only. 10 11 propably.

DR. OKRENT: You see, you can put out quantitative safety goals and say, "We plan to be using these." You don't have to call them "risk acceptance criteria." If somebody thinks this difference in working is beneficial, it doesn't particularly bother me. I think you are talking about the same thing.

DR. LAVE: David, I don't want to be churlish. But I was just trying to object to this notion that there is a schedule of that sort. I don't think there is a schedule of that sort like Kinshen laid out or a 10-9 or some other criteria. But it is necessarily more complicated than that.

24 DR. OKRENT: I wasn't saying it shouldn't be more 25 complicated. Somebody asked me what do I mean by

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"quantitative safety." Well, I said, "Here is an examle that one man proposed, and he gave reasons -- brief, but reasons -- why he thought those were appropriate."

DR. WILSON: You see, Lave's constant comment is 4 you can't make any logical sense out of risk calculations 5 until you consider the benefits. He is constantly beating 5 me on the head with that, and, of course, he's right. And 1 that is why I bring up my comment, "Well, sometimes the 3 benefit of not having to spend a 15-cent stamp is all the 9 benefit I can itemize, but it is still a benefit." And he 10 completes the logical structure. 11

I think that is one of the important things, 12 because you can then stop somebody's arguing with you, and I 13 think -- so I hadn't completely realized that that was 14 Kinshen's aim, but, of course, very little of what we talked 15 about today was directly approaching that. I mean, nowhere 15 17 did Elizabeth Anderson really discuss how they picked up the 10-6 per lifetime, which I think the average on that really 13 would start -- or the origin of that really started with the 19 FDA and it --20

21 DR. OKRENT: The primary focus of the talks today 22 was to ascertain as we could what was going on in some other 23 federal agencies that were working in some way in the area 24 of risk assessment. I never seriously expected them to try 25 to address the question of what should be a quantitative

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safety question.

DR. WILSON: That's a very serious problem for them, by the way, because EPA and FDA get into fantastically large problems at the moment.

DR. OKRENT: Well, I didn't really expect them to get into this problem with regard to the NRC except possibly the man who was from the insurers, and he was possibly the furthest of all of the speakers that we heard.

55, the purpose, as I say, was to see what was going on. I found it interesting to see what, for example, the Bureau of Reclamation was doing and where they stand now. I think that was a pretty giant step from where they were six years ago.

DR. LAVE: But it just seems to me that the next big public stink is going to be over those dams because of the vagueness of the numbers. I mean, there is an air of precision about them which is completely false.

DR. OKRENT: Well, he stated, in fact, to us that 18 the uncertainties with regard to structural failure were 19 larger than those of seismicity, in general. Those of 20 seismicity are large. And he stated that also. The site he 21 happened to deal with was one of those that you might say is 22 a more fortunate one. You have some faults you can use to 23 get a handle on what is the probability of a pretty severe 24 earthquake for lots of sites. You are not in a position to 25

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use some strong nearby faults, and you are less able to say what is 10-4 and 10-5 per year earthquake.

DR. SHINOZUKA: Since this is the first 3 subcommittee meeting I have participated in, I must confess 4 I am completely confused. Are we accepting the kind of ŝ. approach of structural reliability -- and that is what the ő dam safety program dealt with - that kind of approach we 1 are going to accept by way of reaching the consensus as to 3 acceptable risk criteria and the part of the analysis we 9 have to perform? 10

When I talked about - when I talk about this, my 11 overriding concern is the real uncertainties and 12 difficulties we face when we have to come up with numbers. 13 Sometimes I feel it is hopeless, but we have to come up with 14 some numbers. And that person from the Bureau of 15 Reclamation must have had the same problem: that "The 15 liquefaction -- my god, that is a terribly serious problem." 1. And I think that the variation would be 100 percent 13 12 more.

20 So, my overriding concern is how we are going to 21 resolve this difficulty now as a subcommittee. We are not 22 addressing purselves to this problem and just assume that 23 somehow we can arrive at reliability figures, then establish 24 risk criteria, taking the cost-benefit analysis into 25 consideration. Is that what we are doing here?

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DR. OKRENT: I think one could try to answer your question in different ways. One is to say you should be 2 able to develop what constitutes proper safety goals or risk 3 acceptance criteria or whatever term you wish to use for 4 nuclear reactors without having quantified what you think it õ is for the surrent designs, but from other considerations, ć and then, if the current designs meet that, good; and if 7 not, you have to change the designs to meet it. That is one 3 possible approach. 7

Now, another approach and one I am sure that is 10 taken throughout the regulatory business is: they find at 11 some point to which they can go or some point where they 12 are, they think and they decide what the thing looks like, 13 and then they try to rationalize: does this seem to be 14 okay, and if it is okay then they can develop criteria that 15 15 match.

DR. SHINOZUKA: My feeling is I think we could 17 talk about which design is safer, but I don't think we can 18 place absolute values of structural reliabilities. That is 17 20 where my difficulty comes in.

DR. OKRENT: It may depend upon how reliable you 21 think things have to be. That's the only way I can put it. 22 Well, I said earlier -- and I agree with you --23 the uncertainties are not going to be small. 24 DR. SHINOZUKA: So, supposing we agree upon 25

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acceptable risk interpreted in terms of, let's say -probably many people don't agree - but suppose we interpret that in terms of probability of failure. Can we then build 3 or construct a structure which really can perform with that 4 kind of propability? ó

I don't think that is guaranteed. I think we will ŝ. have really difficult technical problems to build that kind 6 of reliability into the structure by way of design. 8

DR. OKRENT: Again, I am going to have trouble 4 10 answering in the abstract. 10-10, yes, we will have trouble. It will be possible. 10-3, maybe. 10-4 -- what 11 degree of confidence do you want? 12

DR. SHINOZUKA: Well. I am simply trying to 13 14 understand what we have to do.

DR. WILSON: Nell, maybe one of the things that 15 -- I think it is an important question because -- are we 16 17 basically trying to set a level which is then for, you say, acceptable risk for a safety goal which, when explained to 13 people, makes them reasonably happy? I mean, when I say 19 "explain to people." I mean to politicians and economists 20 21 and everybody.

So, then comes the question: what at the moment 22 23 seems to be making a lot of people unhappy, and when one looks at it it is not the expected value of the risk people 24 calculate. it is the possibility of very large societal 25

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consequences which they -- so large they can't envisage them, and I keep getting at that on all sides.

So, I think the safety goal can actually be -- it must be adjusted. I think it is probable that a less safe reactor would be more acceptable if it could be more easily õ demonstrated that it has a certain safety level or if it ó could be shown that the consequences of a failure are much 1 3 less severe.

I think this is not usually thought of: "I can't 9 prove it's safe, but it's the best thing I know how to do." 10 Sometimes something is not the best, but you can prove it a 11 little more readily, and I think this is an important 12 question which does contrary to most engineering judgmet. 13

DR. OKRENT: Well, you included two things, 14 though, into your comparison. And I think that certainly 15 the question of severe accidents is a factor in the 15 discussion of nuclear power in what I would call the "risk." 11 It is not just using the expected value, but you could build 13 that into the risk acceptance criteria if you thought that 12 is what should be the goal of the NRC. 20

DR. GRIESMEYER: That was suggested last time. 21 DR. OKRENT: It is possible there is nothing about 22 criteria that automatically says "use a single number, use 23 expected value," or what have you. 24

DR. GRIESMEYER: It also might be that --25

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DR. OKRENT: Or you don't allow for benefits or you don't provide incentives.

3 DR. GRIESMEYER: The framework wouldn't even have 4 to be necessarily insufficient condition; it may just be a 5 necessary condition for acceptance. Because it may be very 6 difficult to come up with a framework a priori that 7 adequately deals with the whole decision process.

But there may be things that you can say are not acceptable risks, so use them as a hurdle and then continue with your decision process.

DR. OKRENT: Well, can I ask: would at least the three of you who have been fairly active in the general area one way or another for many years, would you be willing to sit down in some corner and think about it and try to come up with what you think represents a possible next step or a possible general step or a framework or whatever it is, in whatever way you see it?

And maybe Lester would come up with something that resembles the framework he was talking about, with an idea of how you would pursue it. And I think that would be real nice, in fact, to have.

And if Wilson came in with an approach that was partly the same or partly from a different perspective or whatever --

DR. MARK: And make it clear at what level he

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pv HEE	1	would regard the 15-cent stamp is worthwhile.
	2	DR. OKRENT: Well, more than that. Because that
-	.3	part of it, I think, we have a feel for.
•	4	But if you could try to do this in the next month
-	ć	and I know that is asking quite a bit it would really
	5	be useful.
	1	DR. WILSON: It can certainly be done by January I
	8	by ma.
	4	DR. OKRENT: Well, when I say a month, that is
	10	obviously a round number.
	11	DR. LOWRANCE: An NRC month.
	12	(Laughter.)-
	13	DR. OKRENT: Don't put it that way.
_	14	By the way, I am going to try to get Paul Slovick
ø	15	in joining us in the flesh.
	15	DR. LOWRANCE: I really would like to enter the
	17	mildest complaint that we have today a meeting of
	13	consultants and not a meeting of the subcommittee, because I
	19	find this a little troublesome, because if this is to be a
	20	two-way interchange, that hasn't been achieved. And
	21	although we have had one faithful member and yourself here
	22	all day, it is hardly a committee meeting. Surely, it is
	23	not a quorum.
	24	DR. OKRENT: Actually, though, David Johnson and
	25	Mike Griesmeyer are supposed to be working in this area

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full-time, and Bill Castenberg is working in it part-time. So, you do have the people who are trying to think actively in it. Kerr would ordinarily have wanted to be here, but he had a conflict.

What developed was the Commission thinks it needs comments from the ACRS on what it is supposed to do about the Kemeny Commission and some things like this, and so there are several members who are sitting in another room all afternoon. I think they are still there.

DR. MARK: And all of that blew up after all of this was planned.

DR. OKRENT: Yes. But if you would be willing to do that, I think that it would be, to me, a logical next step. If there is any way in which you can provide further information that could be useful, let me or

15 Gary Quittschreiber know.

And I would like to talk -- sometime maybe I will get you on the phone, Dr. Shinozuka: I would like to discuss some of the things you have in mind and explore them in some more detail, if we can.

And we will also arrange to see that you get documentation. I don't know what Gary Quittschreiber has sent you so far, but we want to make sure you have the necessary background information.

Is that okay? All right.

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pv HEE	1	MR. QUITTSCHREIBER: We have not received comments
-	2	from any of the consultants on your frameworks.
-	3	DR. OKRENI: Well, if you would be willing to,
	4	Griesmeyer and I would appreciate it. You were given
-	5	something that Mike Griesmeyer and I generated in November,
	5	and if you have any comments, we would appreciate it.
	1	Well, thank you all very much. I will adjourn the
	3	meeting.
	÷	(Whereupon, at 6:25 p.m., the meeting was
	10	adjourned.)
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