DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL AND PREVENTION

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

PUBLIC MEETING

OF THE

EPIDEMIOLOGIC RESEARCH PROGRAM

CONDUCTED UNDER THE

MEMORANDUM OF UNDERSTANDING

WITH THE

DEPARTMENT OF ENERGY

The verbatim transcript of the meeting for **Public Feedback and Update on NIOSH Occupational Energy Research Program** held at the Washington Court Hotel, 525 New Jersey Avenue, NW, Washington, DC, on October 27, 2005.

AGENDA SPEAKERS

(in order of appearance)

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INDEX

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P R O C E E D I N G S

(9:15 a.m.)

WELCOME AND OPENING COMMENTS

MR. REED: Good morning. It's my pleasure to open this public meeting of the Occupational Energy Research Program of NIOSH, the National Institute for Occupational Safety and Health. My name is Larry Reed and I'm the Deputy Director for the Division of Surveillance, Hazard Evaluations, and Field Studies, the division that encompasses the principal research program that you're here about today.

A couple of logistics things before we begin. For those of you who are not familiar with the building, I'll start with the basics. Bathrooms are toward the back by the elevators. And also there is a restaurant here, I believe on the next floor -- this floor, okay, and also there are restaurants, I believe, at Union terminal, which is, for those in the DC area know that well.

Also a few logistics things, too, since our meeting is being transcribed, and I'll mention more about why we're doing that, would you please, if you have questions or comments, as you'll see later on there'll be a formal comment period, would you please use the microphone that's sitting there in the center so that our transcriber can hear what's been said and questions

that are being asked.

There's also a sign-up sheet as you're entering the room. If you haven't signed up for this conference, or I should say the meeting today, please do so. We would like to keep a record, in case we want to follow up with people who ask questions or comments for additional detail.

Also there's a sign-up sheet for people who want to make formal comments. As you will see in a moment, we have some periods of time at the end of the morning session and at the end of the afternoon session for formal comments, and I will sort of describe that when we get to that slide in just a moment. We'll also have breaks and coffee in the back of the room -- I should say outside in the registration area and water at the back of this room.

The principal purpose of this meeting today is to help NIOSH, to help our Occupational Energy Research Program shape the future research agenda for where we're going to be going in the next phase of our research. You'll be hearing today summaries of completed NIOSH research, ongoing NIOSH research in this area, as well as some ideas for where we think future research should be going.

At the end of each presentation we're going to

allow for questions from the public about each presentation, and as I mentioned earlier we also have a formal time set aside at the end of the morning as well as at the end of the afternoon session for those who want to make public comments. And we would ask at least to start off, that you limit your comments to about three minutes, and then if there's time, and presumably there should be ample time given the number of people, then we will have an open mike session for additional comments. So you will have ample opportunity to comment.

And this is critical to us because it's extremely important that we have your input at this meeting in terms of helping us shape the future research agenda. This is a living and ongoing effort that we want to continue in the future with meetings like this. So it's extremely important that we get -- engage you in dialogue and interaction to help us shape this for the future.

As I mentioned earlier we're taking a recording here, the meeting is being transcribed. There will be a formal set of proceedings from this meeting that we'll ask that each of you comment on through some type of public, probably Web site method.

Now for the agenda. It's just a brief overview of

what we're going to be doing today. We'll have welcoming comments from Dr. Wade, the division of the Office of the Director of NIOSH; some background discussion and historic history of the program, the Occupational Energy Research Program; a summary of the completed research; that will finish off the morning session. And then in the afternoon we'll have a summary of ongoing -- current ongoing research, and then a sense of where we think we're going to be going in the future with research, and this is, again, the principal task at hand today is to help us with the shaping of this.

As you will see we think we've done much to shape or do good research in the area of occupational energy and energy health affects research. We think we're at a point now where we're going to be moving to phase two of our research program, and this is where the agenda for shaping our future will help us now through public comment. So we've given ample time at the end of the afternoon session for this dialogue with you all.

With that I'd like to actually get a sense of people in the room, and if you could spend just a few moments telling us who you are and what organization you represent, and I'll start with our panel of speakers here with Dr. Schnorr.

DR. SCHNORR: I'm Terri Schnorr with NIOSH.

DR. SCHUBAUER-BERIGAN: I'm Mary Schubauer-Berigan also with NIOSH.

DR. WADE: Lew Wade with NIOSH as well.

MR. DANIELS: Doug Daniels, although it says Robert, Doug will work, and I'm also with NIOSH.

DR. KUBALE: I'm Travis Kubale also with NIOSH.

(SEE INDEX FOR AUDIENCE PARTICIPANTS)

MR. REED: Thank you all. We've got a great mix of people, and we hope to, again, engage you -- don't be shy, we want to engage you in this dialogue for helping shape our future agenda. With that, our first speaker this morning is going to give welcoming and opening comments. Dr. Lew Wade is a science adviser to Dr. John Howard, the director of NIOSH. Lew.

DR. WADE: Thank you, Larry, very much. Can you hear me okay on this microphone? Good. Thank you. I do bring you welcome from John Howard, the NIOSH director. John is busy at work in Des Moines, Iowa. He is attending the University of Iowa's Royal World Ag Forum, a long-standing commitment; otherwise he would have been here with you.

In addition to welcome from John, let me add thanks from John and myself. As Larry mentioned, you're here to help NIOSH and, therefore, we need to thank you for

that in advance. We need to hear from you. We need your input. Please provide it to us. We will take it seriously; we will take it to heart. But let me thank you in advance for your contribution to NIOSH and the evolution, the positive evolution of an already very positive program.

What I'd like to do is just sort of give you context on the meeting coming at it from several points of view. As I'm sure many of you know NIOSH is heavily involved in the Energy Employees Occupational Illness Compensation Act. Under subtitle B of that act NIOSH does individual dose reconstructions for people with cancer.

NIOSH is also involved in that program in making recommendations on petitions for employees to join the Special Exposure Cohort that has been established under that act. There is an advisory board that I serve that oversees the activities, a presidentially appointed advisory board. And any of you who have been involved in or around that advisory board know that this process is unbelievably political, political with a small "p," and it's supposed to be. It's about interest, it's about perspective, it's about all kinds of things that make the business of the program very, very difficult to administer at times.

But what can be a guiding light to the program is a foundation of good, solid, substantial science. Without that science we would be forever adrift in this political -- this political confusion. So I'm here to tell you that the science you're going to talk about today is terribly important. As it provides for many things it certainly provides, again, a beacon for the compensation programs to when they lose their bearings and get too awash in the politics can turn to science, and it's only through good, quality, peer-reviewed science that we can begin to move through some of these very difficult challenges. And I ask you to keep that in mind as you offer your comments to NIOSH in terms of the conduct of the research agenda.

The second context I'd like to bring you really goes to the NIOSH strategic plan. Under John Howard's very able leadership NIOSH has gone through what all organizations go through and that is the development of a strategic plan. I won't bore you with much of that, but to tell you one of the things John has brought to NIOSH is an initiative he calls R to P, or Research to Practice. What that initiative is about fundamentally is saying to the NIOSH research community, both intramurally and extramurally, that we're not done when we complete our research, we're only done when there

has been a positive impact made in the world. We need to be relevant, obviously.

And one of the ways we can go about being relevant is to listen to folks like you as you tell us what your thoughts are, what your needs are as we begin to fashion our program. So I see a meeting like this, I see every time we reach out to the public as acting consistent with John's initiative of research to practice.

Something else that John has brought to the Institute is a statement of the values of the Institute. Now, any of you who have spent long afternoons in strategic planning sessions can easily get bored with this, but John has tried to inspire the Institute by reminding us of what our fundamental values are. And I'd like to just go through them very quickly and focus on a couple of them as it relates to this meeting.

But the values that NIOSH espouses are relevance, diversity, quality, partnership, access, performance, and accountability. No surprise to anyone, but as you imagine trying to move a bureaucracy like ours in a positive direction, it is very important that people don't lose touch with those values.

Let me talk about three or four of them, again,

within the context of this meeting, and the first I'll talk about is diversity. Within the language we use are the words: Our research and interventions reflect the diversity of solutions needed for the American workplace. A powerful thought, but it relates to this meeting. Obviously, we need to hear from you about what the research solutions are that are needed for the workplace.

You'll also hear when our scientists talk to you about an extramural component of our program. It is very easy for a science bureaucracy such as ours to turn inward and only focus on our own ideas and our own research initiatives. What we try to do is make sure that there is an extramural component so there is a diversity of ideas and approach.

So I ask you to think about that as people talk to you about what we're doing intramurally and extramurally, and maybe in your comments suggest things that might be appropriate for us to do in our extramural component. So not just research topics, but think as well about the appropriate vehicle, be it intramural or extramural.

The second value that I'll talk about a little bit is very important to NIOSH, and it's quality. And we say we utilize only the best science, the highest level

of data quality, and the most transparent and independent peer review; critical to us. Sometimes it makes us appear to be slow in the conduct of what we do, but I tell you that it is terribly important that we do our work transparently and that we do our work under the microscope of peer review. Again, I ask you to think about that as you comment upon our work, comment upon our time frames, and comment upon the things that you would like us to do and the way you would like us to do those things transparently and utilizing the highest level of peer review.

The third I'll mention briefly is partnership. We accomplish our mission in partnership with industry workers, federal and state governments, and the scientific and professional communities. From the brief introduction those segments are represented here, but it's terribly important for NIOSH to hear a balanced presentation of the things that we need to do. So if you represent one of those sectors make sure that your voice is heard and made onto the record so that NIOSH can again get the diversity of input that it needs as it imagines its research programs in the future.

I'll end simply with the first value I read and that is relevance, and the only way we can be relevant

is to be in touch with the people we serve, the people in this room and many outside of this room. So it is important that we reach out to you, and when we do we ask you to respond.

So, again, let me close by thanking you in advance for what you bring to us. These are important interactions for us to take place. We value and we will respectfully deal with your input. Thank you very much.

MR. REED: Thank you, Lew. Our next speaker is Dr. Terri Schnorr who is the division director for the Division of Surveillance, Hazard Evaluations and Field Study, she's my boss. Terri is a Ph.D. epidemiologist and she's here to talk with you about the background and history of the Occupational Energy Research Program.

BACKGROUND

DR. SCHNORR: Thank you for preventing people from seeing my technological incompetence. Can you hear me? I'm Terri Schnorr. We appreciate your attending the meeting today. We're very interested in getting your input. The program is just about 15 years old now, and in that time we've accumulated a body of scientific work that we think advances the scientific information on health-related energy research. And so we're

anxious to share that with you today and get your input.

Before others get into the details of the research plan my job is to give you some history and context of the program. There's some key tenets of our work: one is to conduct basically epidemiological research to look at the relationship between exposures and disease; also to develop and refine exposure assessment methods in order to do this. And the third key element is to provide effective communication about our study results. We also -- a key tenet is to contribute scientific information on preventing occupational illness and injury, and also to adhere to high standards and concern for workers' health. So that's the basic mission.

The setting, the reason for the program is that there are over 600,000 current and former Department of Energy workers and Navy nuclear shipyard workers who worked at these facilities from the 1940s to the present in making nuclear weapons. And in those jobs they were exposed to a number of things, primarily ionizing radiation, but also other exposures, such as asbestos, metals, and solvents. And the purpose of our program is to look at the relationship between those exposures and potential health outcomes, primarily

cancer.

Of the three types of work that we do in the program there are two that are really the key focus of the program. Exposure assessment is really a very important element in the research program. We concentrate on doing quantitative exposure in our studies and we use that work and incorporate it into our hypothesis-based epidemiologic research studies.

The third element of work that we do at a smaller level of effort is the health hazard evaluations. NIOSH has a program that provides consulting to employers and employees about health and exposure hazards, and as we get those requests in from Department of Energy facilities the research program for -- radiation research program works with our hazard evaluation program to provide consultation to those DoE sites.

The Department of Energy has many, many sites all over the country. Our particular program has focused on about 14 different facilities in 13 states, and the activities in these programs, of course, range from laboratory workers who developed the nuclear weapons, to uranium processing facilities and nuclear weapon assembly plants, to name a few.

The program began when in 1989-1990 the Secretary

of the Department of Energy convened a panel to evaluate the epidemiology programs at that department. This panel came up with many recommendations, and I'm going to just talk about the few that relate to NIOSH. But one of the key recommendations relevant to us was that they recommended that the analytic epidemiology program at the Department of Energy be transferred to the Department of Health and Human Services so it could take advantage of the robust peer review and open and competitive grants program there.

Another recommendation was that this new program have an advisory committee that could help set the research agenda, determine funding and to conduct peer review. That advisory committee was created; its acronym is ACERER, which stands for the Advisory Committee on Energy-Related Epidemiology Research.

A third element that's relevant to our program is that this panel recommended that the Department of Energy continue to create a public use database that has an acronym of CEDR, so that others could have access to information. And our program provides this. When we complete our research studies we provide de-identified data sets to this public use data set so other scientists can conduct further research.

As a result of the recommendations from this panel

the two agencies entered into a Memorandum of Understanding. And what happened was that the three epidemiologic programs at the Department of Energy were combined under one roof at NIOSH in the Occupational Energy Research Program. The Department of Energy continues to provide funding and input on the research agenda and NIOSH conducts the work but NIOSH conducts the work independently and incorporates both intramural and extramural research activities.

When the advisory committee was formed, which was shortly after the signing of the Memorandum of Understanding, they were very helpful in coming up with a framework in which the program should work. They framed four primary research questions for the program to consider. The first is: are the current exposure limits adequate to protect worker health? They also wanted us to look at different forms of radiation and whether they had different types of health effects.

A key question that they wanted us to look at is whether chronic low-level exposure to radiation had different health effects than acute exposures to radiation. And they also wanted us to look at joint effects of radiation and chemical exposure.

Another important element of the advisory committee was that they came up with several research principles

that they wanted our program to incorporate in all of our work. First of all, when the program was transferred to NIOSH there were several existing studies, so the committee worked with us to determine which studies should be continued, and about 20 of those were transferred over and completed by our program.

There were several elements that they wanted us to incorporate. One is to combine multiple sites into our studies so that we could get greater statistical power in our work. They wanted us to work on improving exposure assessment, and to include minorities and women in our studies as well. And they wanted us to also look at other elements that had not yet been addressed, such as looking at sites that had not yet been studied, looking at current workers, and looking at other kinds of health studies, such as morbidity studies.

So the program took these questions and principles that were provided to us by the advisory committee and came up with specific goals for each of the three elements of the program. For epidemiologic research goals it was first and foremost to look at the relationship between exposure and disease, which is a key element of epidemiology; also to analyze combined

populations so we could look at whether rare cancers had any relationship to exposures; to look at mixed exposures in the epidemiologic studies so we could evaluate risk more fully; and first and foremost to try to provide more understanding of the effects of low-level chronic exposure to radiation.

When the program began detailed exposure assessment was not a common factor. There are many reasons for this, but primarily it's very difficult and very time consuming to conduct. So it was important for the program to create some specific goals as to how we could incorporate this into our work. So we set some goals to improve exposure assessment methods and to characterize the combined exposures; that is, all of the exposures at the facilities, not just the radiation exposures. A very important element was to try to do quantitative exposure assessment in our research studies, and to look at the quality and validity of the data that was available to us.

The third leg of our research program relates to communication. It was important for us not just to have a rigorous scientific program, but to have a transparent and open program so that people understood what we were doing. So we set several communication goals, including involving our partners, the public, in

an open environment and providing information for other scientists and public health research policymakers.

A word about peer review. Dr. Wade mentioned that NIOSH has a very strenuous peer review policy, and for the duration of this program it has adhered to those tenets. Some of the key tenets are that when a research study begins it's required to have peer review by scientists outside of NIOSH and the CDC, and that is done at the protocol phase.

Then at the completion of the work, when the final research papers or reports are written, all of those works, including those that are later submitted to scientific peer-review journals, must undergo another review by experts outside of the CDC prior to submission. And then finally, before those scientific papers are released it's important for us to share our findings with the Department of Energy, site management, and the workers at those sites.

We have a number of ways to communicate. Obviously, with the scientific community there is that standard peer-reviewed literature and reports and scientific conferences, and as I said, we also provide data sets to DoE so that other scientists can do further research. Communicating with the public and the workers is important, so we put everything on our

Web site, and at the conclusion of every meeting, as I mentioned, we create fact sheets that summarize the study findings and meet with the workers and site management to explain what that means to them.

This slide is -- provides a picture of the program over time. The yellow bars are the number of publications per year for the program, and as you see, as the program matured, the number of publications and outputs for the program increased over time. The red bar shows the number of employees in the program, and you kind of see two waves. There was a slightly smaller employment in the early years when the focus was primarily on completing the existing studies that had been transferred over to the program, and then as we began the more complex multi-site studies within the program we increased our staffing in order to handle that increased workload.

And then this line shows the funding for the program, and basically after a sort of startup period the funding for the program was fairly steady over time with a couple of exceptions. Congress gave us a couple of earmarked mandates for us to conduct. In 2001 they asked us to conduct a health study at the Paducah facility in Kentucky, and a grant was given to a university to conduct that research project. And then

in 2004 Congress asked us to evaluate the relationship between radiation and chronic lymphocytic leukemia. And so we've been working on that since 2004 as well and you'll hear more about that later today. And then in recent years, as with all federal projects or most federal projects, as budgets have gotten tighter the funding has declined somewhat. Another way of looking at our work is, as I said, we completed the 20 projects that were transferred over from the Department of Energy, and we also completed 34 projects that were initiated by the NIOSH part of the program, and those 54 projects have resulted in about over 150 publications, and this pie chart just shows you the distribution. And the one thing I think that is important here is that it shows that the extramural contribution to our products is a substantial one and an important part of our program.

Finally, the goal of this program, as is the goal of all of NIOSH, is to ensure that the workplace is a safe and healthy place for the people who go there, and so what you're going to hear today as people talk about specific research studies is that you're going to hear how -- our attempts to make this particular workplace a better place for the people who are there, and we kind of do that in some different ways. There's some

smaller scale efforts, such as, site specific recommendations that we might make as part of a health-hazard evaluation, you know, perhaps changing ventilation or whatever. There's also the health communication. We feel because we provide direct communication to the workers about any risk that they may or may not have from working at the facility, it informs them and puts in perspective this exposure relative to any other health concerns they may have, and allows them to make more informed decisions about their own personal health.

The main part of what you'll hear today, though, is the advances that the program has made in radiation health science. Because of our emphasis on exposure assessment to conduct quantitative exposure assessment whenever possible and to look at all exposures, not just the radiation, we've been able to use that in conjunction with our epidemiology to really try to evaluate the potential effect of chronic low-dose exposure to radiation. And so you'll hear that theme over and over again in each of our studies as we try to sort of address these questions.

And then ultimately the goal is to take this compendium of work and provide it to public health policymakers so that they can use this to conduct risk

assessments and make other decisions on regulation or compensation from the work that we do.

So with that I'll end and answer any questions or turn it over to Travis. Yes?

MR. REED: Could you speak into the microphone, please, identify yourself.

DR. PUSKIN: Jerry Puskin, Environmental Protection Agency. I was just struck by your slide that showed -- looks like your funding was being cut by 67% compared to what it might have been a few years ago. I was wondering if there was any way to carry out these kinds of studies that you've planned now.

DR. SCHNORR: Yeah, well, funding is a little tight in 2006 for a number of reasons for many agencies, and part of what we're doing here is the funding that a program needs is dependent upon what it wants to do and how its priorities fit. So part of what we'd like to hear here is what are the priorities and how do those fit in, and that is something that we'll have to look at. Any other questions for me?

DR. HOFFMAN: I'm Owen Hoffman. I started with this program as an adviser. I was a member of the ACERER committee. It was a product of the Memorandum of Understanding that took place between the Department of Human Health Services and the Department of Energy.

One of the main reasons for this program, which was not mentioned by these slides, was independence from DoE because of the loss of credibility that DoE had in carrying out its own research on worker health. I think that the ACERER was quite effective in helping to articulate the reasons behind the programs, its objectives, and articulate reasons for maintaining levels of funding.

Since 2002, however, there is no ACERER, it was disbanded, and it was disbanded without any public notification or debate. That seems to violate the principles of transparency and openness. So as you can tell from the message that I'm bringing is you've come to the public today to talk about priorities of your research agenda. That was the mission of the ACERER. There is a definite need for continuation of oversight, of stakeholder involvement; certainly this meeting is one step towards regenerating what the ACERER was about, but I think had the ACERER been in place the budget experiences that you had recently would not have occurred.

DR. SCHNORR: I can't comment on why ACERER no longer exists, that precedes my time, but you're correct, because ACERER isn't there to provide that continual advice, that's one reason why we wanted to

have this meeting so that we could get input from the stakeholders on what we should do next. Thank you.

MR. REED: Thank you, Terri. Our next speaker is Dr. Travis Kubale. He's a recent Ph.D. graduate from the University of Cincinnati in epidemiology. Travis is a long-term researcher in the Occupational Energy Research Program and he's here to speak with us and summarize the completed research of the program to date from the beginning. Travis.

COMPLETED RESEARCH

DR. KUBALE: Thank you. The first thing that I'm going to do is that I'm going to just sort of give numerically the number of intramural and extramural studies that we've completed, just sort of give you some sort of idea of what the active has been in the last several years, and then I'm going to talk a bit about some of issues that we face with conducting large studies that are necessary to really ask the primary question that ACERER and our charge has been, which is: what are the health effects, primarily, with the workers that are exposed to low levels of radiation, does it cause cancer, and if so, what are the risks.

I also want to talk about the relevancy of the research that we've been doing to the principles that were established by ACERER and I'm going to use some

several examples; the Idaho National Laboratory Cohort study will be one, the Portsmouth Naval Shipyard studies will be another. Probably the largest study of female workers in the nuclear complex done by the University -- researchers at the University of Buffalo, I'll talk briefly about.

Another charge that we had was looking at current workers, particularly remediation workers, and determining if it was possible to study those workers or to conduct epidemiological studies with those workers, talk a bit about that; and then a morbidity study that was done by Boston University on looking at the impact of downsizing at several DoE sites.

We have today 54 completed research projects, 20 of those were initiated prior to the signing of the Memorandum of Understanding; 34, as Terri said, NIOSH-initiated studies have been completed today. As far as products which are available, on our Web site we have approximately 151 completed products, and that includes reports, manuscripts, proceedings, those types of things. We also, as Terri has said and we'll talk a bit about this in a minute, we have 45 communication documents and these have been documents that we've developed with the Department of Energy, their site labor and management representatives to we think

accurately and clearly communicate the study results to workers at a variety of sites simultaneously.

Again, as Terri said, one of the challenges that we've had is that our studies cover roughly 13 major facilities that are located in 11 states and the study population is approximately 600,000 current and retired workers. To give you an idea of where we have been as far as our studies are concerned, Idaho, the cohort study, we were asked by the governor of that state to conduct the first ever mortality study of those workers. The Portsmouth Naval Shipyard, NIOSH was involved initially in the 1970s, was asked again by the Navy to update that cohort and those studies, we'll talk briefly about it, just been finished in the last year.

In order to put together a cohort of female nuclear workers we had to look at sites, like the Linde facility, which has been closed since the late '40s; Mallinckrodt was a site that was a previous DoE study that was completed by ORNL researchers. We were involved with the Savannah River facility; of course, the Oak Ridge, three facilities there; Mound, at Fernald, and the Portsmouth Gaseous Diffusion facility in Ohio. The Pantex facility in Texas, LANL, and there's also a group of workers from the Zia Company

that supported the LANL facility that has been involved in several studies we've been doing. The Rocky Flats facility, we'll talk briefly about some recent studies there. We did stress and downsizing study was included, five sites, the Nevada test site was one of those, and, of course, we had been involved with the Hanford facility.

Again, just to give you some idea of the difficulty, these were sites that were not only geographically spread out, but these were sites that people prior to my coming to the branch had to deal with access issues because these were, of course, very secret facilities and working that out with DoE did take a tremendous amount of time and effort by both NIOSH and the Department of Energy.

In order to communicate to several sites simultaneously about our research we contacted, at all of our sites, DoE labor and site management and came up, with their input, a way to clearly, we think, communicate the research findings to the workers. They wanted a document that provided, as you can see, information about terms that we use within a document. They wanted information about what the study was about, who was been studied and, of course, the results. They wanted this in a PDF file document so they could post

this on Web sites, they could send it out in mailers to current and former workers. We also -- they wanted to have information about where future workers could contact -- how they could contact the researchers if they had questions and those kinds of things, and also a section on the limitation of the study.

Again, the primary research questions, as Terri has talked about, that we were tasked to try to look at with our research were as follows. The tremendous question, at least, in my view, is the first one, how do the risk from fractionated exposures, radiation exposures, compare with acute exposure risks? Are the current exposure limits adequate? Mary and Doug Daniels will be talking about some of our current and perhaps some of the PNS studies that we hope will address that question. We have been able to look at the risk from different forms of radiation; we'll talk a bit about that, and the joint effects of radiation and other exposures from primary chemicals.

To do this we have used -- the retrospective cohort mortality studies have been the real engine behind trying to address these questions. As you can see there are several steps that are involved with these studies. I want to talk primarily just about the roster development, the vital status follow-up, and

building the work history and exposure databases, which are critical.

Just for an example, for the INL cohort mortality study, we initially identified 101,000 workers, but the real question was, well, how many of those workers were full-time workers so that they could be in the study. We found, for instance, that there we 17,000 individuals that were really military people that were not permanent workers or full-time workers at the site; several were -- many were offsite working at other DoE facilities and were there at INL for short periods of time, some were hired after the end date of the study. We found several that were visitors that had to be excluded, and then there were several that we just didn't have enough information to determine follow-up whether they were alive or dead. And so the final cohort number was some 63,000. But hopefully that gives you an idea of just a simple question of who's in the cohort requires a tremendous amount of effort on the part of researchers.

Again, vital status is extremely important. We looked at vital status, who's living and deceased from 1949 through 1999. We used a variety of ways to do that, usually starting with the National Death Index. If we can't find out the status there we go to the

Social Security Administration Death Master File, and then go through a series of places like Medicare, the Internal Revenue Service, pension benefits to determine if people are actually alive or dead.

Once that is done the cause of death has to be determined. We use the National Death Index and also state registries to determine the actual cause of death, and then that's, at least in this case, is coded to the International Classification of Diseases for Revision 9. So again, there's a large cascade, there's not one registry that you can go to to determine who's living and who's deceased and what the actual cause of death has been.

Very important to build work history and exposure assessment databases because without them we have no quantitative estimates of exposure. The first thing is to certainly understand the facility, what the processes are, what people are doing, where they're doing it, and what they may be exposed to; determining what records need to be captured for the study, which records, exposure records are relevant; capturing the records, and then determining what's available from those records to actually code into the database. Review each person's records; again, the goal is to make sure that you match a person with an exposure at

the facility if you possibly can. Usually the databases have to be collapsed, meaning that there's a lot of editing that has to be done, decisions made as far as categories of workers, and then validating the database.

Again, just to give you an idea of the numbers, for the relatively small case-control study that we'll talk some about, 575 workers, we started with over 10,000 work history records. Those were collapsed down, edited down to about 3400, and those were just for those 575 workers. For the medical x-ray exposures that we extracted from medical records, again, for those 500 workers, there were over 3000 of those dose records alone. And then for the on-site primary work radiation records there were over 7000, for a relatively small number of workers. I want to talk just briefly now and give you some of the recently completed both internal and external studies. Again, the information that I'm going to talk about here is available on our Web site, and we also have information in the back of the room on several of these studies. Again, the Portsmouth Naval Shipyard, we have both a cohort mortality update of that group of workers as well as a case-control study. Those have both been NIOSH -- they're NIOSH public documents and also the

case-control study is going to be published in Radiation Research next month, I believe.

One of the key findings is that the workers at that facility did exhibit a gamma dose-related elevation in leukemia. We also completed -- Mary Schubauer-Berigan just completed with her team the INEL cohort mortality study, that also -- population was part of the 15-country IARC study that we'll also talk about. The finding that I think is key was that most cancers were not associated with radiation, with the possible exception of leukemia, non-Hodgkin's lymphoma, brain tumors, and breast cancer.

And we also -- this was a bit older, but I think still an important study to talk briefly about, the Portsmouth Gaseous Diffusion study, we did do a cohort mortality study at that site and found no radiation-related cancer, and that's a NIOSH report that was published in '01.

Some of our recently completed extramural studies include an interesting finding that was done by our research partners at the Department of Health -- the Colorado Department of Health and the University of Colorado. It was a cohort study finding that plutonium-related elevation in lung cancer did exist.

We also then had a study by -- of Hanford workers

done by the University of North Carolina, and then also a similar study at Oak Ridge that reported that older workers may be at higher risk of radiation-induced cancers.

We also recently, as probably most of you all know, we did contribute to the 15-country IARC study and there were elevations in solid cancers and non-significant elevation in leukemia, and that was just published in the British Medical Journal.

Again, our research principles that we wanted to make sure that we pay close attention to from ACERER were first to consider previously unstudied sites and, of course, INL was a prime candidate to meet that principle. Contribute our combined cohorts for greater power; again, the Female Nuclear Weapons Workers Mortality Study was an example of that.

We think we've done -- in several studies we've improved exposure assessment. A couple of examples that we'll talk some about were at INL where there were Special Exposure Cohorts that were developed, and also at the Portsmouth Naval Shipyard with the work that Doug Daniels did on work-related medical x-rays. Most of our studies -- all of our studies included nonwhites and females.

We -- as far as current workers are concerned, one

of the things that we will talk briefly about is the Remediation Workers Feasibility Study that we did and looking at is it possible to do these analytic studies with probably the largest population of current workers in the DoE complex, and also the stress in downsizing study, and the stress in downsizing study would be an example of a morbidity study that they also wanted us to include in our agenda.

Just to talk briefly about some of these studies individually, the INL Cohort Mortality Study, again, the primary research that we were looking at is that these were -- did the mortality patterns among these workers differ first from the US population; what's the relationship, again, in the workplace with workers that have low-level chronic exposures, what's the relationship between that and cancer mortality. And we looked at the mortality risk in non-radiological exposed subcohorts.

Some of the key characters -- as you can see it was a large study, only 17% were deceased, 57% were monitored for radiation exposure. The primary exposures that Mary looked at were external radiation doses. We did look at some internal radiation exposure, and they also developed exposure-based subcohorts in chemical, construction, asbestos,

transportation, and painting.

Some of the key findings, again, and we find this a lot, but certainly many of you have heard of the healthy worker effect where overall, compared to a United States population, particularly radiation workers are a very healthy group of people was found, and you know this study as well. The overall cancer mortality rate was slightly elevated among the workers. The overall mortality rate was lower, however, among radiation monitored workers compared to non-monitored workers and, again, we find this throughout these studies that the radiation workers are extremely healthy workers.

Non-Hodgkin's lymphoma was elevated in the cohort and particularly among male painters and female construction workers. Asbestosis was also elevated among construction and maintenance workers.

The Portsmouth Naval Shipyard, again, was a study that we -- NIOSH had been involved with first in the early 1970s. We were, again, looking at overall mortality patterns. We also wanted to look at the impact of low level of primarily gamma radiation exposures, and we also wanted to look at the mortality risk, too, among the non-radiation exposed workers.

Again, it was a relatively large, 37,000 worker

population. The percentage deceased, 37 -- or 32 percent is probably the highest of any of the cohorts that we've studied. Usually we're much lower. 36 percent were monitored for external radiation exposure and the vital status was through '96. The primary exposure, and that's one of things that made this site a nice site to study, is external gamma radiation. There is not a tremendous amount of -- there's not a lot of internal exposures, mostly external exposures, which we thought were good, easier to study. The primary outcomes that we were looking at were lung cancer and leukemia.

Again, not surprising, the healthy worker effect, while still there, though, did diminish from the time that we did the study in the early 1970s to this most recent update, but was still there. With leukemia overall, there was no overall elevation in the cohort, however, when we did, and this was very important and one of the things that ACERER was very insistent upon that we do internal comparisons with these large cohort studies. And so we looked at radiation-monitored workers. We did find for leukemia a significant positive trend with external radiation dose.

We also looked at a subcohort of radiation-monitored workers only to look at confounding from

potential chemical exposures, primarily benzene and carbon tetrachloride, and also socioeconomic status and it was still elevated with and without those adjustments. For lung cancer, again, in the cohort overall there was an elevation; however, when we looked at radiation monitored workers there were only elevations in the intermediate dose groups and there was no significant trend that we could find. Also, interestingly enough, there -- when we adjusted for exposures to welding fumes and asbestos, the association went away or was diminished.

We followed the subcohort analysis with a leukemia case-control study where we were essentially again looking at trying to determine if there was a dose response relationship between -- among these workers, exposure to external ionizing radiation and leukemia. We also wanted to look at the risk estimates if we added as a source of occupational exposure exposures from work-related medical x-rays. And we also wanted to evaluate chemical exposures, again, primarily benzene and carbon tetrachloride.

Basically what we found was that leukemia risk did increase with increasing cumulative radiation dose among these workers. We also found that incorporating the doses from work-related medical x-ray procedures

did not change the leukemia risk estimate. We also found that workers that were potentially exposed to benzene and carbon tetrachloride for longer periods of time appeared to have greater risk of death from leukemia.

We're going to -- actually, the researchers at the University of Buffalo that did the Female Nuclear Weapons Mortality Study, again, we had several of the same questions that we had in the other studies, but again, this was probably the largest study of its kind with female workers. The characteristics, 67,000 women, 20 percent were deceased, 32 percent were monitored for external radiation. The primary exposure was external ionizing radiation.

Again, the key findings, not surprising, overall they were very healthy. The mortality rate among these workers was lower than the U.S. population, with some exceptions: mental disorders, urinary diseases, and ill-defined conditions were all elevated. Overall, the cancer mortality rate, again, was lower when compared to the United States population, but, again, among radiation-monitored workers we did find elevations in leukemia and breast cancer.

This, again, is sort of switching gears. We were asked to assess whether current workers at DoE sites

doing primarily remediation work could essentially be studied in the future. So we had a list of questions that we wanted to evaluate. Can the workers, of course, be identified, which is obviously an important issue if you're going to study them later. Is there adequate exposure work history and medical information available, and can the individual workers be linked to their exposure and medical data; and, therefore, can epidemiologic studies be conducted.

What we found was that there are not complete rosters on these workers. There are significant gaps in chemical exposure, work issue, and medical data. The data collection and archiving methods are not standardized within and among the DoE sites and, therefore, the ability to conduct accurate and comprehensive epidemiologic studies of these workers is limited.

The last study that I want to talk a bit about was done, conducted by Boston University on looking or evaluating the relationship between workplace restructuring, which there was a tremendous amount of that going on across the DoE complex, and individual health and workplace functioning. They conducted surveys of workers at all five sites, the percent responded was roughly between 45 and 71 percent, and

the basic findings that they had and that they reported were that if the downsizing process was seen as fair, if communication was open and honest, there seemed to be less job insecurity and fewer reports of different types of morbidity.

They also indicated that workers that were directly involved with the downsizing process, these were people who delivered layoff notices, were laid off and rehired or changed jobs or departments reported much more stress and job insecurity and symptoms.

Just a bit about health hazard evaluations which we have done, certainly NIOSH in our division does a tremendous amount of those, but if you're not familiar with them we do have applications and information about HHEs in the back of the room, but these are when NIOSH responds to either employer or employees requests for assistance to evaluate potential health hazards at a site, and since 1991 we have conducted health hazard evaluations in several Department of Energy facilities. And they typically result in recommendations and guidance to the site for reducing exposures to workers.

Again, this is a busy slide, but I just want to point out that Sandia, the Portsmouth Gaseous Diffusion facility and also Hanford are sites where since the early 1990s we have done health hazard evaluations

looking at a variety of exposures.

Some of the key findings, just in summary, that I want to point out that I think are very important is that most of these cohorts that we have been studying are still relatively young, 85 percent of the individuals are still living, and I think that that's important to keep in mind as we're talking later today about the impact of the research. Also there are very low average radiation or photon exposures, within the 10 to 20 milligray range, and that makes it imperative that we -- Doug and Mary will talk about that today, combine cohorts to address issues like that.

We did find at the Portsmouth Gaseous Diffusion facility no radiation-related cancers, but I do want to point out that only about 15 percent of the people within that population were deceased, so that was a relatively new cohort as well. INL, we've talked about the results there, again, there were only 17 percent of the workers at that particular site were deceased at the time of study.

At Portsmouth where we did find something, I think it's interesting to point out that when we studied that site in the early 1970s, we did find an elevation in leukemia, but it was non-significant. So it was interesting to know with more follow-up and also the

addition of workers we did find, again, a dose-related elevation in leukemia.

Again, the international 15-country study which includes over 400,000 workers is showing some elevations. Again, I want to point out that probably less than 6 percent of that cohort is deceased, so that is a relatively, of course, young group of workers as well. Another interesting finding that Mary and Doug will talk some about with future research today is that older workers may be at higher risk of radiation-induced cancer both at Oak Ridge and at Hanford. Again, looking at a different type of radiation exposure we found that workers at Rocky Flats showed the plutonium-related elevation in lung cancer risk.

The impact of the research, again, the effects we think from low level chronic fractionated radiation exposures really are observed in some of these cohorts. Our improved exposure assessment we think has been able to enable us to analyze mixed exposures. We have observed health effects from different types of radiation exposure, and the health effects with increasing follow-up and addition of current workers, I think it's important to point out that we're starting to see some of those with follow-up and the addition of current workers added to the studies. And we've also

had reduction in worker exposures through our health hazard evaluation recommendations.

Again, for more information we have a current Web site at the bottom where all of the studies that I've talked about are located and you can always call or write.

MR. REED: Questions of Travis?

DR. HORNUNG: Rick Hornung, University of Cincinnati. I actually didn't have a question, I thought you were very clear in what you told us, I just want to make a couple of points to underscore what you said. One is relevant to the healthy worker effect in dose response. I know a lot of people in the room who are involved in radiation research; they probably are aware of these issues, but just for those who aren't.

Prior to NIOSH getting involved in this type of research, and I'm sure Owen would heartily support this, it goes to what he said, all of the research that was done, virtually all the research that was done on the Department of Energy workers was in the nature of SMR studies, mortality experience of the workers compared to the United States, and the conclusion was there's no problem because they're less -- the mortality rates are less than expected.

It was only when looking at dose response that we

are seeing some of these positive results, and I think that's a very important thing for people to understand who maybe are not involved in either occupational health research or radiation research.

And the other point that you mentioned about the 85 percent are still alive, cancer is a disease of old age. So essentially these cohorts that have now been, you know, millions and millions of dollars have already been spent, hundreds of thousands of workers who have been included in these cohorts, they're just now entering the age range where cancer rates are going to start to increase in the peak. So some of the equivocal results that have been found, I think if we continue to study these groups could very well now reach statistical significance, the precision of the estimates will be much better.

And so this is, I think, just a very important group, both nationally and internationally to keep following, especially given all the work that's already been done. It's all set up and ready to go. So I just wanted to compliment you on a very nice presentation and just sort of underscore some of the points you made.

MR. REED: Thank you, Rick.

DR. KUBALE: Thank you.

DR. HOFFMAN: Owen Hoffman. I now realize I have a certain advantage, I'm not a government employee. So the other feds who are in the room are being very quiet and probably will be sending e-mails, but not many making any comments here on the floor.

Excellent presentation and very clear. The issue, though, that came to mind are all the cases where you had statistically inconclusive results and those are being interpreted as no association. Epidemiology cannot prove the negative. And I worry about the communication of no association between radiation and the effect that's being observed when, in fact, it's merely statistically insignificant, but the confidence intervals are sufficiently wide and an association within those confidence intervals cannot be excluded. That's my statement.

My question is, in the light of the recent National Academy of Sciences report, BEIR VII, which concludes -- it doesn't assume, it concludes -- that the relationship between radiation exposure and radiogenic cancer risk is basically linear and not associated with a dose below which there is no risk. How do your studies fit in with this, and how do you communicate risk to the workers at levels that are below the limits of epidemiological detection?

DR. KUBALE: I was kind of hoping Mary would field that one. I will say that as far as BEIR VII is concerned I think the studies that we talked about, Owen, I hope make into the mix, but I think the cutoff was, what, 1999, for inclusion.

DR. SCHUBAUER-BERIGAN: For the BEIR VII report. Owen, I agree with -- exactly with what you're saying. It's very true that some of our studies have detected elevations in risk that are just not statistically significant. So as epidemiologists that's a very important issue for us, and it's a delicate -- it's a difficult subject to communicate well to the workers, because on the one hand the evidence isn't extremely solid for that association that we have estimated to be there, but on the other hand we don't want to minimize potential risks that might exist. And so we do try to provide estimates of risk and bound them in confidence intervals, and to do our best to explain what it means to have a confidence interval that includes the null value, and place it also within the context of our study limitations.

As you say, we have fairly short follow-up. We know that we are dealing with fairly low predicted levels of risk at the average exposure levels that our cohorts have, and so we do our best to try to

communicate those difficult things.

It is also true that not every study that we conduct shows even a point estimate that's positive. Some of them truly appear to be null associations. So we also agree that it's very important to communicate that when we observe it as well, also, again, within the limitations of the study as we see them. But the issue of risk communication that might derive from a risk assessment, I think it's a very different kind of communication that one would do, and we haven't begun to do that as a result of the BEIR VII report's release, and that would be an interesting recommendation if that's one that you want to make.

DR. PUSKIN: This is along the same lines -- Jerry Puskin, EPA. Are there any studies where there's null result, which, given the statistical power you can say you wouldn't have expected to see anything based on current risk estimates like in BEIR VII?

DR. SCHUBAUER-BERIGAN: That's a very good question. I think the results that appeared to be the most null, if I could phrase them that way, are probably the Portsmouth Gaseous Diffusion plant, and yet that study had several limitations with respect to the dosimetry that was available. So we weren't at all certain that we had accurate dose estimates on the

cohort. So it was difficult to determine whether we would have expected to see an association or whether there was just too much exposure misclassification to make that claim.

DR. PLATNER: Jim Platner, I'm with the Center to Protect Workers' Rights. First of all I wanted to support the idea that these kind of conclusions should be presented with confidence intervals. I think that's clearly very important. People can jump to the conclusion that there is no effect, rather than we don't know what the effect is.

The other question I had is, I was curious what kind of data quality assurance you've done as part of these projects. I mean, clearly it's difficult to know that you've captured the full workforce as part of your initial cohort, because certainly with construction, contractors and subcontractors, which is primarily who I work with, DoE doesn't often have that data, and, in fact, the primary contractors may not have that data. How do you deal with gaps in the exposure data? Do you try to match that up with gaps in employment? Because many workers on these sites are there for six months and then they may be gone for a period. Do you use -- most construction workers aren't full time on a specific project, and I was curious how you deal with

data completeness.

DR. KUBALE: Right. Interestingly enough, Mary in the INEEL cohort study had quite a few construction workers. Maybe she could talk a little bit about that.

DR. SCHUBAUER-BERIGAN: Yes, that's a hugely important question, and it's really variable across the DoE depending on the site that you work with. Some sites such as the Oak Ridge National Laboratory monitored virtually everyone, and other sites perhaps didn't do that. That's a real question that we face in conducting any of these studies is do we have a complete set of monitoring information, are there other sources that might be available that we're missing.

If we believe that workers may have been monitored or exposed, yet we just don't have the records, we do conduct several -- we take several steps to try to address that, one of which is to look at workers who might have been doing similar tasks as the worker who is missing data and to try to estimate missed exposures by using the information from nearby workers or workers with similar types of jobs. One of our key exposure assessors is at the table here, Doug Daniels, and he can tell you much more about how that's done, if you're interested.

MR. DANIELS: Hello, Doug Daniels. Yes, now that

you've pulled the gun on me. Clearly we try to start first with quantitative data and we do exhaustive record searches to amass as much data as we can in order to do an appropriate exposure assessment. In periods of time when we don't have monitoring data we do nearby worker and use nearby methods to impute doses. We might also look at distributions based on work history information, look at dose distributions and from that try to ferret out what the exposure should be for a worker assignment.

One of the -- and I hate to jump the shark here, but one of the most important tools that we've been able to develop is through doing these multiple facility studies over the course of 15 years we've amassed a considerable amount of work history as well as exposure information. So that allows us to do detailed searches for work at other facilities that maybe we should account for in our studies, and that's one of the tenets for our exposure assessments is we look for exposure information and work history outside of the study facilities and try to incorporate that in our analysis.

MR. ELLIOTT: Larry Elliott with NIOSH. I want to compliment you and commend you on a great amount of work in the last five years that you've accomplished;

quite an extensive body of work.

I'd like to carry out with a little thought that Rick brought to the mike, Rick Hornung brought to the mike about the early days of these epidemiological studies as they were done under DoE oversight auspices, and primarily they looked mainly only at white males, and you noted that, that you've improved upon that by adding females and minorities. But also they only primarily examined external dose.

And I didn't see a lot in your presentation, and maybe Doug is going to speak to this next, but I'd like to hear more about what you're doing with regard to internal dose and how you're factoring that into your exposure assessment and into your epi analyses. Again, quite a good job and a lot of work done. My compliments.

DR. PINNEY: Is anyone going to answer his question about internal dose?

MR. DANIELS: I'm sorry. You know what? Larry was talking to me at the same time. I can't answer questions concerning mixed exposures. We have taken quite a considerable effort, and you'll see that in my presentation when we're talking about ongoing studies, of including all sources of exposure, both internal and external exposure as well in these studies. And, for

example, for one of the studies dealing with five Department of Energy sites we're looking at leukemia as an outcome and we're looking at plutonium, in addition to the external radiation exposure, in addition to carbon tetrachloride and benzene. So we're trying to take into account that, yes, the workers are faced with other than radiation exposures here and other than external radiation exposures in our analyses.

DR. PINNEY: Hi, I'm Susan Pinney from the University of Cincinnati, and congratulations, Dr. Kubale, on a very nice presentation. I wanted to follow up a little bit on Rick Hornung's comment about the richness of these cohorts in terms of research potential. And Rick mentioned that it's really just maturing to a point in time where there are enough cancers to really understand dose and dose health effects, its relationship. The other point of Rick's in these cohorts is the exposure assessment, and we all like to pick at it and we all like to critique it, but compared to other occupational exposures the data are very, very rich, extremely rich. And I'm doing some work in genetic epidemiology and, you know, one of the cohorts that's being studied for genetic susceptibility to radiation are the childhood survivors of cancer who have developed second cancers. And they're a cohort

because their radiation exposure, because of the records of their treatment, can be very well quantified, but there are major limitations. One kind of radiation, and these folks already have probably some kind of genetic susceptibility, they've already had one cancer and now developed a second cancer.

So I'm thinking in the future, these cohorts are going to be very, very useful or could be very, very useful for looking at genetic susceptibility because of the great work that has been done on the exposure assessment.

DR. SCHUBAUER-BERIGAN: Thank you. Good comments.

MR. REED: Thanks, Travis. I think we're at a logical place for a break. And we're also ahead of schedule. So I suggest that we modify our agenda, if you in the audience agree to this, that we regroup after, let's say 15 or 20 minutes, and then we'll carry on with Doug Daniels' presentation about ongoing research, break for lunch, come back for Mary's futures presentation, and then ongoing discussion and dialogue. So if I'm not seeing any significant concern with that, let's go ahead and break. I have about 10:30. Let's regroup at 10:45, please.

(BREAK)

MR. REED: As I mentioned before our break, we are

modifying our agenda and we're going to be talking about ongoing research that was originally scheduled on the agenda to be in the afternoon. Doug Daniels is the presenter of this summary of ongoing research in the Occupational Energy Research Program. Doug is a health physicist and he is also the acting head of our Occupational Energy Research Program. So, Doug.

ONGOING RESEARCH

MR. DANIELS: Thank you Larry. Can everybody hear me? Great. They gave me two jobs for this meeting; one was to talk about the ongoing studies, and to make sure we had coffee. So I hope there's plenty of coffee. You might need it for the ongoing study section.

Okay, an outline of what I want to discuss today. I'm going to briefly review the Occupation Energy Research Program research goals, I'm going to give you an overview of the ongoing studies, and also talk really briefly about our relational database. Now, I've already mentioned this once before, but we do have a fairly extensive database that we've gathered from the years of research that we have in this program. And we want to talk about a research initiative that was earmarked for us on chronic lymphocytic leukemia.

So research goals. And what I've done here is I've

tried to highlight key words and tricky phrases here so you see a common theme in all of our research goals: Evaluating possible relationships, exposures and injury, we're looking at analyzing combined populations. This was a key tenet of the ACERER committee, our advisory committee in the early development years; the need for statistical power in these studies, and to get that we needed to draw from multiple populations.

Examine mixed exposures. This is important to realize that the workers faced many types of exposures in the workplace other than ionizing radiation. So is there a multiplicative or additive relationship with other types of exposures. And provide research dealing with -- so we can better understand low-level protracted exposure. Unlike the exposures that the survivors of the atomic bomb drop, the life-span study and medical exposures which are acute during one point in time, we're dealing with fractionated exposures over an entire working lifetime.

Exposure assessment goals, improved exposure assessment methods. This was a very important piece of our research at NIOSH. We understood the need to better our exposure assessments for these epidemiologic studies. So we have to characterize combined

exposures, emphasize quantitative relationships, and of course, validate our data. So the common theme here is combined cohorts are needed in order to have appropriate statistical power, we need to consider exposures other than radiation, and we need to do proper exposure assessment.

This is a table of our ongoing studies. The first one -- and I've got them in the order that I'm going to talk about them today. The first one is a case-control study of leukemia and ionizing radiation, and it's a multiple facility study. So this is the combined cohort concepts, and we're hopeful that we will be done with this study in early 2006. We have a chemical laboratory workers cohort mortality where here the primary exposure of concern are chemicals and not radiation, but we are looking at radiation as well.

The Portsmouth Naval Shipyard, you've heard a little bit about the cohort study as well as a leukemia case control study at the Portsmouth Naval Shipyard. Here we're doing a lung cancer case-control study of that same cohort. That's our first group of studies and they're all to be completed in 2006. And then the next two, given current funding projections, we think we can get these next two done in 2007, which involves K25, this is Oak Ridge facilities, gaseous diffusion

plant, multiple myeloma case control, as well as an update to the Fernald workers cohort mortality study. Fernald is close to our facility in Ohio. It's the old Feed Materials Production Center, for those of you who have been around awhile.

Status of these projects. What I've done here is I've tried to break this out based on the basic steps and I've combined steps in doing this research. So the very front end of the research is the exposure assessment, it's usually the long pole in the tent, it takes us the longest time to complete; and then followed by analysis of those data, and then, of course, peer review and publishing the results, as well as worker communication. So it kind of gives you an idea of where we are in our studies in these processes. You can see the longer lead studies, the K25 and the Fernald workers, we're still in the exposure assessment mode there.

In addition to those intramural studies, those are all being conducted by NIOSH researchers, we still maintain an extramural research, as Dr. Wade had pointed out and it's important in our program to maintain diversity in our research. So we have a few ongoing studies being done by researchers outside of NIOSH under the program. One of the most recent, and I

think some of the researchers are with us today, deals with radon and cigarette smoking and lung cancer at the Fernald facility, and this is basically dealing with some very complicated issues involving exposure and radon and how radon -- that source term at the Fernald site. And what this will enable us to do is in our cohort mortality study we'll be able to incorporate this information into our epidemiologic results.

We have another cohort mortality study of Savannah River site workers being completed by researchers at the University of North Carolina. We have a large cohort mortality study that was -- this, again, was a Congressional mandate to researchers, it's a joint effort by the University of Kentucky as well as the University of Louisville. That is scheduled to be completed in 2007. And we have researchers at the University of Washington who are looking at basically a de-identified data using the CEDR database, that's the Comprehensive Epidemiologic Research -- oh, I've forgotten it, but anyway, I define it later on in the analysis. So it's using those de-identified data sets as well as the data sets from the Canadian workers and they're looking at doing some pooled analyses there.

So I'm going to go briefly over some of the study details starting with the in-house studies, the NIOSH

researcher studies. And the first one I'm talking about is the Leukemia and Ionizing Radiation Multi-site Case-Control Study. Again, it's going to be complete in 2006. It's a case-control study. It involves about 1200 workers from a cohort. They were drawn from approximately 100,000 folks who had employment at at least one of the five nuclear facilities in the study. We have those facilities. We have 500 workers at the Hanford facility, Hanford dealing with plutonium production. We have approximately 200 workers working either at Los Alamos National Laboratory or working for the contractor there, the Zia contractor at Los Alamos. We have approximately 250 workers from the Oak Ridge facility. Interestingly enough, this is the X-10 facility, the Oak Ridge National Laboratory or the old Clinton Works, but workers here also shared employment at the other DoE facilities in Tennessee. So you see, we not only have to -- although the Y12 facility and the K25 gaseous diffusion plants are not study facilities for this study, we still have to look at exposures that occurred at those other places.

Savannah River site, we have approximately a little over 200 workers there. And then we have workers at the Portsmouth Naval Shipyard. Now, to give you an idea of the complexity here and, of course, I'm an

exposure assessor so I like to whine about exposure assessment, so this will give you an idea of the overlap of employment that these workers shared just for these 1200 folks selected for this study.

So for example, at Hanford there's 18 workers that also worked at Oak Ridge, and there's nine workers that also worked at Savannah River site. So this is just the overlap dealing with the study facilities, and it doesn't account for employment outside of the study facilities. As I mentioned, many of these workers also worked at Fernald, also worked at Rocky Flats, also worked at Idaho, and with our relational database we were able to find this employment and seek out those exposure records.

The exposures we're dealing with here, again, we're focusing on ionizing radiation exposure; principally this is external ionizing radiation exposure, and we're looking at all radiation types. We also are including in our exposure analysis plutonium, since a fairly significant number of study subjects had plutonium exposure documented and we were able to do dose reconstruction of those exposures. We're also looking at chemicals, benzene and carbon tetrachloride, as well as smoking status. And, of course, the outcome is leukemia, including all subtypes here and, of course,

chronic lymphocytic leukemia.

So the research questions: Does chronic low-level radiation exposure cause leukemia among workers? What is the dose response? Is chronic lymphocytic leukemia associated with radiation? This question is still out there. Is there a smaller effect at low dose rates for the same total dose? How does radiation interact with other workplace exposures, the chemicals and the other types of radiation such as the plutonium exposure?

The unique aspects of this study, this is one of our combined cohorts. We have workers from five facilities, and the driver here is statistical power in the epidemiologic analysis. I think it's easy to see that by combining facilities it significantly complicates the exposure assessment activities that have to go on because the onus is on the exposure assessor to not only assess exposures at multiple facilities, but they have to understand those exposures and normalize them. So you'll have apples and apples instead of apples and oranges.

We have more leukemia cases in this study that have been previously studied. To give you an example, the International Agency on Research of Cancer, this is the 15-country study that you've heard a little bit about today, they have 196 leukemia cases in their study,

whereas in this one we have 257. We believe it will be most informative in the CLL dose response, if any. This is because this study has more CLL cases in it than previously studied; we have 43.

And we're also examining potential interactions and confounding from other exposures, such as, when I say high linear energy transfer there, for those laymen out there, we're really talking about plutonium exposure here, and chemicals as well.

So recent accomplishments. We finished the exposure assessment. Now, for me that was, of course, a very significant accomplishment. And we've managed to assess and assign benzene and carbon tetrachloride exposures. We've estimated dose to the bone marrow. Due to the etiology of leukemia the bone marrow here is the critical organ of concern. And we have published some methods papers for the exposure assessment in the peer review literature.

What do we have left? In addition to that -- we haven't gotten to what we have left yet -- we have completed the smoking status, completed the analysis plan, and we've conducted the epidemiologic analyses.

Now the remaining tasks, and this is -- I've probably shortened this too much, but peer review of the Epi analysis, this is a fairly significant task for

us. We will go through peer review from scientists outside of the institute on our research, which in turn that would allow us clearance to submit to peer review literature. So it goes through two steps of peer review. We have to communicate the study results to the worker. So following peer review this is where we will organize and cooperate in a cooperative manner with DoE, with the department at these facilities and get the word out to the workers on the study results.

Our final step in any of our studies, and this is the savior here so now I got the acronym in front of me, we'll submit all of our data identified to the comprehensive epidemiologic data resource database, DoE maintains this database, and it allow scientists to continue the research using these data.

Now on to another study, we have the Portsmouth Naval Shipyard lung cancer case-control study. 2006, this is a case-control study involving about 5000 workers that were selected from our PNS cohort of approximately 40,000. The exposures, again, are ionizing radiation, and this is -- from a researcher's point of view, the civilian shipyard workers, that environment is really appealing if you're starting external radiation from high energy gamma sources only because that's really their only source of exposure

there. So you understand the exposure geometries, you understand the exposure energies, and, of course, Navy record-keeping is really good and so it enables us to collect a great deal of data that supports the analysis.

We're looking at chemical exposures, here it's asbestos and welding fumes, as well as smoking. Outcome is lung cancer. So you'll see a lot of redundancy here in the questions, so I'll go over them really quickly, but basically: Do these exposures cause lung cancer among the workers? How does the radiation interact with smoking to produce these lung cancer risks? How does radiation interact with the chemicals that are present in the workplace? What is the dose response relationship between the exposure and lung cancer?

The next study I'm going to talk about is the mortality of chemical laboratory workers, and this one is a little bit of a twist from what we normally do. Here it's a cohort mortality study of approximately 7000 workers that were selected from Oak Ridge, Y12, and K25, and the Savannah River site. So it's one of our combined cohort studies that we've selected those people that have primary employment in the laboratory, and the exposure of concern is chemical exposure. So

we're looking at both organic and inorganic exposures that these workers may have been involved in at these laboratories. We are as well looking at ionizing radiation exposure and here we're looking for interaction or confounding as a result of the ionizing radiation exposure to whatever cause-specific mortality is of interest. And of course, it's a mortality study so we're looking at all of them.

So do mortality patterns among chem. lab workers differ from the US population? What is the dose response? And how do chemical exposures interact? So you see, it's a common thread here: combined cohort, mixed exposures and dose response information.

The next study I'll talk briefly about, this is one that will be done in 2007. It's a case-control study of multiple myeloma at the Oak Ridge facility K25. This is a gaseous diffusion plant. It's a small study compared to what -- the other studies we have ongoing. It's approximately 600 employees from the gaseous diffusion plant, and the exposures here, again, this is a different type of radiation. So now we're talking uranium is the principal contaminant of concern, so we're looking both internal exposure as well as external exposure from uranium and uranium compounds that would be present at this facility. And, of

course, we're looking at chemicals as well, which the primary chemicals I've listed here, carbon tetrachloride, fluorides, mercury, nickel, and trichloroethylene. Outcome is multiple myeloma.

So the research questions: Dose chronic low-level exposure to internally deposited uranium cause multiple myeloma? How do these radiation exposures interact with other workplace exposures? What is the dose response?

The final study, at least of the intramural work, is the Fernald Cohort Mortality Study. Again, it's estimated to be completed in 2007. For those who are not familiar with Fernald, it's a uranium foundry. They basically had the capability of taking the uranium from the ore to the final product, to uranium metal. So it's a retrospective cohort mortality study of approximately 7300 workers at the former Feed Materials Production Center.

Exposures, again, ionizing radiation internal and external from uranium. They also had a lot of early work in thorium production, as well as they stored a lot of thorium on-site for many years. Radium, since they were processing ore there were radium exposures, and as I mentioned briefly about some extramural work that's being done, radon exposures are a large concern

here at this facility, as well as chemical exposures. Once again, it's a cohort mortality study so we're looking at all cause-specific mortality.

Do mortality patterns among Fernald workers differ from that of the US population? What's the dose response? How do these exposures interact with other workplace exposures and chemicals?

Okay, briefly about our -- our Occupational Energy Research Program Epidemiologic Data Management System, and I know the acronym doesn't look quite right, but we're undergoing some changes in the names. Relational database of all DoE and Department of Defense workers, these are civilian shipyard workers studied under this program, and it right now contains demographic and work history information, and we're partially complete in migrating the exposure data to this database.

So right now we have workers employed at multiple sites that are linked by one master roster, which right -- currently there are 300,000 workers in this master roster that we have in the database. This is an extremely powerful tool for future research, which Mary will be talking about following me, which allows us to develop cohorts based on types of exposures. If we want to look at workers who were primarily exposed externally to high-energy gamma, we can draw out what

populations we have and we can do feasibility to understand if we have statistical power to see something a priori. So this is an opportunity to really move forward with future research.

Okay, going back to the Advisory Committee for Energy-Related Epidemiological Research, research principles, how do the ongoing studies fit into our research principles? Combine cohorts for greater power. Well, two of the studies I've talked about are combined cohorts. The multi-site Leukemia Case Control Study, or LCCS, and the Chem. Lab Worker Study.

Improve exposure assessment. Well, that's a key tenet to all of our work, so we have a lot of resources dedicated to the exposure assessment and we try to make improvements on each and every one of our studies. All studies include nonwhites and females. Paducah is a previously unstudied site and through extramural research we have now included that as one of our key research principles considering previously unstudied sites.

The remainder there, these are future research needs. Our ongoing research really don't cover these issues and we understand that these are important for future research.

Now, this is a little different for us. The

studies that I've talked about up to this point are really from our original research agenda that was established back in the early to mid-90s with the ACERER committee. So what you've heard about is that initial what I like to refer to as the second generation of research; the first generation being the DoE performed research; the second generation being the Occupational Energy Research Program today. This particular work that I'm going to talk about now was an earmark that we received in 2004 under Congressional mandate, NIOSH needed to investigate any possible links with radiation exposure and the occurrence of chronic lymphocytic leukemia. And as a driver it's recognized that there's a probability of causation of zero assigned to chronic lymphocytic leukemia under the Energy Employees Occupational Illness Compensation Program Act. So currently CLL is not compensable, and the question is raised, well, why is it singled out as non-radiogenic. There's a lot of history behind that, but to make a long story short, the literature today supports that decision that had been published prior.

So NIOSH conducts -- as a result of our mandate NIOSH conducts an expert panel meeting last year to discuss research strategies in evaluating the relationship between exposure and chronic lymphocytic

leukemia. The expert panel meeting, we had six experts and they're both epidemiologic and molecular chronic lymphocytic leukemia research, who were invited to provide opinion, as well as members of the public were there, we had 25 people in attendance. And those meeting proceedings, some copies are available in the back of the room, they're also available on the Web, and if you want a copy, see me after the break and I'll be happy to make sure you get one.

In addition to the proceedings we had done a literature search and developed an annotated bibliography, which we provided to the panel members, as well as the members of the public for the conduct of that meeting, and this bibliography is the available literature that we were able to discover dealing with chronic lymphocytic leukemia research and radiation exposure.

Based on the suggestions from the panel, NIOSH prioritized our existing epidemiologic body of work, our ongoing studies, with a focus on CLL. We pursued pooled analyses with examination of alternate lag assumptions in both the IARC, and this is, again, the 15-country study, and the multi-site leukemia case-control study. So here we went back to IARC, we're a collaborator with the International Agency on Research

on Cancer for that study, and we specifically performed analyses with that cohort for CLL, as well as our own multi-site case-control study. And we also have initiated a fairly detailed systematic review of the literature, so this is a build-on from our early efforts with the annotated bibliography.

So we also, in completed studies, which Dr. Kubale had talked briefly about, we went back and we made sure that we appropriately performed analysis with chronic lymphocytic leukemia as an outcome in both the cohort mortality study of Idaho National Laboratory -- Mary can speak more to that, I believe -- as well as the Portsmouth Naval Shipyard.

Continuing studies is the 15-country study, the multi-site study, and the systematic review. So you see, the results from the first two studies, actually, the results of all of our continuing efforts on CLL are anticipated to be available to the public in 2006. So we are wrapping up that research initiative.

The impact of ongoing -- and I just want to leave you with a few statements here to think about. I think we all agree that in principal occupational studies are preferred for the direct estimation of these health effects to the worker exposures. However, current risk models that we've used as well as our protective

standards are derived from the life-span study and the medically exposed cohort. So in other words, although I think it's recognized that the exposures that the atomic bomb survivors experienced, as well as medically exposed are much different than worker exposures, and yet, our current standards are based on those due to the limitations, at least the limitations that we've had in epidemiology.

Ongoing research demonstrates improvements that we've made in the epidemiology. We have increased follow-up, we have better study designs, we have increased or improved exposure assessment, and we expect that this will provide a foundation for future policies on worker protection, and we'll build from that in future research in addressing -- to continue to address, actually, the relevant worker protection and public health questions.

And I'll leave you with contact information and take questions.

DR. PLATNER: Jim Platner. I was curious -- here you've got about 300,000 in your database now, which is roughly half of the workers that have been involved in these sites. Do you have reason to believe that that's a representative sample, or is it primarily production and full-time employees in that database?

MR. DANIELS: Yes, a very good question. You know, our studies have focused on production workers, and except for our early feasibility work that we performed for remediation workers, and what we're talking about is basically construction workers, and it was evident in our early feasibility work that tracking and exposure assessment and the capability of doing epidemiologic research of these remediation workers was extremely difficult, if not feasible right now without some changes in program.

So we conveyed those recommendations and I'll just leave it at that, just to say that the 300,000 workers, although there are some construction workers in there, the primary population is production workers.

DR. PLATNER: Just sort of related, when you do your case-control and your cohort studies, how do you choose those? Are they also not including perhaps the construction workers or the remediation workers at the proportion that they would be present in the workplace?

MR. DANIELS: I think what I'll do is I'll defer this one to Mary.

DR. SCHUBAUER-BERIGAN: That's a great question. And Doug is correct. I would just add that it's really dependent on the specific study in question. For example, the Idaho National Laboratory cohort, one of

our main concerns was to include all workers at the facility, and that's a very unusual site. It's geographically very dispersed and has a lot of different entities that run operations there. So we included people who were involved in construction. We included production workers, researchers, the people that did supply the services, which was a very large component of the workforce.

All of those workers, including the 30,000 or so that we didn't study, are included in our HEDS database, the relational database that Doug mentioned. So that conclusion is very comprehensive.

For some of the case-control studies, like the multi-site leukemia study, one of the principles we were working from there was to try to select the cohort from previously studied sites and previously studied cohorts. So the five that Doug mentioned were constructed by people before us, by the program researchers that were working under the DoE system. So we did not include the Hanford construction workers, for example, because they hadn't been previously studied in that group.

However, we have incorporated those construction workers as part of the continuing studies that we've done with our partners. There's been a Hanford cohort

study that has been conducted by University of North Carolina researchers and they have agreed to provide -- to share that data with us for this relational database. So that's a very important question and principle that we want to follow-up on is to make sure that we may not have studied all workers. In the cases where we didn't, if we can collect their information from other researches to incorporate into our database we will do that.

DR. PINNEY: Susan Pinney from the University of Cincinnati. Just wanted to make one small correction in what you said about the Fernald radon exposure study. The study is really just an exposure assessment study, radon and cigarette smoking. There's no lung cancer health endpoint in the study. And that was because at the time we submitted that proposal NIOSH already had plans to update the Fernald workers cohort mortality study.

MR. DANIELS: Thank you, Sue, that's a very good point. I should have mentioned that.

DR. PINNEY: I just want to make sure you know we finished our work.

DR. HOFFMAN: Owen Hoffman. I was looking through your slides and just wanted, again, to make the point that some of your questions that you're asking as part

of your research objectives may not be answerable by epidemiology alone. So I have several follow-up questions to that; one is, to what extent is recent information in radiobiology combined with epidemiology in your attempts to answer your research questions? To what extent is uncertainty in exposure assessment used to modify your projections of statistical power? My suspicion is most of your studies are low-power studies, even your combined cohort studies are low-powered studies because of the complexities of accurate ascertainment of individual exposure. Therefore, questions like, does chronic low-level radiation exposure cause lung cancer among workers; the negative cannot be proved. And so the question really should be modified.

MR. DANIELS: Thank you, Owen.

MS. CONNELL: I want to go back to the cohort question. I'm Carol Connell with ATSDR. I know military exposures are not being considered at these sites, however, if somebody had military background and then worked at one of these sites, are you including that in their total dose?

MR. DANIELS: And I can speak to the studies involving the leukemia case-control study as well as the Portsmouth Naval Shipyard, and the answers are yes

to both of those. Where we had access to medical records and we could pinpoint exposures in the military we did so.

MS. CONNELL: Do you know anyone doing any studies on the military exposures? I've been asked that.

DR. SCHUBAUER-BERIGAN: There are periodically studies that are published about militarily exposed -- folks exposed to radiation in the military, and one that has recently come out or at least within the last five years is a study of Navy nuclear submariners. I believe there's someone here from -- John, perhaps you can address that from Department of the Navy. There also have been in the past studies of participants in the atomic tests.

MS. CONNELL: I've been asked more site-specific questions for military that initially went in and helped construct these facilities and get them started in the early days, and that's really where I've been asked questions on. Also, I know that you're getting ready to do the Paducah -- look at Paducah, and one thing -- I did the public health assessment on Paducah, and one thing you need to be aware of, it's not like the other gaseous diffusion plants.

In the early stages they did ore work, later on they did their own uranium hexafluoride production, and

then later on they did recycling of the spent uranium, so they have all the constituents of recycled uranium. And then they also did work for others, which was military projects. So Paducah is very different from Portsmouth or K25.

DR. HORNUNG: Rick Hornung. I just had a question about the CLL study. You may have mentioned it and maybe I missed it, but did you mention how many cases you think you're going to have?

DR. SCHUBAUER-BERIGAN: In the multi-site leukemia study it's 43.

DR. HORNUNG: The CLL?

DR. SCHUBAUER-BERIGAN: CLL cases.

DR. HORNUNG: So you have 43. And in the analysis are you getting the cases from IARC plus your work plus -- I mean, how are you assembling the -- how is the analysis going to be conducted?

DR. SCHUBAUER-BERIGAN: The 43 cases are from the five sites that have already been included in the multisite case-control study. We haven't yet pooled together those cases plus all of the other cases we've observed across the rest of the complex, but that is one of the ideas that was recommended, and I'll actually be talking about that this afternoon, projections, what could we do on CLL with more of a

combined approach pooling cohorts, not only from the DoE complex but from other Western populations; like, there were a lot of nuclear workers in the UK have been extensively studied and have great dosimetry and might actually be very suitable, have sufficient follow-up to be able to address that.

DR. HORNUNG: That are in the IARC study anyway?

DR. SCHUBAUER-BERIGAN: They're in the IARC study, yes. We've looked at subsets of the IARC population that we think would be most informative.

DR. PUSKIN: Jerry Puskin, EPA. I was wondering about this Fernald radon exposure assessment. From what you've seen, can you say whether it would be useful to do an epidemiological study of radon-induced lung cancer in -- I wondered how high the levels were and how well they can be estimated.

MR. DANIELS: Well, clearly there's considerable uncertainty in any analysis, especially a retrospective analysis of radon exposures because there's going to be a lot of assumptions that were used. However, the models that have been developed for this exposure assessment have been tested through some empirical data as well. I mean, we had the capability of having some real-time radon monitoring at the site to look at radon dispersion patterns, as well as Legacy Glass was

analyzed and looked for tracks in order to tell hot spots and help fortify the radon models that we have.

So certainly, as Owen alluded to, there's uncertainty in these exposure assessments, and he made a very good point, how are we incorporating that uncertainty in our analysis, and because of the recent advances in computer processing and computer programming we're able to do some things to take into account these uncertainties through simulations and through modeling. And so hopefully we will see what impacts we have in the uncertainty in the radon models that we've developed.

DR. PUSKIN: But are the levels considerably higher than in homes, lower than in mines?

MR. DANIELS: Yes, they're considerably higher than homes.

DR. SCHUBAUER-BERIGAN: I'd like to also address that question that you touched on that Owen raised and it's a very good one. For many of these studies we conducted power analyses several years ago, and I think the technology, as Doug mentioned, has improved to the point that we could incorporate other sources of uncertainty besides just statistical uncertainty in not only our power analyses but in our risk estimates as well.

If you've done any work on this, Owen, you'll know that it's a very challenging endeavor, even though we have computer technology that supports it. There is an aspect of the 15-country study that is looking at this, just how models, the uncertainty in doses, incorporate that into the epidemiologic results, and I think you'll be seeing some results from that in future publications of the IARC study.

DR. HOLAHAN: Vince Holahan, NRC. One of the things I'd like to just note, and I think it's worthwhile, is the fact that you're looking at confounding factors, especially other occupational -- whether it be heavy metals or fumes or whatever. In particular, I was looking at the Portsmouth Navy Shipyard study on lung cancer, because these things are not easy to do. And I guess I would ask this question, you're looking at chemicals, asbestos, and welding fumes. What kind of welding rods? In this time frame you're probably looking at the possibility of thoriated welding rods, you've got a 2-4 percent thorium composition, and there it's not the fumes, it's the grinding, and you can get significant lung doses from the radiographers or whatever who were doing the grinding operations. So I don't know if you're looking at those details, but those are the type of things you

have to obviously be particularly concerned about.

MR. DANIELS: Thank you very much.

MR. REED: Thanks, Doug. I have 11:35 now. I would suggest that we break for lunch. I know there's at least one person who signed up for comment, and we will have ample time in the afternoon after Mary's presentation to have this dialogue and public comment interchange. So I would suggest that we regroup at ten after one. That gives us a good hour and a half to break out for lunch. If you don't want to stay here there are other places in the area for lunch. So we will begin promptly at ten after one. Thank you.

(LUNCH BREAK)

MR. REED: Good afternoon. For those of you who may have joined us just for the afternoon session, we've modified the agenda a bit and we will be leading into actually the futures part of our discussion. Also if you are new to the meeting this afternoon, would you please sign the registration list so we can contact you and follow-up with a copy of the proceedings as well as other additional information that we have from this meeting.

So with that as a backdrop -- also, I understand that coffee is coming at some point and someone will let us know when it happens.

The talk this afternoon -- the primary talk this afternoon is Mary Schubauer-Berigan who is a research epidemiologist who began her career in the Occupational Energy Research Program at NIOSH, and recently, within the last year I believe, changed programs to the Industry-Wide Studies Branch where she's doing epi methods research development, but nonetheless still plays an important role in our energy research program. With that, Mary will give an overview of the future sort of ideas for possible research in the Energy Research Program.

FUTURE RESEARCH

DR. SCHUBAUER-BERIGAN: Thank you very much, Larry, and I also wanted to extend my welcome and thanks to all of you for attending. I think this is the session at which we really are looking forward to getting your input on our ideas for the future energy -- Occupational Energy Research Program. So, again, the coffee will be forthcoming soon, and in the meantime I'll try not to put you to sleep in the post-lunch period of time here.

Just as an outline of what I'll be talking about this afternoon, first I'll be giving you some information about the setting in which we currently operate. You've heard a lot this morning about the

research drivers from the ACERER committee as well as several other groups and mandates that we had to conduct research. I'll be trying to place those into the context of the present day and what it is that's driving our research right now.

I'll talk a little bit about then what we consider to be our primary research questions for future work, and to discuss some of the ideas we have for proposed future projects. Again, these are just ideas that we have that we see as stemming from the questions that we believe are currently the most pertinent. We certainly welcome your input and hope to get that today.

Lastly, I'll frame the program and the future questions that we hope to address in the context of some other things that are occurring right now, such as the opportunities for public and stakeholder input into our program, the effects of a review by the National Academies on our program, along with our sister agencies within CDC, which are also funded under the Memorandum of Understanding with DoE; talk about resource issues and potential future impacts that we expect our program to have.

You've heard today about the ACERER committee, the Advisory Committee on Energy-Related Epidemiologic Research. This committee was established, as you know,

by the recommendation of SPEERA and it met and made recommendations to our research program between 1993 and 2000.

In 2000, in late 2000 there was a very important second influence on our program, which was the Energy Employees Occupational Illness Compensation Program Act that was enacted by Congress in late 2000. In 2004, as you've heard, we received a mandate to study chronic lymphocytic leukemia, and most recently, as we've already discussed to a limited extent today, the National Academies this summer released its most recent report on the biological effects of ionizing radiation, and that is the BEIR VII report. I'll expand on what we see as the questions that were really addressed that we feel were most pertinent for us from these different groups and activities.

The ACERER questions you've already heard, I won't belabor these too much, except to just frame them again in terms of the questions we're trying to address: Are the current exposure limits adequate? Do the health risks vary by radiation type for different forms of radiation? Are the risks from fractionated exposures similar to those from acute exposures? Can we control for confounding by other factors in these occupational studies? And can we evaluate the interaction of the

effects of radiation and other workplace exposures?

The EEOICPA program, and Larry Elliott spoke about that this morning, about some activities within NIOSH that the group in the compensation program addresses, there's an advisory board that has issued a number of questions that we feel are also very relevant for us to address in our program. The first of these you've already heard and became part of the later Congressional mandate, is CLL risk associated with radiation.

A second question that was raised by the advisory committee for this program is, what is the best way to incorporate worker studies into the risk models that are used as the basis for compensation? A third question is very similar to one that the ACERER committee posed, how does radiation interact with smoking and also other workplace exposures in causing lung cancer and other cancers?

Number four, how should radiation risks be modeled for rare types of cancer? And there is a long history of the modeling that's occurred for the compensation program, but suffice it to say that there are questions about the ways that cancers that have generally low numbers in the types of studies that form the basis of these risk models and how those should be incorporated

into the probability of causation estimates. Lastly, what is the effect of age at exposure? Are workers really more susceptible at older ages to the effects of radiation at producing cancer?

In 2004, February of 2004 we did receive a mandate to conduct epidemiologic research to evaluate the link between radiation exposure and the occurrence of chronic lymphocytic leukemia, and you've already heard from Doug Daniels this morning about the activities that we have going on currently to address this question.

Lastly, the BEIR VII report, and I believe it was Owen Hoffman this morning who raised some of the questions that were resulting from that program and wondered how we would be factoring those into our research agenda. The BEIR committees have a long history of reviewing and combining together research from all different sources, and really evaluating the most critical questions and then coming up with lists of recommendations of studies. So this slide kind of combines those two elements; one, the summation of risk that BEIR VII produced and also a list of questions that they developed as a result.

There still are questions about the effects of chronic low-level radiation exposure, and although the

committee has reported that the linear no threshold model is the most appropriate for estimating risk, there are still questions in the literature about whether we really know that from direct observation.

Second, is there a smaller effect at low dose rates? Currently the BEIR committee recommends the use of what is called a DDREF, a dose and dose rate effectiveness factor, and if you had -- if you assumed that the risks were equivalent at high and low dose rates you would use a DDREF of 1. The BEIR VII committee advocates something a little bit higher than 1 as their central estimate, something like 1.5. And what that means is that their assumption is that radiation produces fewer effects, smaller levels of effects at low doses per unit of dose than at high doses. But we recognize that this is still a very important topic for future research.

The question of the forms of interaction between radiation and other exposures is still an important question, but they really began to raise some questions that had not appeared very extensively in earlier BEIR reports, one of which was whether there are issues of genetic susceptibility such that groups of people may differ in their susceptibility to the effects of ionizing radiation. They also wondered if valid

biomarkers of exposure to radiation could be developed and used.

So for this presentation and in thinking about our program we've tried to synthesize all of these different questions and groups of questions that have been raised by these various organizations into a number of questions that we believe are still very relevant for the OERP to address. You've heard this morning about studies that have answered or begun to answer some of these questions, but we believe that the questions themselves are still relevant.

Number one, not only does low-level workplace radiation -- exposure to radiation cause cancer, but what kinds of cancer and what is the quantitative level of risk per unit dose? Number two, we know a lot more now than we did before about the effects of low-dose gamma or photon exposures from the workplace, but we still have a lot of questions about the relative effects of different forms of radiation of, say, neutrons compared to gamma exposures, or of plutonium or uranium or other internal emitters compared to gamma radiation, and these are very important questions because the DoE workforce, as you've heard, has been exposed to a number of different forms and types of radiation.

Number three, the question about dose rate is still highly relevant: can worker studies help us to address this question of the dose rate effectiveness? Should we continue to apply DDREFs of greater than 1 to risk models, or is there direct evidence that would suggest either a different value or a value of 1.

Number four, the question of interactions of radiation with either smoking or with workplace factors and exposures in causing cancer is still of keen importance to the workplace.

Number five, how do workers vary in their sensitivity to radiation? As the BEIR committee expressed there is interest in genetic susceptibility, but for a long time in the radiation world there's been interest in more of the standard epidemiologic factors, like, exposure age or attained age, the age that the worker is when they get their cancer; gender or sex, whether women are more or less sensitive to radiation than men.

Lastly, we still want to address the question that was posed to us by the mandate, the Congressional mandate in 2004, that is, does radiation cause chronic lymphocytic leukemia and if so, what is the dose response? So again, these questions are a synthesis of all of the questions, combined with an understanding of

what it is that we still don't know.

So in the context of these questions we've identified a number of potential projects that we believe would be of high priority for future research, and you've heard some about these this morning, but I wanted to expand on them here. First, we believe that we now have the ability with the HEDS database to look across the entire DoE complex and to develop exposure-based cohorts that help us to answer key questions, and I'll talk about some of these questions in context in a few minutes. Some of the cohorts that we believe would be possible to identify using this database are cohorts exposed primarily to external sources of radiation, like gamma or neutrons, cohorts that are exposed primarily to internal sources of radiation, such as plutonium or uranium.

A principle that we would use in conducting this kind of research would be to identify workers using our relational database that could be used to identify workers that have minimal potential for confounding exposures to other substances. And as an example, the IARC 15-country study, this was one of the advances of this study is that it looked -- in evaluating risk from gamma radiation it really looked exclusively at the workers that had gamma radiation. It excluded workers

that had primarily or even substantial amounts of plutonium exposure, it excluded workers that had high levels of neutrons. And this permitted the data analysis to focus just on gamma as a source of exposure, and that lack of confounding allowed a more precise estimate of strictly the effects of gamma radiation.

As a principle we plan to use the latest vital status ascertainment for all of these studies. Now as we do studies on a cohort by cohort basis there's a certain lag, periods of time that elapses between the completion of the study and the exposure assessment in developing the study database. Allowing us -- having a data structure that allows us to continually update vital status ascertainment and cause of death ascertainment will allow us to more quickly, we believe, get these studies underway and completed.

We also think it's important, for the reasons that Doug mentioned this morning, to consider including additional nuclear naval shipyards, particularly for studies of primarily gamma-exposed workers. This is a cohort that has phenomenal exposure assessment data, they have sufficient presence of records, and perhaps most importantly minimal confounding from other sources of exposure that would allow us to evaluate this

question specifically for gamma radiation.

We also think that it will be important not only to pool cohorts within the DoE complex, but to combine our cohorts with other occupational cohorts that can address these questions. An example of this is the 15-country IARC study. We currently are talking with IARC about expanding follow-up for that cohort, and perhaps even expanding the study design to include other types of exposures in addition to just external gamma radiation.

As an example of this, chronic lymphocytic leukemia, although it's a common leukemia type, it is a fairly rare cancer on its own. So it's difficult even within the entire DoE complex to have sufficient power in a combined study setting to evaluate chronic lymphocytic leukemia, but by pooling the nuclear -- the DoE cohorts and the naval shipyards with other cohorts that have sufficient numbers of cases we feel that we can answer this question with sufficient power to address this question. And it's very likely that other individual cancers will also benefit greatly from this approach.

We also believe that it's very important to begin to study cancer incidence in the nuclear workforce. There are many cancers that have fairly low fatality

rates; for example, certain types of skin cancer, most types of skin cancer, prostate cancer, and breast cancer, and to the extent that we think it's important to study these cancers, which we do, it would really be done best in an incidence study design.

This has its own challenges, one of which is that the DoE workforce is pretty mobile, and it's not sufficient to just go to a single state's cancer registry and identify incident cancers from that registry. We would have to do a nationwide search and certainly have to do a questionnaire-type design, which would allow us to evaluate other factors in addition to workplace exposures.

And lastly, I'll not talk much about it right here, but in several minutes I'll talk about our thinking that we currently have on current worker exposures and health effects. And this is an area I'll say right now that we really could use input from you and other stakeholders on what is the best approach to evaluate health effects and exposures among the current workforce.

I have a slightly different set of slides here than you have in your handouts, and that was intentional. The next few slides go over each of these questions, and I'll go through this rather quickly hoping that we

can come back to this slide later if these questions -- particular questions are of great interest to people in the group.

But in your handout in addition to the future studies that address each question I also have identified our ongoing studies that we believe address these questions as well, and many of these that you'll see are conducted by our grantees and our extramural partners and we believe provide additional strength to our intramural studies.

So the first question of whether low-level workplace exposure to radiation causes cancer has several facets to it, as people have alluded to today. We believe it may be possible to establish a gold standard, an occupational gold standard cohort, much like the lifespan study is a gold standard cohort for looking at acute -- effects of acute exposure to ionizing radiation.

We also believe that it's very important in this type of cohort to incorporate uncertainty in dosimetry of these cohorts into our epidemiologic analyses, and this is what we were discussing this morning in response to Owen Hoffman's question. In order to address this we believe that future studies will need to take this combined cohort approach in which we've

already assembled and assessed the uncertainty of the dosimetry data, we've conducted follow-up and we're able to identify people who should be in this combined cohort who have minimal potential for confounding from other sources. We also recognize that there is great strength in combining our cohorts with those of other countries and other types of occupational cohorts, and we believe this will be a very important tool in addressing these two very important points.

In addition to looking at all cancers or all types of leukemia we think it's important to estimate risks for cancers that have unknown radiogenicity. And I think one of the things for me personally that the compensation program has done is to kind of illuminate what it is that we know and what we don't know about individual cancers and their radiogenicity.

For example, malignant melanoma is a form of skin cancer, it's the most fatal form of skin cancer, but really there are not very good studies out there about what the effects of radiation are in producing malignant melanoma. It's a difficult cancer to study because, again, you have to study it in a morbidity or incidence design rather than simply a mortality design.

Prostate cancer is another cancer that has a fairly low fatality rate and it's difficult to study for that

reason. We feel that it's going to be important, again, any time that you analyze one specific cancer type, doing a combined cohort type of approach is really essential, as well as desirable to pool analyses of our cohorts across both the DoE complex and to combine them with other researchers' studies as well.

To address the question of whether different forms of radiation may have different effects and what those effects might be we think it's essential to directly assess risk from exposure to internal radiation and neutrons. Now, for neutrons, unfortunately, it's difficult -- we believe it will be difficult to isolate neutrons as a single exposure type because neutrons in the DoE world tend to co-occur with plutonium and with gamma doses, and so identifying a cohort that's exposed primarily to neutrons or substantially to neutrons will be difficult.

So we have identified this as a feasibility study for neutron and internally exposed cohorts so that we can evaluate the data or our partners can evaluate the data to see which types of radiation would lend themselves best to this approach. Once we've determined that we would do, again, a HEDS-based combined cohort approach, and it's certainly possible and perhaps desirable to pool our analyses with those

of other studies, if it's possible, to identify non-DoE cohorts that have primarily or even substantial exposure to neutrons or internal emitters.

Another important component of this is improved assessment of organ doses from internal sources of radiation, and I know this is an area that some in the audience have a great deal of experience with. The international standards for doing organ dose assessment have been changing and improving over time and as that's happened we've been able to improve our own assessments of organ doses from internal emitters and we are working to improve that. Now, that needs to be incorporated into epidemiologic analyses, and doing this is very, very difficult for a large group of workers. So we would think that nested case-control studies within these combined cohorts would be the most suitable approach to consider this.

Lastly, neutron organ dose characterization is another important aspect of a combined cohort study to evaluate risks from neutron exposures, and this would also be part of a feasibility study in nest design.

The third research question is whether the dose rate affects the level of cancer risk, and we believe this is most suitably addressed for gamma-exposed cohorts because of the difficulty of assessing organ

doses over time for internal emitters. We think that a combined nuclear Naval shipyard cohort could be extremely informative. As I said they tend to be primarily exposed to external radiation, gamma radiation, and so one could compare workers with high doses received at a high-dose rate to workers with that same high dose that was received at a lower dose rate in order to evaluate what the relative -- what the effects are for the dose rate factors, and ideally to come up with a DDREF that's based on human data rather than on biological or animal data or in vitro data.

The concept of interactions, on your handout you'll see I cover issues of smoking and lung cancer and many of our current studies address that. I'm going to focus instead on interactions of radiation with other workplace exposures. It's very difficult in advance to specify what this kind of study might look like, although, we know based on our current experiences that based on the amount of effort required to do the exposure assessment that, again, this would most likely be done with individual hypothesis-based nested case-control studies.

The question of variability and sensitivity to radiation has many different facets. We think that we currently have a good start on trying to understand the

dependence of radiation risk on the age at exposure. We hope that we can continue this. It would certainly need to be done in a combined cohort setting. We have individual cohorts right now that seem to suggest there is an effect, others that suggest there may not be an effect, but to answer this question we need to pool all of the data that we have and perhaps pool with other researchers' data in order to answer this question.

Studies of cancer in female nuclear workers are also important. We have learned from the female nuclear worker study that Travis discussed this morning and believe that further follow-up of specific cancer types could be very informative in this group of workers.

Lastly, whether chronic lymphocytic leukemia is associated with radiation is an ongoing question. We will continue to work on this question to complete our current studies, but we also are investigating and conducting some power analyses to look at an approach combining our cohorts with those of other researchers, and particularly those of workers in the UK and other Western populations that are included in the IARC combined nuclear workers study because this is a fairly rare cancer and we would need to have sufficient follow-up to account for a very long latency period

between exposure and this particular outcome. We think that that would be required in order to study this thoroughly.

So just to summarize all of this, we think that the combined DoE study approach really has a lot of strengths in helping us to address all of these six key questions. Studies that pool our cohorts with those of other investigators are very, very helpful as well; although, we do note that in many cases it's difficult to look at interactions in a combined cohort setting because of differences that researchers have and the ability to assess exposures to other factors in the workplace. We also believe that looking at cancer incidence can help us to address these questions for specific cancer types where it makes the most sense to do so. Now I'd like to move on to issues that we see regarding current workers. We know that workers in the D&D era, the decommissioning and decontamination era, may face different hazards and health risks than workers in the era that we've previously studied. There are concerns about the adequacy of monitoring records for both radiation exposures and for health outcomes.

We also, as you've heard this morning from Travis' presentation, have questions about the information

quality that would allow us to conduct future epidemiologic research among current workers. We have recommended improvements to DoE, which they could implement on their information systems to improve the situation for workers who are involved in cleanup activities, and to follow up with this -- with DoE would be a step that we would need to take in order to adequately study current workers.

So one question that you may want to ponder is: What are the most important health issues for current workers? Are we really trying to answer the same questions or are they a very different group of workers who are facing very, very different types of exposures.

Now I want to move into some of the opportunities for input that we are foreseeing. We do produce a public health agenda, which is updated annually, and this is open right now for public comment. Many of the studies that I've described to you in this presentation are discussed in that public health agenda. If we don't have copies of that in the back we have it on our Web site, and you can certainly get a copy of it if you would like to contact Doug or me or anyone else in the OERP. We also hope that this will be the first in a series of meetings to gain input from you, from the public and our stakeholders on our research agenda.

This is the first such meeting, but it certainly, we hope, won't be the last.

We also think that it's important to revive partners meetings which have been held in the past periodically to discuss issues that we face with our research partners in the extramural community, as well as worker representatives in DoE to talk as a group about what we're finding and what avenues look most promising.

We also plan, funding permitting, to produce requests for proposals from our potential grantees, and these have included university researchers as well as worker representatives who may partner with university researchers. We also have done in the past and plan to continue to gain input from the compensation program on questions that they believe to be of greatest importance.

Some of the other factors that I wanted to alert you to is the fact that there has been a call by DoE for a National Academies review of all three of the CDC programs that are funded under the MoU, and this will take place -- the initial meeting for this will take place next week here in DC at the National Academies. Those of you who would like to are certainly welcome to attend that or to comment on it if you have an interest

in doing so, and there's information about this on our Web site, which we can point you to after this meeting.

We also have corresponded recently with OSHA, which has, as many of you know, indicated a potential interest in rulemaking on ionizing radiation and we are providing input on that potential. As we've discussed with several of you today, resource limitations and the nature of -- the cyclical nature of funding are a perennial problem with any program like this, and we do feel that this will continue to be an issue that we'll face and that will affect both us and our research partners.

I'd like to talk briefly about -- you've heard something about the impact that we believe our program has had, and I'd like to talk about in more detail where we think we'll have an impact most substantially in the future. First, we believe our program is producing research that is extremely important in supporting risk assessment for radiation standards. As you've seen we're able to actually produce quantitative dose response models, and we hope to evaluate dose rate effects to determine if really there should be an application of a dose and dose rate effectiveness factor in models of exposure and response.

We believe that standards that might be developed

could be applicable not only to workers, but to members of the public who may be exposed environmentally, or certainly many of us know that diagnostic radiation use has generally increased in the public in recent years, and information from a chronic low-dose exposure, such as workers receive, could also be applicable to those exposures as well.

As far as the compensation program is concerned there is, as you know, probability of causation risk models which make use of epidemiologic data, and those certainly could be at sometime in the future based additionally on information from worker studies in addition to the basis -- the current basis. We also may expect to see use of information on mixed exposures to radiation and other workplace agents, such as solvents or asbestos, as part of this compensation program. Also we anticipate that we'll continue to, as called on by DoE and worker representatives, to collaborate on health hazard evaluations with others in NIOSH in order to produce worker exposures, and really, this also may serve as a sentinel event type of monitoring so that we can get an understanding of whether there are emerging health concerns among the work force.

In summary, we think that many of the initial

questions that ACERER raised were very prescient and in fact are still awaiting resolution. We think that occupational radiation studies that we're conducting are really operating near the limits of epidemiology, and I want to explain what I mean by that. In the study that you've heard talked about today, the recent study by Travis Kubale and his colleagues on the risk of leukemia at the Portsmouth Naval Shipyard, the study was able to detect a significant association of leukemia with external radiation exposure. And with the improvements in exposure assessment techniques and a statistical modeling that was done, the study was able to detect a 12 percent increased risk of leukemia with a 95 percent confidence interval of 1 percent to 24 percent at the 75th percentile of dose in the cohort, and that dose was fairly low, it was 15 millisieverts. That's a very challenging thing to do epidemiologically, and to be able to continue this kind of work will require us to continue applying excellent exposure assessment and epidemiologic methodology.

We recognize that the implications, both scientifically and from policy, have only increased in recent years, particularly with the additional impetus provided by the compensation program. We conclude that the OERP research agenda is addressing highly relevant

public health questions and, therefore, this is an optimal time to get input from all of you about our proposed agenda and what you think that we should be studying.

I'll leave you with this last slide that summarizes our questions, kind of grouping the low-dose gamma effects, dose rate differences and differential sensitivity, along with the other questions that we've raised. And I think at this point Larry Reed will come back and try to facilitate a discussion and question and answers about these issues.

MR. REED: Thanks, Mary. Are there any questions on Mary's presentation, first?

MR. POTTER: Herman Potter from United Steelworkers. In your slide on issues regarding current workers, I notice you mentioned that NIOSH has recommended improvements to DoE on information systems for workers involved in cleanup. Keeping in mind that it seems like the multi-tiered-many-contractor-on-the-site system has been set up even more frequently now than what has been in the past, how is that going to affect your recommendations or has it been part of your recommendations?

DR. SCHUBAUER-BERIGAN: That's a great question. We did finish that work several years ago and we know

that the systems have evolved since that time. We haven't gone back to evaluate what, if any, the implications of more recent changes to their systems has been on that recommendation. We have been out communicating our study findings at the various DoE sites, and we do continue to hear that concern expressed by workers at the facilities that those information systems just aren't there, and we believe that it will be necessary to follow up with that, with DOE on that. Yes, Owen?

DR. HOFFMAN: Owen Hoffman. I was very interested to hear the results of the Naval shipyard workers. I wasn't aware of any of the details. But it seems like your study is beginning to produce evidence to answer some outstanding questions, even in the presence of BEIR VII.

One of those questions stems from position statements made by the Health Physics Society that there is no evidence for risk below a cumulative dose of 10 rads. And the numbers you just quoted to me, when I do the translation from the new units to the old units, is a statistical significant for leukemia at 1.5 rad, which gets very close to the lower limits of detection for even in utero exposures.

One of your lead questions that you design your

research around is: Does radiation exposure in the workplace cause cancer? I think that's another type of question that could potentially be reformulated, because obviously the answer is -- given our currency of knowledge the answer is yes. The outstanding question is by how much, or what are the limits below which epidemiologically we no longer can determine a statistically significant risk, even though that risk may be present?

DR. SCHUBAUER-BERIGAN: Those are excellent reformulations, but I think the entire field has moved -- of epidemiology and radiation epidemiology in particular has evolved to the point that we're able to directly estimate risks at that low of a level. An example from the non-occupational arena would be the recent studies of residential radon exposure. For me, as I look at it, the key really is exposure assessment, having good exposure assessment within these studies has been critical to being able to evaluate this.

So you're right, we may need to rethink and reformulate some of the questions that really motivate our program, and as I look at it things like the dose rate factor are some of the critical questions. Some of the next emerging questions, I think, are questions about the relative effectiveness of different kinds of

radiation. Many of you know that those are based now on primarily animal studies and studies of in vitro effects. So is it possible to actually answer those questions from epidemiologic data, and that is an unknown, certainly.

MR. ELLIOTT: Mary, an excellent presentation and, again, my compliments on a lot of good work. I'd like to take you back to age at exposure and see if we can understand what the current thinking is on how to go about assessing age at exposure. It's my working understanding that it all falls to how you categorize or place in categories your study subjects, and that in and of itself can lead you to different conclusions. So do you have any thoughts on that or where you're going to take that in the future?

DR. SCHUBAUER-BERIGAN: Well, that's an excellent question, too, and it allows us to go into a little bit more detail on that. Researchers have looked at this question in a detailed way at the Oak Ridge National Laboratory, and currently two different groups of researchers have looked at the ORNL data and come up with somewhat similar conclusions. On the one hand it does appear that older workers may be more sensitive to radiation than younger workers, but on the other hand an alternative explanation might be that workers of a

certain birth cohort, who were born in certain periods of time, have other confounding exposures that are really the cause of that apparent effect. And so we are considering this question really carefully.

One source of information that we think will prove very informative is the IARC combined international study which does have a charge to look at age at exposure within that cohort, and based on what I've seen I think we can expect to see publications addressing that sometime in the next six months or so. That would be one approach to consider.

At other times we have developed proposals within the OERP to try to address this issue using a combined cohort approach, because again, to tease out whether it's really age at exposure or birth cohort would require us to have a larger pooled group of workers that have a range of values of both exposure and birth cohort in order to address that question definitively.

DR. PLATNER: James Platner with the Center to Protect Workers' Rights. I think it's a great set of initiatives or directions, but much of NIOSH now is pushing to move towards what is called intervention research where we're actually trying to look at effectiveness of field interventions, and more -- certainly in construction, more targeting of task-

related exposure assessments.

And I guess I was just curious how -- whether there's any of that sort of research that you're considering related to ionizing radiation, and I can imagine there's challenges because certainly in construction a lot of the radiation may occur -- may result from relatively infrequent exposures that may not be directly related to the project that the construction worker is working on. And so I was just curious if there's any way we can identify areas where particular attention needs to be paid to a certain type of contract or a certain type of task that workers are assigned to.

DR. SCHUBAUER-BERIGAN: That's a great idea, and I think you've hit upon something that many of us have been discussing in NIOSH recently, because as Dr. Wade mentioned this morning and Larry Reed, NIOSH is very, very focused on impacts and research to practice developments. So we've taken a very -- begun to take a careful look at this kind of thing in our program, and the kind of idea that you mention, looking at task-based work within the construction work force, I presume you're talking about reducing -- assessing and then reducing exposures to the workforce.

DR. PLATNER: One idea that came to mind, I don't

know if it's feasible, we're currently discussing with the University of Tennessee evaluation of the Oak Ridge's CAIRS injury database trying to identify distributions of injury types based on the type of work that's involved in the contract. If something like that could be linked by Social Security to your HEDS database, you might identify kinds of contracts that DoE should pay particular attention to radiation safety on, even though they might not involve direct work with the radiation source. They might be just in a certain building or adjacent to a certain type of work. It's hard to know when your exposure isn't continuous from identified sources.

DR. SCHUBAUER-BERIGAN: That's true. I mean, you've touched on the CAIRS system and that's a good segue to something we should mention, which is that DoE under the MoU retains responsibility for looking at surveillance in its current workforce. And so we have talked to them about ways that our two groups can interact better, and I think that would be a great example of that kind of situation. Thank you.

DR. HORNUNG: Rick Hornung, University of Cincinnati. I wanted to expand a little bit on what Larry Elliott mentioned a few minutes ago about age at exposure effects. I think we really ought to expand

that and you have a wonderful opportunity, I think, with the data that's been collected, to look at the whole aspect of temporal effects from these kinds of studies. All the epidemiologists in the room know how challenging it is when you do a cohort study to deal with temporal effects and includes not just age at exposure, but time since exposure, attained age, calendar time, all different sorts of things that are very difficult to study, particularly when you're looking at chronic long-term exposures that may go several decades.

So I think it would be a wonderful opportunity using this data to not only get more precise estimates of effect modification and that sort of thing with regard to radiation exposure, but this could really shed a lot of light, given the volume of data that you have and the good exposure assessment, into methods to look into better ways to look at temporal effects in all different types of cohort mortalities.

DR. SCHUBAUER-BERIGAN: Absolutely. I think that's a great -- a very valuable suggestion. And speaking personally, although I've moved into an epidemiologic methods position, I'm very excited to be able to evaluate these questions using data from these kinds of studies. Because you're right, we have such good

exposure information that really can't be duplicated in any other kind of exposure.

We also think that -- Doug mentioned the current grant that we have ongoing which is being conducted by Suresh Moolgavkar at the University of Washington, and really he's looking at biologic models that would help address these temporal questions, and we're really watching that closely and hoping that we'll see some biologically based hypotheses generated for that kind of research that could be used to generate additional study ideas for us.

DR. HOLAHAN: Vince Holahan, NRC. I'd like to make a couple of comments on some of the questions you proposed. The first one is, the biological end point you're looking at tend to be cancer.

MS. SCHUBAUER-BERIGAN: That's right.

DR. HOLAHAN: And what I would suggest is that you might want to consider some of the non-cancer diseases, cardiovascular disease. We've known for five or ten years that there's an increase in cardiovascular disease among the Japanese a-bomb survivors. More recently we've gotten information that there might been an increase among the liquidators at Chernobyl in their Russian federation, but there's a lot of confounding there because the lifespan for many of the Russian

males now is decreased to 58 years, and smoking, diet, alcohol consumption also tend to confound that type of end point. But in Geoffrey Howe's more recent article that went into the 15-country study, there might be the suggestion of cardiovascular disease there and he mentioned that. So this might be an area that's worth following up, at least something to consider.

MS. SCHUBAUER-BERIGAN: That's a very good point, and I didn't mention it, but we are aware of those findings, as you say they've been out for five to ten years. Our studies, for example, the Idaho cohort did look at cardiovascular end points. In general, though, we deal with the healthy worker effect, and one of the diseases for which you commonly observe that is cardiovascular diseases. So we would need to have more information about these lifestyle factors that they are experiencing in order to address that. But that's a great suggestion for a more detailed actual design approach to look at that question.

DR. HOLAHAN: The second point is you were talking sensitivity of workers or differences between workers, and I would say the one that might be of interest is going to be more on the gender question. Obviously BEIR V suggested that there was a small gender factor; BEIR VII said there was almost a 50% difference,

UNSCEAR might even go beyond that. So I think that is going to be something that we might have to consider.

And the problem that you're going to run into is, at least in the nuclear field, most of your workers are males. Those females that are there have very small doses. Therefore, I'd suggest that you think outside the box a little bit because where you're going to see medical exposures among females are going to be more in the medical community. And you may have to reach out there and look at the nuc med techs and see what's going on there because that's where they're going to have exposures.

MS. SCHUBAUER-BERIGAN: That's an excellent point. It's very true, women are generally a smaller percentage of the workforce and they tend to have lower average doses than men by a large degree. We are also very aware of the research that's going on at the National Cancer Institute with their study of radiologic technologists. We had at one time a component of the exposure assessment for that study, and so we're partnering with NCI on that. But we do agree that that is a very important question, and where we can study it effectively in the DoE workforce we propose to do so.

I think following up on this very large cohort of

female nuclear workers is a very promising approach as well. We've gotten great data on them, they're very young, we would need to do incidence studies of breast cancer, if that was an outcome that we would consider, which I would assume it is, or thyroid cancer, and in order to do so we would need to do an incidence design and need to think that through very carefully, along with the power analysis based on the overall low exposures in that workforce. But those are great suggestions as well.

DR. HOLAHAN: Finally, you were talking about different types of radiation, I would suggest soft x-rays. And the reason I say that is, again, the National Academies both in BEIR V, BEIR VII, suggests the RBE might be 2 or 3, we're constantly looking at RBE of 1. This is going to more important for the medical community, but, again, I'm not sure who's looking at this, especially when you start talking out interventional cardiologists, as well as the patients, but that might be something that's worthwhile.

MR. REED: I'm sorry, you said soft.

DR. HOLAHAN: Soft x-rays.

MR. REED: Could you explain that?

DR. HOLAHAN: 50 KeV. Yeah, soft photons, any soft photons.

DR. SCHUBAUER-BERIGAN: Lower energy photons. Those are all great points. We are keeping an eye on that in our exposure assessments and Doug can speak to this more from his perspective as the exposure assessor. In the multi-site leukemia case-control study we do have the soft x-ray component. It's fairly minor in relation to the high energy photons, the badge doses that we typically record, but plutonium doses convey a soft x-ray component to dose as well. We're also in that study looking at work-related medical x-ray exposures, which in the 1940s to the 1960s were photofluorographic and were soft x-rays. We are somewhat limited in our abilities there, I think, just because of the power issues, but those are excellent points. It would be one that we would want to consider in a feasibility study, I would think.

DR. PINNEY: Do we have time for one more question?

MR. REED: Absolutely, yes.

DR. PINNEY: Mary, I have one other question for you. I'm thinking about exposure, and as Owen said looking at our confidence intervals or our uncertainties around exposure, and there's one exposure especially related to lung cancer that for the most part we've had a huge uncertainty and that's smoking. I know all of the issues and especially in doing

mortality studies. Have you had any thoughts over what you might do to improve smoking characterization in these studies? Because I think it is really impacting on your ability to see what the true effect is.

MS. SCHUBAUER-BERIGAN: That's an excellent point, and certainly it's affected, for example, the IARC 15-country study, which has over 400,000 workers and very few of which actually had smoking data. That's one reason that we're taking a very close look at this with PNS, but we are finding it challenging to do a records-based study that addresses smoking. But as you say this is an issue for all occupational epidemiological studies that look at lung cancer.

We're currently trying to evaluate existing records at the DoE workplaces, and that was one reason that we incorporated cigarette smoking into the multi-site leukemia study. Although leukemia is not strongly related to smoking there is an association and we're trying to understand to what degree we can assess smoking and surrogates for smoking in the DoE workforce. And we actually had a fellow who looked at that and produced a report on it and we're digesting that to see what results that may have for future studies of smoking-related cancers.

DR. PINNEY: I had a graduate student who did the

same thing.

DR. SCHUBAUER-BERIGAN: Yes, I know you clearly have experience with that at Fernald.

DR. PINNEY: Right. And she came out with for ever never smoker really good surrogate data, pretty good for duration. When you got down to pack years, no, it wasn't as good. But in modeling smoking and looking at another risk factor, ever never helps tremendously, just knowing that the person never was a smoker.

I guess my other thought is: have you explored the opportunity to tap into the DoE medical surveillance programs to capture smoking data that you don't have currently?

DR. SCHUBAUER-BERIGAN: Yes.

DR. PINNEY: Even among those -- or the compensation program, even among those who are applying for deceased persons.

DR. SCHUBAUER-BERIGAN: We have considered it for the surveillance database. We talked briefly about this over the lunch break, but we know that -- we have been involved in an advisory capacity on some of the former worker surveillance -- medical surveillance programs and have begun talking with the different principal investigators of those projects to evaluate whether we could share data with them and make use of

that for our studies.

I'm always a little concerned about selection bias when we have self-selected individuals who come in for surveillance, and certainly for the compensation program we would only be getting information on people with cancer, and it may even be related to their exposure if low exposed individuals were less inclined to apply for the compensation program. But those are all certainly things that we would take a look at.

Larry is going to lead us in a discussion of the general issues, so if your question doesn't pertain specifically to my presentation perhaps we can let Larry lead that, or are there more questions for me? Thank you.

GENERAL ISSUES, LARRY REED

MR. REED: I actually had a couple of slides, but I think Mary's last slide here is actually a good starting point. I think we've heard a lot this morning about the work that we've done so far within NIOSH to what we think is advancing the state of science in the area of radiation health effects, particularly exposure assessment and radiation epidemiology. But we think, also, I think Doug used the term phase II of our research; phase I being the DoE initiated work that we helped finish, and then phase II being the second

generation being the work that NIOSH initiated.

We have purposely not started many new research projects in the last year to finish off those projects that had begun, and now we're at a prime opportunity and prime time to start phase III of this research effort. I'm not a content expert, I'm not a health physicist, but there are some things that pop to my mind, and so I'll just toss one out maybe to help initiate this process. Being a former policy person within NIOSH I couldn't help but be intrigued with the opportunity to investigate exposure limits, and Dave Hamel from OSHA is here in the audience who is the project officer for the OSHA rulemaking or knows the proposed rulemaking for ionizing radiation and can speak to this better, but my sense is that current exposure limits are based on dated acutely exposed populations, and now we have a wealth of data for low-level exposure and is this the time for us to consider doing risk assessments in the area to look at, you know, better exposure limits, those that are based upon these new data. So that's one idea that intrigued me as a non-expert. But I would like to hear some dialogue on is, this the point where we can and should be doing this, thinking about this.

I was also intrigued by the gentleman, I forget his

name, from CPWR who mentioned intervention research because that sort of is another area that I'm a bit biased about being from the former head of the engineering branch within NIOSH and that was our bread and butter. But I've heard many people, Mary included, saying that this is not an ideal population to work with because, one, exposure levels are relatively low, and, obviously, because of the latency period for cancer it's not a good population to study from the standpoint of measuring sort of before and after effects of an intervention. So I guess some further dialogue on that I would love to hear.

I'm sure there are an infinite number of possibilities, you know, injury data we heard someone say that there's a database that we could tap into, although, we aren't necessarily experts within the fields studies division of NIOSH, there is a division of safety research that does have expertise in injury, epidemiology and injury surveillance.

So these are a number of things that I guess I would like to hear about because, as Lew Wade mentioned this morning, this is a great opportunity for us to get input from public stakeholders such as yourselves. I think Owen mentioned also this morning that with the demise of ACERER we have no surrogate now or this is

our closest surrogate to a public forum for input. So again, now is the time to help us with this future research agenda, generation III or phase III of our life.

DR. PINNEY: I'd like to make a comment about -- Susan Pinney, about the radiation risk modeling, and going back to a lot of that has been done on the basis of acute exposures. I think not only has it been done on the basis of acute exposures, but with the a-bomb survivors in an ethnic group that some preliminary genetic susceptibility studies show really as an ethnic group have lower susceptibility than the Caucasian population in the US, so that's certainly a factor to be considered.

DR. HOFFMAN: Owen Hoffman. I think it's really important that the research agenda be continued. You look for opportunities to extend the applicability of your research findings to a wider audience, as Mary alluded to, not just the workers, but also to the extent that it relates to our overall knowledge and understanding of radiogenic risk and the extent to which that in turn can modify future revisions to radiation protection standards.

One of your questions, or maybe one of the questions of the ACERER was: are the current worker

health standards sufficient or are they sufficiently protective? And I wondered if you don't already have an answer to that. Our group is one of the groups that contributed to the development of the interactive radio epidemiological problem that many people think is the program that produces probability of causations. Not really. It's a program that looks at quantitative uncertainty in the excess relative risk. It's the excess relative risk then that is used to estimate probability of causation, those with potentially radiogenic disease, namely cancer.

Based on my experience in running the interactive radio epidemiological program, and looking at confidence intervals associated with that, as well as information that would lead to potential compensation of a worker with cancer, I would conclude that, no, the current radiation protection standards for workers are not sufficiently protective, and I would wonder whether or not you would be able to say that you have information that would contradict, at least the impressions that I'm coming up with.

DR. SCHUBAUER-BERIGAN: I think those are excellent questions and there's so many facets to that. One could consider the standards themselves, the US standards. One could consider the recommendations that

ICRP makes, the International Commission on Radiologic Protection, or one could consider actual exposures that workers are getting, which may or may not have much relation to those standards. So we are looking at that as we speak and trying within our own program to look at when would be the best time for us to get involved in that kind of risk assessment work. So we would take your comments very seriously and will consider to -- continue to consider that question.

With regard to leukemia we do believe that the Portsmouth Naval Shipyard study is very informative and very important. It's also one of five component cohorts within our multi-site leukemia case-control study. So we believe an optimal time to really take a close look at that for leukemia would be at the completion of that study. For example, that would be a point at which we would look very seriously at leukemia as an outcome in relation to perhaps the standards that are currently in place.

MR. REED: Not to break this momentum, but Doug just passed me a note saying that there is coffee now in the back. What we can do is take a short caffeine break and regroup at 2:30 and then carry on this discussion, which is very important to us.

(BREAK)

MR. REED: Let's regroup, please. To reconvene, I checked the list of people who would want to speak and make public comment, and we do have one person on the list, and there may be others who also want who just haven't put their names on the list, but in checking this out we have Herman Potter, and I would ask that he come to the microphone and give his public comment, please.

PUBLIC COMMENTS:

MR. POTTER: My name is Herman Potter. I work for United Steelworkers. I formerly worked at the gaseous diffusion plant in Portsmouth, Ohio, for a number of years prior to working for the Steelworkers. Basically, I'm here representing the International Union. United Steelworkers has about 850,000 members in North America. We represent members at Rocky Flats, the three gaseous diffusion sites of K-25, Paducah, Kentucky and Portsmouth, Ohio; represent members at Idaho National Laboratory in Idaho Falls; the Hanford site; the Waste Isolation Pilot Plant in Carlsbad, New Mexico; Mound, Ohio; and the Brookhaven Laboratories in New York.

While the USW supports NIOSH in its efforts to initiate and continue health studies of workers in the DoE complex, we're concerned about NIOSH's independence

from DoE and have recommendations on the specific activities planned for 2005 to 2010 for the various sites. In the document, in the introduction of the document it says that implementing the proposed activities on the agenda is contingent on funding by Congress and acceptance by DoE.

It is our understanding that the 1990 MoU DoE and DHHS removed DoE from a decision-making role in what studies would be conducted. In your response I'd like for you to elaborate on this and perhaps clear up any misunderstanding we may have of DoE's role in this area.

Also we recognize that the document presents only a brief description of past work and planned studies. It does not mention getting any worker involvement in providing information from institutional memory or from focus groups or risk mapping sessions, and since we know that there is a lot of data that's missing or has never been taken or assigned, and there's been some problem with the data -- the data record-keeping process, we think that that would be a good source of information to actually confirm or evaluate whether that data is good. We feel that it's essential that the workers should be identified as a necessary source of information in the document. We gave some examples,

and some of those examples was the neutron issues at the gaseous diffusion sites. At one time they were not -- they were not even considered on the dosimetry, on the TLD badges. It wasn't until workers who were involved with the programs and actually in discussing these issues with NIOSH we discovered that that was -- it was almost a laughable situation that these things were not being captured, even though the workers fully knew that they were measuring neutron radiation because it was operational data information.

United Steelworkers recommends that DHHS/NIOSH contract with an independent auditor to evaluate the various studies conducted at the sites after their completion. The use of auditors have proven very beneficial in evaluating the NIOSH site profiles for radiation dose reconstruction. The auditing contractor has pointed out some areas where radiation doses were most likely underestimated which can result in compensation claims denied. We just -- we felt that that was a good -- a good example of a checks and balances system.

USW is glad to see that NIOSH intends to update mortality studies at sites where positive results were found, however, the study should also investigate the statistical estimates of these exposures. The

University of North Carolina under a grant from NIOSH is updating a Hanford worker mortality study that will use new methods to estimate doses previously assumed to be zero and to account for effects of internal dose. This approach seems to be more creative and productive for one rather than relying on previous NIOSH studies and DoE data.

United Steelworkers encourages NIOSH to use -- to review alternate forms of information, such as operational data, environmental data, and area monitoring data that is nowhere -- seemingly nowhere linked to occupational exposure data to compare and estimate differences of real exposures versus recorded exposures.

We recommend that dose reconstruction using the following practices: employee interviews, historical operational data, raw data review and evaluation, et cetera. This is a deviation from the practice of relying on previous studies that use this data that may be convenient, but it's not necessarily accurate. Historical work practices, process descriptions, job descriptions must be documented and used in any health study. Local union halls have a source of documents and should be contacted for this information, and in many cases they have, but not always.

NIOSH should consider lessons learned in the review of dosimetry records under the Energy Employees Occupational Illness and Compensation Program Act program, including, but not limited to, considering only external dose. The fact that workers were often not monitored for radionuclides which were not prevalent at the site but had high dose consequences, such as plutonium and neptunium, and the job titles found in dosimetry databases are often not representative of the individual's job history and may only include first or last job.

Also, we recommend that NIOSH revisit updating -- we recommend that NIOSH look at morbidity studies. NIOSH should consider conducting morbidity studies on these populations and on workers at other sites where positive but non-significant associations were detected. These would include INL where external radiation exposure was linked with brain tumors, leukemia, lymphatic cancers; and ORNL X-10 where an excess of leukemia, all causes of death combined, all cancers combined and lung cancers was found. We're happy to see NIOSH recognize the need for morbidity studies in uranium, Rocky Flats and Portsmouth workers. However, we believe there are many more such opportunities and unfilled needs for morbidity studies

in the DoE complex.

Occupational mortality studies have been completed at two of the three gaseous diffusion plants in the United States. Each found no significant health risks, but each had tantalizing elevated risk estimates. The PGDP is the third of the three plants because of the exceptional public health databases in Kentucky, notably a cancer registry, there is the potential to better assess the health risks to these workers.

Owing to recognized limitations of death data and in light of improving survival with many cancer diagnosis, the distinction between incident and mortality could double or triple the number of events to be studied. Such larger numbers of observations may lead to potential findings of elevated health risks among this workforce, risks that were undetectable with a smaller number of events identified solely by the death certificates.

And that's all I have.

MR. REED: Thanks, Herman. Doug, would you like to respond to that one question?

MR. DANIELS: Yes, this is Doug Daniels again. With the question arising about the NIOSH independence in research with respect to the MoU language, that's still a fact. We determine our research agenda with

input of partners and stakeholders such as yourselves, and DoE currently doesn't have a say in omitting or adding to, other than that which is already given to stakeholders and partners. So we do solicit input from DoE in developing our research agenda, but they don't dictate the research agenda. That's still true as it was in 1990.

There's some very good information in this statement and, of course, we're not prepared to respond to all of them, but there were some key aspects that I think is important, which we really haven't discussed much today, and that is, in our early work in the exposure assessment, the point, and a very valid point I might add, was made that we need to gain institutional knowledge of these workplaces because you can't rely wholly on just records data. And that's true, and we did, in our exposure assessments and our data collection we did interview former workers as well as former supervisors and the like in order to gain some of this important institutional knowledge. And we haven't done much of that recently because, as I mentioned before, the exposure assessment piece is a large piece and a lot of that work is done up front.

So what's been happening most recently within the OERP is the analytic portion of taking those data and

doing the epi analysis. Now, future studies would require more records capture, would require more knowledge gathering. So it's a very valid point that we would need to turn to unions and the workers and the like in order to gain some more institutional knowledge of these exposures so we can make improvements for future exposure assessments. I think that was a very important point.

In regard to the Los Alamos National Lab study, we all agree, I think, that it's vital to continue to follow-up these cohorts and that we're only beginning in the most recent future to reap some of the benefits of additional vital status information and additional follow-up. Case in point, the Portsmouth Naval Shipyard where initial studies that were performed in the '70s, where you had 17 percent deaths, were less informative than the current work where we have 32, 36 percent deaths. So I would submit that a follow-up of Los Alamos National Lab cohort would be a prudent step for future research.

Mary, do you have anything?

DR. SCHUBAUER-BERIGAN: And your points as well about morbidity studies in particular and cancer incidence is certainly something that we recognize, even for cancers that in the past have had high

fatality rates that may now have fewer and longer and longer survival rates. I think it will become increasingly important for us to tap into cancer incidence registries and that kind of effort in order to study these outcomes effectively in the future.

MR. POTTER: I might add that we have -- Labor has worked very well with NIOSH over the years, especially in the health hazard evaluation program. And speaking specifically from working at the Portsmouth site, we had acknowledged -- we suspected many times that the programs were not adequately monitoring the data that they were required to keep at that time. This dealt with radiological data and this dealt with chemical exposure data. And I must say that we worked very well with NIOSH to gather those things because they're less likely to argue with you guys. I mean, that's the bottom line. They will argue forever with us even though we know that there's something right. We just do not have the technical credibility.

Now, we have found that, and I can speak specifically of the neutron data as an example, the neutron, it wasn't until a year after, a year after we found the neutron missing from our TLD badges that the Paducah site admitted that they weren't monitoring for it either. Now, the reason why we knew about it is

because we measured their badges. We were getting their data and we were telling the labor union in Paducah about that data, and the management and the contractor, the contractor and the DoE there still maintained that that information wasn't there, there was no neutrons there.

DR. SCHUBAUER-BERIGAN: You're making excellent points. In most of our studies, as Doug said, we have made an attempt to go beyond just the data that we get from DoE. I think there have been some examples of this for the Fernald cohort study that's currently underway to look at environmental data, releases from the site and other sources of information to estimate doses that wouldn't be measured either via monitoring or the badges.

I'm not involved directly in those studies, but I can speak for the multi-site leukemia study, which although the K-25 gaseous diffusion plant was not officially a site within that study, we had workers at ORNL who moved across to that site. We are aware of the limitations in the data, the monitoring data for those workers. And so Doug, who is the exposure assessor on that study, used representative sampling that was done and other information that we got from those other sources to help fill in the gaps to try to

produce better estimates of missing data.

We also do agree that it's very important to get review of our studies by persons in -- the workers themselves or their representatives. So that's part -- one of NIOSH's mandates is to conduct tripartite review and that's a very important component of our studies so that we do get a sense that we are conducting research that reflects the studied understanding of workers and management representatives as well.

MR. POTTER: I just wanted to stress utilizing other sources, because I think we all know those same conditions are continuing today. We still have -- the Labor still has to provide documentation that for some reason is not getting to NIOSH, not getting to the epi people and not getting to the health hazard evaluation people. So stepping out -- being a little bit skeptical of that data and challenging that data a little bit, that was our point in making that we want to make sure that there's clear distinction between the goals of NIOSH and the goals of the DoE.

MR. REED: Great. Good points and we'll make sure that we enter this into our public record, Herman. Thanks.

Does anyone in the audience want to comment on what you heard Herman say? Is there anyone else who would

like to give some public comment now, sort of formal or informal? Rick?

DR. HORNUNG: Rick Hornung, University of Cincinnati. This is a bit of our departure from our more scientific discussions, but I couldn't help sitting in the back listening to all of the presentations, first of all, I think I can speak for everybody in the room saying we were credibly impressed with all the work that's been done in the past, and the future research agenda, I think, looks promising also. But the real bottom line is, and I think most of us want to see this happen, is that future research gets funded. We saw how the funding level has been cut in recent years. You're about to be evaluated by the National Academy of Science, DoE, I think, at least I've heard rumors, is kind of wanting to pull back a bit from the epi research, so you're going to need sources of funding, and one thing I've sort of learned in being in academia for the last nine years is when all we do it seems like is write research proposals, and you have to have a hook to what you're proposing.

Recently, I won't mention names, but someone who is a rather high scientific administrator at UC said, I don't care what you write in your proposal, make sure the word "genetics" gets in there somewhere. And Susan

mentioned genetic susceptibility. So I'm saying that somewhat facetiously, but you had that in your proposal as looking into that. I suggest maybe you move it up a little higher and think maybe in more detail how you might do some genetics susceptibility studies using the NIOSH database or future data collection.

Another thing is, I've heard a lot, and this is the NIOSH way of thinking, this is the reason I guess NIOSH was created, but the motivating factor for doing research is to influence occupational health standards and I've heard that mentioned all throughout today. The other thing I've learned since being in academia more so than when I was at NIOSH is you really have to consider politics, unfortunately, when you're thinking scientifically. So in the current political climate I'm not sure if tying your research to occupational health standards is the only way you want to go.

So I was trying to think, what are the other ways to sell your program. So what are the -- other than genetics, are there other hot topics? Well, one thing that's on everyone's minds is terrorism. I sit on the Radiation Advisory Committee for EPA Science Advisory Board and they've already come to us to discuss dirty bombs, what do you do if a dirty bomb goes off in the United States. What is going to be the concern? It's

going to be the cleanup of the effects of such a radiologic device, and it's going to be how low do the levels have to be in that part of the city for workers, office workers maybe, to go back in and work with no fear, at least no excess fear of getting cancer later.

Well, those are two areas that I would that NIOSH could -- the research agenda could address, one would be cleanup workers who are currently cleaning up DoE sites, and the other being chronic low-level exposure that you already mentioned, where you could sell this as being a much more relevant exposure than an acute exposure in the Japanese a-bomb survivors. That's all that comes to mind right now.

MR. REED: I have one, and this is outside of your area, because I know your area of expertise, but what about nanotechnology? Those of us within NIOSH know that it's a hot area, growing commercially exponentially so. Is this an area of relevance within the energy arena?

DR. HORNUNG: I don't know what the tie would be there with your database, but I mean, I guess that's the kind of thinking that I'm advocating is thinking how when you talk to NAS and when you talk to DoE, and some people have -- represent organizations here that lobby Congress, so I think these are areas that could

be brought up as -- that would be beneficial from a continuation of the funding of NIOSH.

I know the other one, because of all the problems with fossil fuels now there's been an increased interest resurrected in nuclear power again. So once again you're going to have problems with waste disposal, chronic low-level exposures, things of that nature if we start building more nuclear reactors. So I guess my recommendation is to try to -- when someone says, why do we want to continue to fund this research, is to think not just worker occupational health standards but of other ways your research can influence and help other segments of the society. Thank you.

MR. REED: Thanks, Rick. Comments from our experts?

DR. PLATNER: Jim Platner from CPWR. I just wanted to encourage you as you discuss this MoU with Department of Energy to think more about what NIOSH might be able to do in terms of future or ongoing exposures and data collection systems, because it's really a shame that the different sites have datasets that with some significant effort can be merged, but why not just collect standard data fields. I mean, there's no need to have on every site a different set of fields that you're collecting, and it seems like it

could be structured sort of like ABLES with the blood leads or something where there's certain fields that states have to collect, and if they want to collect more that's okay, but they need to at least collect core data. And even if it wasn't merged, even if it was maintained locally it would be really valuable to have the same data collected in the same format across sites. And if you get annual doses, it's really difficult to compare those directly with individual badge doses, and if there was some policy or consistency in that it would be quite valuable.

MR. REED: Jim, while you're there, could you expand on your earlier comment regarding intervention studies?

DR. PLATNER: Well, I mean, I think in construction or remediation, which is where a lot of the exposure is occurring now, I think there's some real challenges because last month's dose isn't predictive of next month's, you know, the sources are less well defined. And I think there's -- the exposures are more related to management of the job tasks and implementing controls, even when last week's badge reading was zero, and I think there's a lot of management of detail on the contractor's part that's important to keeping doses down.

And I think there's a variety of interventions that could be tried that are used by some contractors that you could in effect set up an experiment to demonstrate effectiveness of those practices using the exposure data that you collect. So I think it would be interesting to try some applied intervention evaluations like that as part of your research agenda.

MR. REED: Thank you.

DR. SCHUBAUER-BERIGAN: I think that's a great suggestion, and I would ask that we form a dialogue about what you view to be the most successful contractor programs across the complex and talk with Doug and Travis about that in the future.

I did also want to comment about your suggestion to make better use of the surveillance data, and I think that we do need to do that. We have begun talking with the different groups that are involved in the former worker surveillance program. There have been ongoing meetings that really haven't met actively recently, but at one time there was a lot of discussion about how do we make these datasets more standardized, how do we collect our data in a way that we can use them across the complex as a national surveillance for certain outcomes and exposures. And to the extent that the former worker surveillance programs continue, I think

that that effort needs to continue, too.

DR. PLATNER: Well, I think that's something that should happen and can happen pretty easily. I think the difficult challenges that DoE still provides surveillance for its current employees, that's sort of like an epidemiologist using a survey instrument that somebody else wrote. You might be able to pick out some good questions in there that you can use the data from, but it's always nicer to write your own survey instrument. So if NIOSH could work with DoE in some sort of formal way to design data collection that actually meets your research needs, I think that would be better than just hoping they collect the right data.

MR. REED: Thank you.

DR. HOFFMAN: Owen Hoffman. As I sit here I try to think back to outstanding questions that have occurred, and in the various meetings, either of ACERER or the site-specific subcommittees that haven't made it onto your slides, these are outstanding issues that I think that are there. And one in particular was raised by a guy by the name of Chuck Broscius at Idaho, you remember him, and the solution was to get him off the committee as opposed to answering his questions.

We have on this slide interactions of radiation and other workplace exposures. What Chuck was concerned

about was interactions of radiation and other radiation exposures outside of the workplace. Now, usually we aren't concerned about that because the paradigm is that the maximum radiation exposures to workers are the exposures that occurred at the worksite where they're handling radioactive materials. But there are exceptions to this paradigm, and one, of course, is for thyroid cancer and exposure to iodine-131 released either at the sites or to weapons testing from the Nevada test site that did a fairly good job to the entire United States and beyond.

I know that in the worker compensation program this isn't taken into account even though foodstuffs brought on-site are contaminated from off-site sources that were affected by on-site releases. So to what extent, especially when you're looking at the exposures to workers who were part of the 1950s and 1960s cohort, are DoE and DoD related off-site exposures taken into account and/or on-site exposures due to the importation of contaminated foodstuffs from outside the plant into the plant.

MR. DANIELS: You raise some very interesting and excellent points about the exposure assessment and where we need to go. It's sort of been the common practice that if you have reason to believe that the

exposures that occurred elsewhere than the plant that you're studying are randomly distributed among the population that you're studying that it, in fact, won't have any effect on the epidemiologic analysis. But that was true with medical exposures and -- for a long time, and then we showed just looking at that one aspect that, hey, there's a considerable amount of exposure which is work-related that is attributed to medical x-rays that were conducted as a condition of employment. So perhaps -- and, obviously, in that case that's no longer randomly distributed among your study population.

So we -- to the extent practical in our exposure assessment we try to quantify all sources of exposure, including medical exposures, whatever data we have, but the systems just aren't in place to go retrieve all of that information now. And maybe perhaps what we're suggesting is, I've heard talk about standardizing worker surveillance data, that would be a key source. Anyone who's done studies of multiple DoE facilities understand just dealing with the various recordkeeping among -- each facility had its own procedures, its own plan, and even there own units, in some cases. So just standardizing the data can be rather difficult.

So maybe if we were to focus efforts in trying to

standardize these datasets, trying to make it easier for us to amass relevant exposure data outside of even the study facilities will further increase our precision and accuracy in the exposure assessment and even lower the bar epidemiologically, if that's a word.

DR. SCHUBAUER-BERIGAN: I know exactly what you're talking about, Owen, and collecting the kind of data that you're talking about, looking at atmospheric deposition doses, internally and to thyroid from atmospheric testing, that would require a tremendous amount of additional data collection just epidemiologically, questionnaire data about where the worker spent their early life, for example, to figure out what those doses would be.

Speaking individually as a researcher, one place that intrigued me very much about this, and you mentioned Chuck Broscius so I will, too, he was on the health effects subcommittee for the Idaho National Engineering Environmental Laboratory, and I did get a chance to talk with him a couple of times about his concerns. We did recognize that there was a potential for unmonitored exposure from releases at the chemical processing plant there, and our partner at NCEH, who conducted the exposure assessment there, we had many discussions with them about how we might take into

account those airborne releases into our exposure assessment. It was a very challenging concept to do this.

I think as Doug said, it's taking us to a different level of exposure assessment in order to try to reconstruct those doses, even from an on-site atmospheric release. And I agree that it's probably the next generation of studies and research questions that will have to be addressed, and probably to a large degree using simulation to determine the impact that that might have on the risk estimates.

MS. CONNELL: I'm Carol Connell with ATSDR. I was a nuclear regulatory inspector for many years and one thing I know from -- I agree with him about talking to the workers because if you want a really accurate dose where you're going to try and change standards and stuff, then you need to do more than what you've done, I think. The workers, for instance, some workers didn't even wear their badges, they would leave them -- doctors I know would leave them on their lab coats hanging in their office. Where they wear them on their bodies is very important to the type of work that they're doing. Also ring badges. For years I used to go into a lab and they'd wear them like a regular ring. And the main reason for it was extremity dose and the

film badge should be facing the palm of the hand, especially when you're working with beta emitters. So those are the kinds of things that you can only find out if you interview the employees, and I think that's real important.

MR. REED: Other ideas as we try to identify the universe of research topics here? I know we're all tired, but one thing that we want to leave the door open for you to submit comments. We obviously have a transcription, or will, of this meeting today. We also have one set of written comments. We want to leave the door open for people who attended here and others among our stakeholders to provide comments, and that was listed, I think, in the *Federal Register* notice for those of you who received it, and I think we should resend that to everyone who attended this meeting, I think, Patty, we could rely on you to do that. Patty Gudlewski helped us with the administrative aspects of this meeting. Thank you, Patty.

So I think to that end we have talked about leaving the record open for comment to December 1st, and that will form the sort of collected information of what we will use to help us develop our agenda, our future research agenda; obviously, in addition to the fine record we have here.

Related to that, Mary mentioned that we have what we call our DoE research agenda, we re-up every year, and, Steve, could you comment on that and talk about the comment period.

DR. AHRENHOLZ: Steve Ahrenholz and I'm with the Occupational Energy Research Program at NIOSH as well. And it's been mentioned a couple of times today in the presentations that you've heard. What it's entitled is the Agenda for DHHS Public-Health Activities for Fiscal Years 2005 to 2010 at U.S. Department of Energy sites. Now, what this document has is really an overview of all of the work that has been and is being done and some of what is proposed across the DoE complex.

And this particular document actually goes beyond just what NIOSH has, it also includes what NCEH and ATSDR have because it pertains to what is done under the Memorandum of Understanding between DoE and DHHS. And we do update this annually, and we are interested in people's comments on that as well, which, if you do have the opportunity to take a look at it you can give us feedback on what we have going on, what we are proposing; we have it broken out by sites. We also have a section in it at the back that lists all of NIOSH's multi-site studies, so there is some separation like that.

We had some copies here today, we didn't bring a lot of them because we didn't know what the interest was. It is available on our Web site and we have -- you have information on the NIOSH Web site and how to get to the Occupational Energy Research Program. There's actually -- you go to the NIOSH and then there's this additional part here (http://www.cdc.gov/niosh/pdfs/hhsdoe_2005-2010-2.pdf) that will actually take you to a PDF copy of the 135-page document. You can download it as a PDF or you can print it off, however you would like to look at it.

We would like comments, if you are so inclined to provide some to us, as Larry said, by the first of December. You can send them to the Health-Related Energy Research Branch, you have contact information and the mailing address at the back of several of the presentations today. If you want to send them electronically you can mail them to me at this CDC e-mail address because I'm one of the people that collects them, along with my counterparts at NCEH and ATSDR. And then we'll be looking at these to see what comments we can and need to address as far as our next revision, which would be for 2006 through 2011.

It usually comes out about April or May. It depends. DoE does have an opportunity to put some of

their information into it as far as their surveillance activities go, but then it is normally available and we are interested in feedback from people.

There was a letter here that said November 1st, but that was when I was sending this out in August and we didn't have all the final arrangements for this meeting yet. So that's why there was the November 1st date. But through the end of November will be just fine.

MR. REED: Thanks, Steve. So, again, to reiterate, there are two items on the table here, there's one additional time for comment related to our discussion here today that will help us shape our research -- future research agenda, and it is a December 1st due date and we will send out the Web link for that, Patty will, to the participants, and separately this -- the research agenda that Steve mentioned that's also due December 1st in terms of comment.

So what we have in terms of follow-up actions in addition to that from you, we have promised -- I mentioned earlier this morning that we would develop proceedings from this meeting. The proceedings will roughly take the shape of a verbatim transcript of what was said here today, and then we will attach that to an executive summary, which will be our sense of the discussion points. And then our intent is to send that

out when it's finished, we don't have a timeframe for that yet, but to you, the participants, in draft form, and if you'd like to comment on that you certainly are welcome to do so. And we will lock that in at some point, finalize it, and make it a part of our -- the public record that is available through the OERP Web site. So that's a deliverable from us to you and for the future of our research program.

As Mary said, I just want to close by saying that we -- our intent is to have future meetings like this. And as I mentioned earlier it's our way of getting stakeholder input, which we found to be extremely valuable, and we appreciate the time and energy and effort that you spent today to help us with this. So we look forward to doing it again on a periodic basis.

DR. SCHUBAUER-BERIGAN: I would just like to add one thing. Apparently there were some people who were curious about the National Academies review and the schedule for that. There will be a meeting, a two-day meeting next week, November 3 and 4th, and the times are approximate at this point. There's a public session that's open on November 3rd, that's Thursday morning of next week, and it will be at the Keck building of the National Academies, approximately 9:00 or 10 o'clock or thereabouts, and if you're interested

in more information I can get that to you via the Web site or via e-mail after today's meeting. The second part of that would be the following day, Friday, which will be the NIOSH presentation.

In terms of the overall schedule, as we've been informed by the National Academies, there will be our initial meeting, there will be a deliberation by the committee that's reviewing the programs, followed by request for information from us, and a meeting to be held at a later date in which much more detail will be gone into. So those of you who are interested in following that process can look at the National Academies Web site, and if you're not already on our e-mail list you can talk to Travis after today and get on that list and we'll update people on the status of that effort.

I also wanted to recognize Dave Back who helped us greatly getting set up today and providing a lot of the materials that you all are carrying with you as you go away. Thanks, again, to everyone for coming.

MR. REED: Thank you all and we appreciate your input and support for our future agenda. Safe travels.

CERTIFICATE

I, SUZETTE M. MAGEE, Certified Court Reporter, do hereby certify that the foregoing meeting was held on October 27, 2005, at the Washington Court Hotel, Washington, D.C.; that I did report the proceedings thereof; that the foregoing pages, numbered 1 through 162, inclusive, constitute a true and correct transcript of the proceedings thereof.

SUZETTE M. MAGEE, CVR, CCR #93079
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