U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES (DHHS)

CENTERS FOR DISEASE CONTROL
AND PREVENTION (CDC)

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NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH (NIOSH)

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PUBLIC MEETING TO SEEK COMMENTS ON THE CURRENT NIOSH POLICY TO CLASSIFY CARCINOGENS AND ESTABLISH RECOMMENDED EXPOSURE LIMITS (RELs)

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MONDAY,
DECEMBER 12, 2011

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The meeting convened at 9:00 a.m. in the Hubert H. Humphrey Building, Room 800, 200 Independence Ave S.W., Washington, D.C., Paul Schulte, Ph.D., presiding.

PRESENT:

PAUL SCHULTE, Ph.D., NIOSH/CDC
JOHN HOWARD, M.D., Director, NIOSH/CDC
T. J. LENTZ, Ph.D., NIOSH/CDC
KATHLEEN MacMAHON, DVM, NIOSH/CDC
FAYE RICE, MPH, NIOSH/CDC
RALPH ZUMWALDE, MS, NIOSH/CDC

PUBLIC COMMENTERS:

GINO BEGLUITTI, National Center for Environmental Health (NCEH)/ CDC
KATHLEEN BURNS, Ph.D., Sciencecorps (via phone)
ANNA FENDLEY, United Steelworkers Union
BOB GLENN, Glenn Consulting Group
WILLIAM KOJOLA, American Federation of Labor and Congress of Industrial Organizations (AFL/CIO)
DAN NAPIER, Industrial Hygienist
JAMES MELIUS, M.D., DrPH, Laborers' International Union
JOHN SCHWEITZER, American Composites Manufacturers Association
DARIUS SIVIN, Ph.D., International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW)
LAURA WELCH, M.D., Center for Construction Research and Training (CPWR)
KIMBERLY WISE, Ph.D., American Chemistry Council

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

9:12 a.m.

DR. HOWARD: Thank you very much. And welcome, everybody, to our meeting on carcinogen policy and recommended exposure limits. Thanks very much for coming today. We appreciate your time from your busy schedules.

This is an important meeting for us. It's sort of a kickoff to get some good thoughts going about these important issues. And we hope that you will participate both today as well as throughout the process.

And it is my job to introduce the head of our initiative, Paul Schulte, who is also Director of the Division of Education and Information here in NIOSH, actually in Cincinnati. And he will be making a presentation, introducing the team that's working on this.

So thank you again for coming. I appreciate all of your time. And we look forward to all of your good comments for us.

Thanks.

Paul?

DR. SCHULTE: Thank you, John.

WELCOME, INTRODUCTIONS, AND OVERVIEW

DR. SCHULTE: Good morning, everyone. And, as Dr. Howard said, thank you for coming and being willing to share with us your thoughts and opinions on NIOSH's cancer policy.

We hope to examine that policy and consider revisions, which we will make available for public comment in a further public meeting in the future. I will get into that more in a moment. First, some housekeeping details.

For exits, you go through the double doors there and then the next one. And the steps are right on the left.

With regard to this meeting, we haven't been able to get the Web portion up. And so those people who are watching it on the Web will only get the audio, but won't be able

to see the slides in my presentation. We will make those available on our website.

The meeting will include remote participants in a variety of cities, primarily NIOSH locations participating via the Envision system. So, if you hear voices coming from that system, that is who those people are. We will also have some people who are participating by telephoneand we will hear them, too.

One of the things we would like to do is just have everyone introduce themselves so that we can make sure that we have a full roll, particularly for the people who are on Envision and on the telephone.

All of this information that will be presented here today will be put in the NIOSH public docket, so the comments as well as any written materials that you have submitted will be accessible and in the public domain.

Ideally, your oral comments will

be amplifications of material that you will submit to the docket in writing, but it's not necessarily required.

And so if we could just go around the room, and then we'll go through the virtual land to identify people. So, Dr. Howard?

DR. HOWARD: John Howard with NIOSH.

MR. NAPIER: Dan Napier, industrial hygienist.

MR. GLENN: Bob Glenn, Glenn Consulting Group.

DR. WELCH: Laurie Welch with the Center for Construction Research and Training.

DR. WISE: Kimberly Wise with the American Chemistry Council.

MR. STRACHAN: Dan Strachan, National Petrochemical and Refiners Association.

MS. FENDLEY: Anna Fendley with the United Steelworkers.

DR. SIVIN: Darius Sivin, United Auto Workers.

MR. SHUDTZ: Matt Shudtz with the Center for Progressive Reform.

MR. JAKES: Henry Jakes with Vegnan Environmental Services.

MR. KOJOLA: Bill Kojola, AFL/CIO.

DR. MELIUS: Jim Melius, Laborers Union.

DR. COGLIANO: Vince Cogliano, U.S. EPA.

MR. HEARL: Frank Hearl, NIOSH Washington, D.C.

MR. SLAWSKI: Jim Slawski, FAA.

MR. WALKER: Chris Walker with Keller and Heckman.

MS. MARSHALL: M. J. Marshall, Dutko Grayling.

MR. SCHWEITZER: John Schweitzer, American Composites Manufacturers Association.

MR. SNYDER: Jack Snyder with the Styrene Information and Research Center.

MR. MARKS: Howard Marks, National Asphalt Pavement Association.

MR. STRODE: Rob Strode, industrial hygienist.

MR. RASMUSON: Eric Rasmuson, industrial hygienist, Chemistry and Industrial Hygiene.

MR. COBLE: Joe Coble, OSHA National Office.

DR. SCHAEFFER: Val Schaeffer, OSHA.

MR. WHELAN: Bill Whelan, Bechtel.

MS. HEGSTAD: Maria Hegstad, Inside Washington Publishers.

DR. BRAY: Patty Bray, OSHA.

MS. EDENS: Mandy Edens, OSHA.

MR. BEGLUITTI: Gino Begluitti, CDC, National Center for Environmental Health.

MR. SCHUMACHER: Randy Schumacher, Schumacher Partners International.

MR. ZUMWALDE: Ralph Zumwalde, NIOSH.

DR. MacMAHON: Kathleen MacMahon, NIOSH.

DR. LENTZ: I am T. J. Lentz with NIOSH.

COURT REPORTER: Hi, my name is Jim Cordes. I'm the transcriber.

DR. SCHULTE: As you gather, then, your remarks will be transcribed. Those remarks will be posted on the website.

MS. RICE: Faye Rice, NIOSH.

DR. SCHULTE: Okay. Can we go to the Envision in Cincinnati?

MS. DAMES: Barb Dames, NIOSH.

DR. SCHULTE: Lauralynn?

DR. McKERNAN: Yes. Barbara announced herself and I did as well.

DR. SCHULTE: Lauralynn McKernan. Okay.

Morgantown?

DR. SULLIVAN: Patricia Sullivan, Morgantown.

DR. SCHULTE: Atlanta?

(No response.)

DR. SCHULTE: A little delay here, it seems. Any other NIOSH site?

(No response.)

DR. SCHULTE: Okay. On the telephone?

(Telephone introductions.)

DR. SOFGE: Chris Sofge from NIOSH.

MR. TRIPPLER: Aaron Trippler, AIHA.

MS. COOPER: Linda Cooper from NASA.

DR. BURNS: Kathleen Burns from Sciencecorps.

DR. SCHULTE: Anyone else?

(No response.)

DR. SCHULTE: Okay. Thank you all.

Just one other note. The docket on obtaining opinions about the NIOSH cancer policy will be open until December 30th of this year. So there's still time for their

submissions.

PARTICIPANT: On the phone, the voice quality is poor. Could I ask that people speak closer to the phone as well as the microphone?

DR. SCHULTE: Okay. Frank, I'm standing right next to it. Maybe I could do it this way, make it easy. How does that sound? Frank?

PARTICIPANT: Way better.

DR. SCHULTE: Okay. Thank you.

Okay, ladies and gentlemen, I am going to give you a bit of an overview about what we are thinking about in terms of the current cancer policy, some of the history, some of the background. And then we will have time to go through each of the five questions. After that, we will at the end of the day also have a general comment period. So you can speak multiple times if you would like.

So the purpose of this review is to reflect on the fact that there are some

issues in the NIOSH cancer policy that both NIOSH staff and stakeholders have had some concerns with.

The most critical of those issues is the term "potential occupational carcinogen." And throughout our history, but more in recent years, there was concern that the term "potential" conveys uncertainty that's not warranted with many known carcinogens, such as asbestos, benzene, cadmium, and many others.

And so, consequently, we're thinking that there is a need possibly to revise the policy to address the issue of the term "potential occupational carcinogen."

Additionally, the NIOSH cancer policy only has one category: "potential occupational carcinogen." And we are concerned that the classification scheme does not have the capability of incorporating levels of uncertainty in the policy. And so, whereas, other kinds of classification

systems, such as that used by NTP [National Toxicology Program] or that used by IARC [International Agency for Research on Cancer], allow such incorporation of such uncertainty.

So the first part of this examination will be about NIOSH's cancer classification system. The second part will focus on the setting of recommended exposure limits.

This is not something that is specific to carcinogens, but it plays out a lot in thinking about carcinogens. So we thought we would examine some of the questions that have been issues in recent years. And these include such things as the level of residual risk. If we make a recommendation to reduce the risk below 1 in 1,000 cancers for a working lifetime, is this an appropriate cut point? And what do people think about the level of risk that still remains?

We also have, in our recommended exposure limit policy, language to the extent

that we need to think about the recommended exposure limit to the extent that it's feasible. Historically, we have approached this to mean if it can be done or envisioned in a single facility, that that was an adequate assessment. This is different than the definition of technological feasibility that OSHA uses. So how should we continue to interpret this statement?

And then there are a number of technical features, such as the action level and questions about what is its utility. Historically, the action level was designed to address sampling variability, but it was also used as a trigger for various actions, including medical monitoring.

Should we still have an action level? Should it be formulaic - - formulaic being, historically we have often said the action level is one-half of the REL or recommended exposure limit? But maybe it should be based on the distribution of

sampling results in a particular location. So there are those kinds of questions.

And then the third category of issues is that since the Occupational Safety and Health Act of 1970, we have learned an awful lot about cancer and particularly occupational cancer. So how should the advances in our knowledge of cancer science be incorporated in the NIOSH cancer policy if we revise it? So, those are sort of three overviews of the issues that are of most concern.

So I will continue with this overview. We will then, as I said, have input on the five questions. These were the questions that were posted in the Federal Register on August 23rd, 2011. And then, in addition to comments on each of the individual questions, we will also have a final comment period at the end of the day.

With me today is a panel of NIOSH staff. They have introduced themselves. They

will be sitting up here after the presentation: Thomas Lentz, Faye Rice, Ralph Zumwalde, and Kathleen MacMahon. They are here to help amplify any of the remarks that we want to make concerning the issues and also to draw you out in terms of comments that you might make. So they're here to help in this process.

Now, occupational cancer is not a disease of the past. In fact, it is a very significant disease that burdens the workforce in the 21st century. It is still a significant cause of morbidity, mortality, and societal burden.

Currently, there are millions of workers who are exposed to OSHA-regulated carcinogens and tens of millions of workers with past exposure. And it's estimated that annually, out of 600,000 cancers, 4 percent or 24,000 deaths result from workplace exposure.

These numbers are generally underestimated. And they're underestimated

for a number of reasons. Historically, the assessments of attributable risk have been conducted only on a few carcinogens and cancer sites. So there hasn't been really a comprehensive analysis.

Secondly, the role of carcinogenic exposures in what analyses exist has not been strong in the area of assessing the risks to women or to subpopulations at high risk.

And, then, thirdly, we are now starting to see more robust assessments of the attributable risk. I'd point to the paper by Rushton and colleagues in the U.K. that shows attributable risks ranging up to 10 percent.

So if 4 percent of the deaths are due to occupational causes, when we talk about new cases, it is estimated that there are about 48,000 new cases of cancer a year that are attributable to occupational exposures.

And when you rank the causes of cancer, this is third, behind cigarette smoking and diet. But it is first when you

subdivide the rankings according to whether the carcinogen exposures are voluntary or involuntary. And so occupational carcinogenic exposure is an involuntary situation, whereas, cigarette smoking and diet for the most part are considered voluntary exposures; albeit, there is an argument to be made about the complexity of the voluntary nature there. Nonetheless, occupational exposure is a critical cause of cancer.

Now, we are interested in the NIOSH cancer policy, in cancer from a variety of occupational hazards: radiation, viruses, and chemicals. Historically, most of our focus has been on cancer related to chemical exposures. And so I am going to give you a little bit of the background on chemical carcinogenesis.

Most of you know this quite well. Some of you have written the book on it. To some of you, it may be somewhat unfamiliar. And so I will cover that as well.

You can trace back the thinking about chemicals causing cancer at least to Percivall Pott some 200 years ago, when he identified scrotal cancer in chimney sweeps. That observation wasn't built on too much until at least about 100 years ago, when the beginning of animal studies, particularly skin painting studies with polycyclic aromatic hydrocarbons and tars first started to show cancers on the skin of animals.

That continued to grow. And it was in the '70s, between the 1970s and the 1990s that we started to have a systematic testing in chronic bioassays of various chemicals for carcinogenic potency. And, in fact, by 2000, one examination by Ames and Gold showed that over half of the synthetic chemicals that were tested were positive for cancer in rats and mice.

Another way to think about it is that of the approximately 200 agents known to cause cancer in humans, nearly all had been

shown to cause cancer in rats and mice. And this is critical, because many times when an agency has to make a cancer determination or a recommended exposure limit, it is based on animal data. Ideally, we would like to know what is happening in workers, but in many cases, we don't have those data. But we do have animal data.

The good thing about having animal data is that we can preclude or we can precede human exposure in many cases or extensive human exposure and thus prevent unwarranted exposures. Nonetheless, there is a good correspondence between cancer in animals and cancer in people, particularly workers.

Now, cancer is a multi-stage process. It has various modes and mechanisms of action. You can at least think of them broadly in terms of genotoxic and non-genotoxic modes of action. I will talk about that a little further.

This slide just depicts the

multi-stage carcinogenesis process. In general, the cancer process involves interference in mutation in the DNA and resultant genetic changes, of which the organism selects for variations of those changes. And over a period of time in a variety of steps, those changes amass and malignant tumor holds sway and is formed. So this is the general flow for carcinogenic exposure and particularly chemical carcinogen exposure.

It is more of a complex process than that last picture showed. It has both endogenous and exogenous kinds of co-factors that need to be considered. There is also the capability of the body to repair various mutations that occur.

There is variability in people or in animals in the way they respond to cancer, both in terms of activating carcinogens as well as in repairing damage from carcinogen exposure. So cancer is what is considered a

stochastic type of process.

This slide -- I don't know if you can read it. It is just a list of some of the classic carcinogens: various metals, cadmium, chromium, nickel, bis(chloromethyl) ether, asbestos, diesel exhaust, cutting oils, vinyl chloride, aromatic amines, benzene, ethylene oxide, some of the classic carcinogens that we have identified in occupational safety and health.

Also, this slide again depicts sort of the multi-stage process, but it shows one other feature; that this process takes time. And so we have the whole concept of the latent period, the time between first exposure and the appearance, the clinical appearance, of indications of cancer.

And so on average, we think of the latency period in chemical carcinogenesis to be around 20 years. But we know that it is variable for different types of cancer, different doses, different types of

carcinogens. And so latency periods have been shown in the literature to range from 5 to 40 years.

So NIOSH is mandated to study a variety of hazards to workers, not only carcinogens. Today we are focusing on carcinogens, and they are clearly part of the NIOSH mandate. And I am going to read this, because this is a critical piece:

"NIOSH is mandated to develop criteria dealing with toxic materials and harmful physical agents and substances, which will describe exposure levels that are safe for various periods of employment, including, but not limited to, exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience." This is the basis for our cancer classification and our recommended exposure limits.

We have a long history of

establishing recommended exposure limits for carcinogens. To date, the NIOSH pocket guide lists some 135 substances as carcinogens. And NIOSH has developed recommended exposure limits for most of these.

These are important tools for the occupational safety and health community for employers and workers, because often, in the absence of a regulatory level or permissible exposure level, companies utilize NIOSH recommended exposure limits as de facto in-house guidance, so that they try to use that as the basis for their control programs. So there is a long history and a large impact of NIOSH recommended exposure limits.

So what we are talking about today is cancer policy or occupational cancer policy. And this is a brief history of occupational cancer policy.

So if you recall, 200 years ago Percivall Pott essentially made the first observation or one of the first observations.

A hundred years ago it was animal testing. In the '30s and '40s is when we started to see the beginning of policy related to the underlying science. So we have in Ontario, workers' compensation for cancers related to coal tar exposure. In Germany, we have compensation for occupational lung cancer.

Then in the '70s, right after the OSH Act, we have the emergency temporary standard for asbestos. This was followed by the OSHA standards for 14 significant carcinogens and for vinyl chloride.

In 1976, NIOSH issued its cancer policy in the form of a presentation by Dr. Fairchild at a scientific meeting. And I'll get into that in a bit.

In 1977, OSHA proposed a regulation for identifying, classifying, and regulating potential occupational carcinogens. NIOSH testified in support of that. That was enacted in 1980.

In 1985 and in the '80s, we

started to see the emergence of various cancer hazard classification systems. So we had the NTP and the IARC system.

Then in 1995, NIOSH revised its cancer policy, not the classification part but the part that relates to the establishment of recommended exposure limits. I'm going to go into some of these in detail.

And then in 2010, triggered by our work on the “asbestos road map”, where people were concerned that we used the term "potential occupational carcinogen," we moved to establish an internal committee to review the NIOSH cancer policy. That's the group that has fostered this meeting today and is moving to assess the policy and revise it.

So just amplifying some of those issues, and where NIOSH's cancer policy stems from, I refer to a paper published in the New York Academies of Science by Fairchild, “Guidelines for a NIOSH policy on occupational carcinogenesis”.

Much of the verbiage in the paper talks about the growing concern about the increase in the unregulated numbers and quantities of synthetic chemicals. Back in the '70s, chemical carcinogenesis, awareness of it was growing rapidly. There were a number of agencies that were being established to deal with hazardous substances and particularly carcinogenic substances in all components of the environment and the work environment also. There were concerns about the impact of these kinds of chemicals, particularly on workers and particularly involving cancer.

In the core of the policy were these items here. In the absence of solid evidence to the contrary, there is the possibility of carcinogenic effect in humans for any chemical conclusively shown to be carcinogenic in one animal species. In other words, if there was one study that showed cancer in animals, that was enough to trigger

the labeling of it as a carcinogen.

Again, you have to remember this is the time in the mid-70s when, while there was a lot of information about chemical carcinogenesis, it was still in a maturing, evolving state. And the concern was to be as protective as possible.

Consequently, in addition to frankly malignant carcinogens or responses, benign neoplasms were also considered to be an indicator of cancer. And so the concern there was that in some cases, benign neoplasms could transform into malignant neoplasms.

Additionally, there was another criterion -- I didn't have it on this slide -- that any substance that reduced the latency period for a particular cancer would also be considered a carcinogen.

And, then, finally, the approach to dealing with this kind of information was that NIOSH would recommend generally no detectable level or the lowest feasible level

of exposure.

So this was the core of NIOSH's cancer policy. And pretty much it stayed in existence and some parts of it are still in existence today. Some have been changed, and I will show you where the changes occurred.

In 1978, then, NIOSH testified on the OSHA notice of proposed rulemaking for its cancer policy. And NIOSH supported that it was in general agreement with this policy and with the definition of potential occupational carcinogen as stated in the OSHA cancer policy.

NIOSH then used the term "potential occupational carcinogen" for the first time in 1978 in the glycidyl ethers criteria document and used it subsequently in various documents, criteria documents, and current intelligence bulletins pertaining to occupational carcinogens. And so, as I said, this policy has continued to this day.

These are just details from the

OSHA cancer policy under potential occupational carcinogen. And, essentially, it was similar to what I mentioned for the NIOSH policy for a potential occupational carcinogen: any substance or combination of substances that caused an increased incidence of cancer, including benign and malignant neoplasms in humans or at least one animal species by any route of exposure.

It did preclude results of tumors in locations other than at the site of administration. The focus here was for dermal or IP [intraperitoneal] kinds of studies to distinguish carcinogens that might be an artifact of the method of exposure, as opposed to an inherent effect.

And then any substance also that has metabolized, it may not be a substance that is carcinogenic in and of itself, but once in the body, it becomes metabolized to a potential occupational carcinogen. It was also considered a carcinogen.

Then this policy persisted until 1995. At that time, NIOSH made a modification in the recommended exposure limit part of the policy, particularly because of advances in the science and the ability to start to do analyses of risk and to quantify those risks and, in part, as a result of the benzene Supreme Court decision.

So, in 1995, NIOSH issued a policy that said that the RELs will be based on health effects from animal or human data measurable by analytic techniques. But it added the language that "RELs that could be feasibly achieved by engineering controls."

At the same time -- that language indicated that in some cases, there would be a residual risk. But the 1995 policy said that NIOSH would project the full range of risks that various exposures could result in and eventually select a limit that may have some residual risk. So it was somewhat of a departure from the 1976 policy that strove to

identify no detectable level or minimum feasible risk.

As I said, since the 1970s, there have been many advances in cancer science. And this slide depicts four categories of those. There has been great understanding of the mechanism of chemical carcinogenesis. I showed you some of the slides that depict some of the richness of that understanding: the multi-stage nature, the involvement of genes and oncogenes.

There has also been a capability now to look at vast numbers of chemicals with high-throughput methods so as to identify potential carcinogens that would then be subject to further animal bioassays. So this is a new approach.

As I said, there is also the ability to identify, to utilize genetic and epigenetic data to identify high-risk subgroups. One of the things that has not been done in the cancer policy is to identify

where there were individual subgroups that could be at high risk. Should there be specific standards for people who are at particularly high risk due to various genetic characteristics?

And then, finally, we are at a point now where we may not have the wherewithal to individually go through specific chemicals one at a time, but we have now the development of new approaches in terms of hazard and control banding that may allow us to think about groups of chemicals and recommended exposure limits or at least guidance for those groups of chemicals.

So that brings us to today. We're here to see public input on the revision of the cancer policy in terms of both the cancer classification and the development of recommended exposure limits.

So we have a number of ways of doing this. We will have this public meeting. As I said, we have the electronic docket. We

would appreciate particularly comments in writing, but we welcome your comments here today. And, as I said, the docket will close for comments on December 30th of this year.

Here is the schedule that we hope to follow and we have been following since December 2010. We have been doing committee work internal to NIOSH. This is the public meeting.

Following this meeting, building on the work that we have done internally, building on your comments and the comments in the docket, we will put out a new policy or a clarified policy sometime in the spring of 2012. We will have a public review of that document, probably another public meeting. And then we hope to aim toward publication in the fall of 2012.

PARTICIPANT: What is the URL for that docket again?

DR. SCHULTE: Sorry. CDC.gov/NIOSH/docket.

PARTICIPANT: Thank you.

DR. SCHULTE: Now, the meeting today will go through the five questions that were posted in the Federal Register. I'm going to just go through them briefly. We will then have comments on each one. And then we'll have general comments at the end of the day.

First question, should there explicitly be a carcinogen policy, as opposed to a broader policy on toxicant identification and classification?

In other words, if we're going to have a carcinogen policy, why don't we have a reproductive toxicant policy or a neurotoxicant policy? Is there any value in having a specific policy for carcinogens or having a more generalized policy?

Second, what evidence should form the basis for determining that substances are carcinogens? How should these criteria correspond to nomenclature and

categorizations, such as known or reasonably anticipated, et cetera?

In other words, there are various classification systems that are in existence that allow for more nuanced interpretation of the scientific information of its sufficiency and certainty. How should the NIOSH carcinogen policy relate to that kind of thinking?

Should 1 in 1,000 working lifetime risk for persons occupationally exposed be the target level recommended for exposure limit, the REL for carcinogens, or should a lower target be considered? Again, for those -- most of you are familiar with it. The 1 in 1,000 is the level that the Supreme Court identified in the benzene decision as at least the level where action would be taken. And so 1 in 1,000 is what NIOSH has been using because we provide our information generally not only to employers but to OSHA. And that is the level that OSHA has been using in

recent years. Should we think of a different level of lifetime risk?

In establishing recommended exposure limits, how should we interpret the phrase "to the extent feasible"? As I said, we have historically used a very minimal definition of "the extent feasible," meaning if it could be done in a single facility or even in some cases if it could be envisioned as capable of being done on the horizon, such that it in some cases might even force the technology a bit. What is the opinion of people on this issue?

And then lastly, in the absence of data, what uncertainties or assumptions are appropriate for use in the development of recommended exposure limits? What is the utility of the action level, and how should the action level be set?

So these are the five questions that we will be discussing today. And at this point, I will invite the panel to come up. And

we will begin the discussion of the first question. So if the panel would come up?

We have two hand-held mics, so you can use these. Please use these when you have questions. Identify yourself for the record. And we'll start with a minimum -- or a maximum of five minutes for comment. And if we get through and there is still more to say, people can have a second five minutes.

It is suggested that maybe you come up to the podium. If you want, you can come up to the podium, I guess, or you can speak from your location.

So the floor is open. The first question is: should there explicitly be a carcinogen policy, as opposed to a broader policy on toxicant identification and classification? And so the floor is open for your comments. I take it by your silence that you don't think there should be a --

(Laughter.)

DR. SCHULTE: Maybe before we get

to the questions, we'll take a moment to just see if anybody has any opening remarks that they want to make regarding the cancer policy in these deliberations today.

(No response.)

What if you gave a party, and no one showed up?

(Laughter.)

DR. SCHULTE: So, ladies and gentlemen, this is a meeting to get input from the public, so we're looking forward to your thoughts. Clearly, this audience is not all in agreement with the approach we are taking or doesn't think that it should remain the same. So I would love to hear some comments. Here you go, sir.

DISCUSSION OF 5 QUESTIONS

DR. SIVIN: Darius Sivin, UAW.

I would like to endorse the idea of NIOSH developing policies for other health endpoints besides carcinogens but not as a replacement for its carcinogen policy.

I think NIOSH should finish the revision of its carcinogen policy on the schedule it has more or less presented today and then proceed to reproductive toxicants and other kinds of health endpoints but should not -- I would be concerned that if you tried to throw it all in one basket, it would never get finished and there would be no policy.

DR. SCHULTE: Other comments?

MR. KOJOLA: Bill Kojola, AFL/CIO.

Yes. I would agree with Darius's comment. I think NIOSH has had a carcinogen policy for more than 35 years. Clearly, this is a major undertaking to issue a revision. I think NIOSH should stay focused on revising a policy that is explicit for carcinogenic substances and make it more relevant to the 21st century.

So I think that if you were to interweave this into a much broader policy about a whole host of other toxic chemicals, that the whole system would literally bog down

and the carcinogen policy, a new one, would not see the light of day.

I think it might be useful if NIOSH were, once it finishes a revised cancer policy, to think about whether or not it is appropriate to have policies on other classifications of toxic chemicals and that given time, resources, and importance, you know, make some decisions internally about whether or not it has the capability to do so and then move that forward.

DR. SCHULTE: If I could draw you out just a bit, so, implicit in or even maybe explicit in what you said was your belief that there should be a revision to the policy given the issues that I have raised today?

MR. KOJOLA: That's correct.

DR. SCHULTE: Okay. Other comments?

MR. GLENN: Bob Glenn, Glenn Consulting Group.

I tend to agree with the previous

two comments. I stepped out for a moment, so there may have been more than two.

But I think, also, whenever you look at an agent, you need to somewhat consider the total body of evidence about the toxicology of the material. And certainly there are some situations where there may be a non-malignant process, at least to cancer. And quartz comes to mind.

I think there is growing evidence that if crystalline silica and quartz are carcinogenic, it's possibly related to silicosis being a mechanism. So I think those things need to be considered as well. I am sure you would. But I just thought I would point that out.

DR. SCHULTE: Thank you.

Other comments? Anyone on the phone? Did you raise your hand, sir? No. Anyone else?

(No response.)

Okay. I don't think that's such a

meaty question. I am going to just move on to the next one, get into something with a little more oomph to it. We can certainly reflect back on any of these.

What evidence should form the basis for determining that substances are carcinogens? How should the criteria for this evidence corresponds to nomenclature and categorizations used in other classifications?

In other words, should NIOSH think about establishing a policy that is more nuanced, that allows for uncertainty in the sufficiency of evidence to be part of the classification? Comments? Yes, sir?

MR. NAPIER: Dan Napier.

I guess what I want to do is ask you a question back. Are we saying, should we make this more acceptable to others or listen to other criteria or is NIOSH going to be able to say, here is an outline of different items that we can consider? How do we open that consideration, and exactly how far -- are you

asking, how far should NIOSH go as far as accepting what studies from where or are you simply saying: what further definitions should NIOSH develop so that we can then make more favorable or more easily compare other data?

DR. SCHULTE: What we're saying is that there are a lot of uncertainties in the evidence base for determining whether something is a carcinogen.

Right now, the policy is that if there is one study in animals that shows cancer -- tumors, be they malignant or benign, that is adequate. Is that a sufficient kind of basis to use for determining a hazard classification or should we have a more robust basis?

Should there be multiple species or, another type of example, what if we have various kinds of in vitro studies that show progressions of biologic changes consistent with cancer? Would that serve as appropriate evidence in making a cancer classification?

Organizations like NTP and IARC have classification systems that allow for uncertainty. We have one category. Something is or isn't a potential occupational carcinogen.

And so what is the opinion of people about the advisability of that or should we think of another approach? Do you want to ask a question or do you want to follow up on that?

MR. NAPIER: Well, my own opinion of course is that we should have a more of a best approach to these items.

DR. SCHULTE: In the back here?

DR. MELIUS: Yes. Jim Melius, Labor.

The first question -- I'll start with, actually, the second question -- is that certainly a dichotomous approach for classification, which NIOSH uses now, there's a lot of shortcomings in terms of what it communicates both to people working as well as

professionals working in the field and to regulatory agencies.

And the level of scientific information that is usually available for most or many substances that we are evaluating for carcinogenicity is usually fairly complicated and includes multiple different types of information, and a dichotomous classification system simply doesn't capture that complexity very well.

I think the question what do you replace it with and then how many categories, what do you call those categories, and then how do you fit the available evidence to those categories is sort of a separate question, but I think, first of all, the issue is, you know, is the current system adequate? And I think it is inadequate.

It is misleading in many different ways given the current scientific knowledge of the amount -- just sort of the volume of information we often have on particular

substances. Having just one classification really can be misleading, doesn't capture the fact that for certain substances, we have much more definitive information -- Paul, you used asbestos as an example. I think there are many others from all along the spectrum, that the field of occupational health would be better served if we had a more complete classification system similar to what is already in place by many other groups around the world.

DR. SCHULTE: What ones of the existing classification systems do you think are admirable -- or not admirable but should be considered to be possibly modeled after or even adopted in that case?

DR. MELIUS: The ones I am most familiar with off the top of my head would be -- I mean, certainly IARC - I think what is important is not only what is -- I think three things. One is number of levels you have in the classification system. One, what do those

-- that nomenclature that you use, what does it convey?

Does it sort of fit how the people, scientists, people working in occupational, environmental health, how they sort of generally consider a substance that there are meaningful differences between categories; and then, secondly, that you have clear rules on how you classify things within those particular -- those systems?

And, for example, both NTP and IARC have developed fairly explicit approaches to classification. I just came back from IARC. So that is what is on my mind. And I am kind of familiar with that, more familiar with that, at least recently.

And I think that system works very well because, again, there's judgment involved. The science doesn't always fit the classification. But if you at least have a clear set of rules that you follow or guidelines that you follow for doing that,

then the people in the field understand that, both from the regulatory side as well as the professional side. Then I think it does help to communicate, better communication on what we know about a substance, what its degree of hazard and risk might be.

DR. SCHULTE: So there are sort of two issues there. One is the content of the classification system. Is another one the issue of the transparency of the process?

DR. MELIUS: Yes. I think you have to assume that -- I am assuming that there is a transparent --

DR. SCHULTE: Right.

DR. MELIUS: -- process there that involves I think significant peer scientific input into that process. These aren't simple judgments to make all the time. The science is complicated. It can stretch over, back to Percivall Pott, I guess. But, even over time, the science has changed and so requires a good understanding of the epidemiology, toxicology,

and some of the mechanistic work that goes on now. And how does that all fit together? What is good science? What is bad science?

So that is why I think it is important that the classification system and the guidelines you set up, you know, fit how the scientific community to the extent that there is agreement within the scientific community, how that fits into the review of the evidence and puts it into some sort of a nomenclature system.

I think it is hard de novo to come up with a nomenclatures system because people have worked in the field. We are used to how NTP does now. We are used to how IARC does now. We are used to other policies within other different agencies and so forth under that, but I think -- which should make it easier to do though I think there are some decisions to be made as to how you think it should best be done, what do you want to -- your communication to OSHA, your communication

to the field, and how you're simply not just copying what another -- it somehow conveys that you are making an independent evaluation. You are not just accepting what IARC, NTP, or some other agency has determined.

DR. SCHULTE: Does someone want to speak? I want to follow up there for a second. Then we'll get to that gentleman. So how important do you think the independent determination is? For example, NIOSH is part of the National Toxicology Program, yet we have our own cancer classification system. What issues would preclude us from utilizing the NTP system, for example, as our classification system?

DR. MELIUS: I would think -- I'm not saying that you couldn't use it, but I would think that you would have to take into account, one, NIOSH's focus on occupational health.

The NTP has a broader mandate. And, secondly, you have a mandate to make

recommendations to OSHA, which I don't believe NTP has, at least not formally, though it certainly could be their review and documents can be used in OSHA rulemaking or other OSHA action.

But I think it's those two. It is something different. I don't think that the NTP system is something that is necessarily appropriate for your mandates. It may be, but I don't think so. I think it may take some modification to do that.

DR. SCHULTE: Right. There are some discordances between our classification and NTP classifications already. Certainly that would have to be addressed.

Let's see what this gentleman wanted to say back here.

MR. BEGLUITTI: I was just going to build a little bit on what he was saying there at the end. Gino Begluitti with NCEH.

I would caution against wholesale adoption of a classification system because in

doing that, you also adopt the chemical specifics of that. If you take it from IARC or if you take it from NTP and you have a different end user, like he's saying, NTP takes into environmental and everything. You are basically occupational.

So I would caution against just wholesale adoption of a categorization process, but it is very hard to start off brand new, so just something to think about.

DR. SCHULTE: Good. Good comment.

DR. SIVIN: Darius Sivin, UAW again.

One example for which NIOSH should be exercising its own judgments, workers are occupationally exposed to ethanol. Ethanol may also be carcinogenic by oral ingestion of large quantities over long periods of time. That would not be a route necessarily relevant to occupational carcinogenesis.

So another agency might have a reason to classify ethanol as a carcinogen

while simultaneously NIOSH might have a reason not to classify it as an occupational carcinogen. And that would be an important reason for NIOSH to make its own judgments.

DR. WELCH: Laurie Welch with the Center for Construction Research and Training.

I get a sense there is definitely support for a multi-layered carcinogen system, but I want to support the longstanding NIOSH approach of identifying possible or potential human carcinogens based on animal data. I wouldn't want to see a classification system that required a very high level of evidence before it is labeled as a carcinogen, which could happen with this process.

You could say, "Okay. Well, a single animal study, well, that's not enough." And in some classifications that exist, that is not enough, but I think that for protecting the workers in this country, it is for beginning to identify those as potential human carcinogens. So they stay on a list.

So there is some concern. It raises concern within the manufacturers or the workplaces that are using that. As we were talking about it, I was thinking, "Well, so what is the endpoint for NIOSH? What's a NIOSH REL for?"

I mean, we like to think that OSHA would take it and make regulations and maybe before I die, we'll see a process that speeds that up faster, both within NIOSH and within OSHA. But it has a whole lot of other benefits, basically putting, you know, manufacturers or users, primarily manufacturers of compounds on notice that this potentially should be labeled as a carcinogen.

And without NIOSH or NTP or some organization putting it in the category of a potential human carcinogen, that is not going to happen. It is not going to happen just based on some animal studies existing.

So setting a criteria document, having an REL of any kind, whatever we do with

the other questions starts action happening outside a regulatory environment that's I think very important. So I just would emphasize that that current policy I wouldn't want to take off the criteria that are being used, but they could be nuanced into different groups.

MR. KOJOLA: Bill Kojola, AFL/CIO.

I think there is no question that the term "potential" is not a useful term. And clearly your review of the asbestos work had brought that to light. So, you know, we need to have a classification scheme that does have layering, some layering at least, at least two categories known. And we anticipated it or suspected or whatever, whatever criteria you end up using.

You know, I think NIOSH really needs to look at the various schemes that are out there, IARC and NTP, of course, but not adopt those in totality and allow yourselves as an agency to be dictated by whatever

chemicals IARC or NTP choose to evaluate and to classify. I think that would put NIOSH in a straitjacket that would not be useful for those of us who work in occupational safety and health.

An example, there may be substances that NIOSH wishes to make some hazard determination as to the carcinogenicity that IARC or NTP aren't dealing with. And then you're stuck.

You know, it might be several examples that we can think of, ultrafine titanium dioxide or carbon nanotubes, what have you, that IARC or NTP might not address for a considerable period of time. That is an issue in the occupational health community that NIOSH wants to and needs to speak up on. So I would caution you not to just adopt wholesale and allow yourselves to be wagged by another tail.

DR. SCHULTE: Thank you.

Could I ask people who are on the

phone or on Envision to make sure you have muted your system? We hear some background sounds. Thank you.

Sir?

MR. NAPIER: Dan Napier again.

One of the things that I am looking at -- I am a fairly practical guy -- is that in California, we have developed about 14 new PELs in the last 4 years. So in about 33,000 years, we will be through the first 100,000.

And so there's just a huge -- my suggestion there's a huge amount of information out there. And I have always looked to NIOSH for guidance and more of a, yes, you produce a REL or some level, but I am more thinking that from NIOSH, I am going to get the kind of guidance that will assist me in looking at something that is completely different that nobody has looked at yet and may not.

You've got a small, limited use of

some item. What are the appropriate guidelines that I can use?

MR. GLENN: Bob Glenn.

I would just add my support to the procedure where you would develop a multi-bin, if you will, type of a process. I am not sure what you call those or the criteria for them certainly, but I think, you know, there is a wealth of knowledge about what we know about some materials and very little evidence on others.

And, for instance, you know, the one positive animal study, while I think that has some -- certainly needs to be considered, it also needs to be considered how sound is that one positive study? And I think when you start looking at animal experimentation, it is important to look at multiple species.

Is there any sex-specific change or carcinogenesis you are seeing? Is the dose appropriate? Is the route of exposure appropriate and things like that? And that

might depend on where it would drop out, similarly with epidemiology. You know, what is the SMR, and have its confounders been looked at sufficiently? The exposure is fine. So I think you need to consider many things when you do that and look at certainly all of the evidence.

DR. SCHULTE: So you are suggesting that we would have multiple criteria based on the sufficiency of the evidence, maybe multiple categories, then, that result from that?

MR. GLENN: Yes. For instance, on the SMRs but below 130 or the 130 to 200, 200-300, wherever -- you know, do you have exposure response for those as well, the things we normally do but have more criteria? So you come to this decision logic where it goes here and people know why it's going here and such and takes some of the more judgment out of it in some ways. But that would be a thought.

DR. SCHULTE: Thank you.

There was a hand in the back.

DR. MELIUS: This is Jim Melius from Laborers again.

Just a follow-up on Bob's comment. I think that you always have judgment, but I think that what is important is that whatever your classification and system and so forth helps you communicate what judgment went into that. You do need sort of guidelines and criteria, but at least if you have those guidelines, you apply scientific judgment to a process beyond that. Then it communicates something to people in the field, although they may not always agree with it.

It may change. Science may, new science may, change it and so forth, but I think if you have clear guidelines, I think it does help the process a lot.

Just back in thinking about it, you also ought to need to think about with your classification system. So how does it

communicate into the field within NIOSH and to other processes?

So to some extent, you are going to use it as a basis for developing RELs, but that process is slow. And it takes time and may not be adequate information to do that in a meaningful way at the point in time, but it is one part of what you are communicating.

But given that this basically should be a hazard determination, I think the other point is that it also -- gentleman from California mentioned that it actually also helps to communicate with people in the field on something new.

You alert somebody. But when you are alerting them, you are also conveying to them, you know, that there is a certain type of evidence available for this particular substance that would indicate, at least to the degree of hazard, what the scientific evidence is and may not include an REL, but it would help for people in the field to know how

should they be approaching trying to control that particular substance.

And I think that is a really important function for NIOSH. I think in the past, it has worked well. It is certainly something that can be done more quickly than a full REL but it is very important.

DR. SCHULTE: So a number of commenters have spoken about the risk communication function that is attached to the hazard classification. And I think that's, in part, what you were saying. And you also brought up the idea that there are a range of classification outcomes that can occur. So we might identify a substance for which there is preliminary but disquieting information about a potential carcinogenic hazard versus a substance where there is a well-established evidence base and we are deliberating on that.

And so if I heard you correctly, you are talking about a system that can address both of those kinds of situations so

that in some cases, we can do an alerting function. In other cases, we are doing more a confirmatory kind of function.

And so I think that makes thinking about a system even more complex, but I think it's a kind of complexity that we need to address. So thank you for that.

It is now 10:25.

MR. ZUMWALDE: Paul, can I --

DR. SCHULTE: Yes?

MR. ZUMWALDE: Before we break, here, can I just expand on that? I think one of the things that sets NIOSH apart from the other organizations, like NTP and IARC and maybe GHS [Globally Harmonized System for the classification and labeling of chemicals], that are in the process of doing hazard identification, is that the Institute as part of its responsibility is to take the next step.

So, whatever hazard classification system we may want to derive, I think the

expectation is, what do those messages mean in terms of risk management? And so as we go through the process and look at a classification system, in parallel, we are going to be thinking about how we are going to communicate that message for the hazard classification in terms of what the expectations are from a risk management standpoint. And so we are interested in terms of not only the classification system, but we are also interested in terms of how one might communicate that in terms of risk management.

And, as I said, the other agencies are just involved in hazard identification and don't go through that additional step; whereas, NIOSH feels that this is an important step for us, whether it is an exposure limit, or some other kind of action in a workplace, maybe respirators, maybe medical surveillance. Those are the kinds of things that the Institute, will be thinking about as we go

through looking at the classification system.

We are interested in any comments you might have on a classification system that would be appropriate for NIOSH to consider, and also what are the implications in communicating that classification, such as, what are the expectations of workers and employers for each of those particular classifications.

DR. SCHULTE: And if you have further thoughts on that after the break, we will entertain them. So we will now take a break until 10:40. Thank you.

(Whereupon, the foregoing matter went off the record at 10:26 a.m. and went back on the record at 10:43 a.m.)

DR. SCHULTE: Let's continue on. We were discussing question 2. We are talking about other classification systems, other ways of thinking about the evidence that would form a classification system.

It was pointed out to me -- and we

have considered this. I didn't mention it. There is a system that NIOSH and OSHA both have supported publicly. And that is the Globally Harmonized System for cancer classification that came from the U.N. And, indeed, that is a system that the U.S. is going to adopt that OSHA has supported and NIOSH has testified in favor of. It has these three categories: category 1, subcategory A, "known human carcinogen based on human evidence;" category 1, subcategory 1B, "presumed human carcinogen based on demonstrated carcinogenicity in animals;" and category 2, "suspected carcinogen based on limited evidence in humans or animals."

Clearly if the United States is supportive of this through various agencies of the government then manufacturers will be required to in some ways respond to thisThe question would be, how would a NIOSH system that is different relate to this or if this doesn't have the levels of detail and nuance

that we have been talking about, are there subcriteria that might be important or would each of these -- could each of these have different kinds of risk management potentials that would follow from them?

So are there any thoughts about the Globally Harmonized System, its utility, how it fits in? It certainly puts a primacy on human evidence, so known human carcinogen if you didn't have human evidence, then the highest category would be presumed human carcinogen. And that could be based on animal data or suspected carcinogen based on limited evidence in animals and humans.

Any thoughts about that particular one that people -- that particular classification system that people have had? Everybody seems to like it.

(Laughter.)

DR. SCHULTE: This commenter here.

DR. WISE: Kimberly Wise with the American Chemistry Council.

I think that, as you mentioned, since NIOSH has already been supportive of GHS as well as OSHA, that you should make sure that if you are going to adopt a different classification system, that there is some concordance with the GHS. You want to make sure, obviously, that you are not confusing industry by developing several different types of classification schemes that aren't in concordance with each other, specifically the GHS classification system.

I think also a lot of the other speakers have pointed out making sure that if you are developing a classification scheme in itself, that you really look at the full body of evidence. And so you want to make sure that there are some clear definitions in the type of --

PARTICIPANT: Can you please pass the microphone?

DR. WISE: Does it sound like it's turned off? No? Yes?

DR. SCHULTE: Keep talking.

DR. WISE: Okay. So hopefully the people that are online can hear me. I will try to speak up a little bit louder. And maybe it will come out a little bit clearer.

But I just want to make sure that, one, if you are going to adopt a system that you try to be in concordance with GHS because it has already been supported by, like you mentioned, NIOSH and OSHA, that if you are developing a classification system, that you really do look at the full body of evidence, you look at biological plausibility in the animal data that you have, the route of exposures, as mentioned by a couple of the speakers as well, so just to make sure that if you are going to go from just the one category that you currently have, which is possibly based on just one animal positive result, that it is clearly understood what those other categories mean and what type of data is actually going into those categories,

especially looking at the quality of the data that is going to be put into those categories so when you are looking at the scientific database and you have several animal studies and you have epi data that is available, what is the weight of the evidence?

So are you going to be taking the weight of the evidence for the epi data in higher consideration versus the animal data that you have and if you in the absence of epi data, is certain animal data going to be given more weight? But you make sure you have to look at the biological plausibility of those, obviously the route of exposure and making sure that the route of exposure is applicable to the occupational exposure that you are going to be setting your recommended exposure levels based on.

DR. SCHULTE: Right. So I think you made two great points there. Certainly the concordance issue is important. If NIOSH comes out with a classification system that

isn't in concordance with the GHS system, that I think could lead to confusion. So certainly we need to look at the crosswalk between those two.

The other thing is that for a variety of classification systems, you have the end category, but then you have subcriteria to determine whether or not something fits into those categories. And that is where I think we will have some possibility for some play and some manipulation.

You identify various kinds of criteria, the full body of evidence, and so forth. Clearly that is where we might put that as part of the criteria for whether something fits into one of those categories. So thank you for those comments.

There's another one back there.

DR. MELIUS: Yes. It's Jim Melius from the Laborers again.

I think that there are sort of

naturally those three general categories. I agree with the previous speakers, the comments on that, and I think the benefits of that approach.

The only hesitation I have is I think, one, NIOSH needs to think, are those adequate for what you are using your nomenclature for and your policy for under that?

I don't think you want to go into a system where you have ten categories and that's just confusing. But I think at the same time, you know, like you add a category for inadequate evidence or no evidence. Sometimes like knowing that there is no evidence is very useful. It hasn't been tested yet.

Now, is that worth a separate category? I don't know. But I think it's sort of thinking about how the classification system would be used and what does it convey to people.

I don't think you want to get beyond, you know, three, four, five categories depending on how you want to number them or whatever.

I think what is absolutely critical is the determination basis for it. Is that determination something that people understand and can utilize, may not always agree with it, but at least they understand how those decisions are made and how those guidelines might be interpreted?

And, then, secondly, does it keep up with the science that has -- I mean, we pointed out, Paul, this is a rapidly changing science. And certainly critically in the area of so-called mechanistic data, there's lots of changes there that I think will probably become more and more important to understand and more and more important to our classification system as we appear to be doing fewer long-term animal and epidemiological studies that we have sort of relied on in the

past. And I think we will have to rely on that more and coming to some agreement. How that data fits into the classification system I think is going to be critical.

And I worry about adopting somebody else's system, an assumption that you would then parrot that system when, in fact, you know, -- and this applies to IARC or NTP or anything, where you may be out of sync with them just in terms of timing, you know, let alone in terms of how your evaluations are being made.

So, again, it needs to be compatible. It needs to be something that communicates consistently. But at the same time I think it has to be clear there is some independence of the evaluation there. You are not replacing there, at least not under the current scheme.

DR. SCHULTE: Right. And at the same time that there is independence, there has to be some way to say how they link or how

they relate to each other in some way.

DR. MELIUS: Yes, absolutely. Yes.

DR. SCHULTE: I think there is a comment up here. Bob?

MR. GLENN: I would like to certainly agree with Jim on that. And also I think before our break, Ralph Zumwalde pointed out a very important part of what would be necessary for your carcinogen policy. And that is, unlike IARC and NTP, you need to go further than just hazard identification. So that alone says that there needs to be no doubt perhaps more robustness to your policy than those mere hazard identification policies.

And I also tend to agree. I think there needs to be concordance with GHS, but I don't think that should drive you to solely adopting something that is going to fall out into one of those classifications.

I think one thing that I thought of since we have started, too, and that is

yours is somewhat differently as well because; whereas, the environmental agents are generally just a single agent that a population might be exposed to, which would be a carcinogen, we have the possibility of having multiple carcinogen exposures in industry settings and certainly even exposures to other materials that might modify the action of a carcinogen, either positively or negatively.

I'm not speaking pharmaceutical industry but manufacturing therapeutic drugs come to the mind, where people have exposures that could affect multiple organs, could be different mechanisms. I mean, it's just a whole host of things that need to be thought of in that.

DR. SCHULTE: Clearly the multiple exposure issue and the mixture issue have been nagging aspects of this whole area for a long time. To the extent that we can make any kind of contribution to that, that needs to be

looked at.

I'm not sure what kind of contributions, really, are -- you know, that the group wisdom has on that thus far, but at least acknowledging what we don't know may be a step forward.

MR. ZUMWALDE: Yes. A couple of the comments that I heard expressed concern that adopting a current classification that is used by someone else may not necessarily meet the responsibilities of the charge of NIOSH, that somehow those classification systems may deviate in some way in terms of what NIOSH responsibilities are.

In reality, though, the data sets are pretty much the same in terms of any organization in terms of looking at the hazard classification. So NIOSH would most likely be looking at those same data sets that other organizations look at.

What I haven't heard and what might be of interest to it is if NIOSH would

adopt the same or very similar classification systems, say, maybe NTP, would that be an advantage to NIOSH in terms of maybe having chemicals already gone through a process of hazard identification and being classified as a carcinogen?

Is that an advantage for NIOSH in terms of not having gone through maybe that process itself for those particular chemicals but adopting their hazard classification, say, NTP as an example since they have gone through that process? Is that somehow an advantage for NIOSH? And does that provide some opportunity then for NIOSH to go the next step in terms of applying whatever risk management recommendations might be appropriate?

DR. SCHULTE: Of course. And I think that is a correct set of questions. Clearly when we look at other systems, if, say, another classification system has identified something as a carcinogen by an oral route, I think it would be incumbent on

us to ask the question, well, what does that really mean for worker exposure and, indeed?

So in other classification systems where they have that as the basis for a determination, there would have to be some stipulation of if NIOSH adopted that system of us taking it the next step and asking, "Well, what does that mean in an occupational sense?" or the reverse is true.

For example, on titanium dioxide, we stipulated that we were only talking about occupational inhalation exposure of titanium dioxide aerosols. We weren't talking about titanium dioxide in food or in sunscreen or things of that nature.

So, I mean, I think it's clear that our mandate, our specific mandate, for occupational issues needs to be a driver in whatever interpretation of a system that we use or a system that we develop.

Other comments? There is one in the back, too, after Bob.

MR. GLENN: Another good point, Ralph. I think, as you point out, I mean, these people have gone through the process. They have gathered the data. They have analyzed the data, looked at it very carefully.

I think for NIOSH, this could be very good use for prioritization of which ones you would want to tackle first. And by doing that, you can look at such things as what is the potency of the carcinogen that's been determined by these other groups and then start looking at occupational factors, like how many people are exposed, what is the exposure, is the route appropriate for what is known from other exposures and things like that? So I think it certainly would be useful as a prioritization for your own policy.

DR. SCHULTE: Is there someone in the back?

DR. MELIUS: Yes. It's Jim Melius again.

Just to follow up on that and your comment, Paul. I mean, I don't think it matters specifically which classification system you adopt and what the exact names are and so forth, but I think you can certainly -- since you are going -- if you do go to a multi-tier system, that you would be basically utilizing the information that has already been identified, whether it is by NTP,IARC, MAK [Maximale Arbeitsplatzkonzentration (maximum concentration of a substance in the ambient air in the workplace)], or whatever, that have done these classifications, I think your caveats, Paul, in terms of route of exposure information like that are important. Plus, there are always issues of timeliness of information.

And, you know, I think many of us here in the room fought the TLV [Threshold Limit Value] update issue. And that becomes critical. It also may be that you need to be sure that whoever you're adopting from

actually considers the same type of information.

But I don't think you are talking about a straight across-the-board adoption. You are talking about -- adaptation. I think you are talking about a new review where you might utilize the information that was gathered as part of these other reviews, classification reviews, and would be using that for your own purposes. And, as Bob said, you would be using it for prioritization also. Is there a gap that could be filled and so forth?

I think it is appropriate. I think for most substances, I think it would be relatively straightforward. I do think you would also end up -- you know, no matter what you do, you end up refighting some of the battles that have gone on in the past and may still rage, again, without naming any suspects in that, but it certainly is going to raise issues where people have disagreed with

whatever was done with substance X. They are going to take a new shot at it with NIOSH.

DR. SCHULTE: Well, I mean, I think part of the issue is not to have to refight the same battles if you adopt a system, a classification system that has already vetted material in terms of its classification. Why refight that battle?

DR. MELIUS: Well, I don't think you can avoid it because I think the fight isn't over the classification system. It's over the --

DR. SCHULTE: Application.

DR. MELIUS: -- interpretation. And I think invariably there is additional information. I could be wrong, I mean, but, you know, again, hypothetically, NTP makes a classification, you know, in October, you adopt it in November.

You know, it is pretty much going to follow that. Again, there may be some information you would want to do. But I think

adopting something that is older, a year old even, there is new information.

If you look at at least the media war over the IARC cell phone classification, you know, immediately as soon as a new study comes out, it gets touted as either supporting or refuting the IARC classification.

DR. SCHULTE: Right.

DR. MELIUS: So I think you are going to have to deal with that issue anyway.

DR. SCHULTE: Thank you.

Could I ask those on the telephone or Envision to mute? Thank you.

I saw another question. Bob and then Laurie?

MR. GLENN: Bob Glenn.

One other thing I was thinking about that as you put this together -- I am not suggesting you do it, but you might give it consideration. And that is as you develop your policy and your criteria, you also include what are the critical knowledge gaps,

it fell into this bin because this is what we know about it, but what would have been nice to have to make a better determination of where it would be?

DR. WELCH: Laurie Welch.

I actually disagree with Jim a little bit. I think by the time something becomes a known human carcinogen, say by IARC, new information is not going to undo that.

There may be new information, but it takes so much information to get it into that category that it's -- I mean, maybe 20 years later, something could change, but it's unlikely. So I would like to see something where NIOSH would have the flexibility to adopt existing classifications.

Probably all the ones that are on the IARC known human carcinogen list are already on the NIOSH carcinogen list but to not have to go through a totally complete new review but some flexibility.

But if something is just a

possible human carcinogen and the data is ten years old, you would want to look at it again. So you wouldn't be stuck with the categorizations, but you would have the option, as Ralph suggested, of moving forward quickly with ones that have been designated as known human carcinogens.

Then, instead of spending a year doing a review, if there is a way -- and that is somewhat of an internal NIOSH process if you can -- if it requires making a statement that you are going to adopt somebody else's list to be able to shortcut that review, then you have to do it.

If you can do it internally as a procedure without necessarily having to state it, that would probably be preferable. Make the judgment based on the evidence.

But I would hate to see NIOSH spending time doing detailed reviews on things where it's well accepted and the evidence is there but still having to go through a process

where someone pulls all the papers and you have a committee and you have peer review.

I mean, I think about the "asbestos road map," took I don't know how many years. You know, National Academy Committee. I mean, that was really overdone, a peer review of a peer review of a peer review, reminded me of Love Canal.

You know, it was kind of like it was -- yes, it was controversial. Some parts of it were controversial. But it just seemed that amount of time -- you can't spend that on everything. You won't be able to move forward.

DR. SCHULTE: Right. And I think the realization that a number of speakers have pointed to is that it is the actions that stem from the classification that may be the more important thing.

So what risk management guidance do we develop or what kind of communications do we develop, everything ranging from an

alert about a concern to full-fledged risk management strategy for something that is clearly carcinogenic?

I think we need a system that looks at the range of actions as well as the classification and then also that looks at the criteria that feed into the classification.

So there are really three areas where we can have some variability and different approaches. So I think that has been nicely drawn out by some of these questions and comments.

Should we move on, then, to the third question? Let's do that. I see no hands waiting to speak on this topic. The third question is, should 1 in 1,000 working lifetime risk for persons occupationally exposed be the target level for a recommended exposure limit for carcinogens or should lower targets be considered?

So just to clarify, again, we're moving now from cancer classification to

recommended exposure limit development. This is a generic issue, but we have chosen to speak to it for all kinds of hazards. But we have chosen to speak to it specifically because we have had a lot of experience with it in the area of carcinogens.

Again, the 1 in 1,000 risk level derives from the Supreme Court benzene decision. And it clearly has been used in many of the latest NIOSH criteria documents in the risk assessments and as a cut point for the recommended exposure limits.

Any comments on this issue? There's one there.

MR. KOJOLA: Well, this is Bill Kojola. Well, the short answer about whether or not NIOSH should use 1 in 1,000 is no. We don't believe it should.

Let me just read you the two sentences out of the benzene decision with regards to this risk level of 1 in 1,000 that I think are instructive because I think that

there are a lot of misconceptions about what the benzene decision really said. It says, and I quote, "Some risks are plainly acceptable, and others are plainly unacceptable."

If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant.

On the other hand, if the odds are 1 in 1,000 that regular inhalation of gasoline vapors that are 2 percent benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it."

So, really, what we are talking about is not something that is drawn in concrete from the benzene decision that 1 in 1,000 is the pivotal point around which NIOSH or even OSHA should be establishing either recommended or mandated exposure limits. And

we are looking at, instead, a wide range here, which I think needs to be sort of part of our understanding of where this question derives from and how we ought to be approaching it.

Clearly there is a huge range here of 1 in 1,000 to 1 in a billion. And that range in between those two limits is something that I think is worthy of a policy consideration's influence on how NIOSH develops its RELs and, indeed, even on the agency, OSHA, which is charged by statute for actually establishing required and mandated permissible exposure limits.

So I will end it there. I may have other things to say later on as this discussion unfolds, but, you know, that is the context under which we are operating here.

DR. SCHULTE: Thank you for reading that and clarifying that. For people who hadn't remembered where that fit in, that puts a little more perspective on it.

Indeed, just to remind folks, our

current policy is that we communicate and project a range of risks at all levels. So from 1 in 100 to 1 in 100,000 risk, we generally and routinely have been putting those numbers in our criteria documents.

So one is the issue of we provide to the public and stakeholders what the range of risks are. Two, then we ascertain what we think is a risk level that has a certain health protection but has some level of practicality. And so there are sort of two issues there.

Now you are suggesting that maybe -- you said that you didn't think that we should use the 1 in 1,000 risk level, presuming you were suggesting that we would use a lower risk level, such as 1 in 10,000 or even lower. Is that what you were saying?

MR. KOJOLA: Correct.

DR. SCHULTE: So when you start to do that, then you are essentially at levels that are possibly quite difficult to achieve

and/or to measure. And OSHA certainly does not use those kind of levels in developing their permissible exposure limits.

So if we are to be of any service to OSHA to have a recommended exposure limit at 1 in 10,000 or 1 in 100,000 because it may not be of utility, I would like to hear some comment on that particular issue.

DR. SIVIN: Darius Sivin, UAW.

We would like to see NIOSH affirm that, at least in principle, one loses no right to protection by crossing the threshold of the workplace. And that at least in principle, workers are entitled to the same de minimis risk of 1 in a million that EPA says we have the other 16 hours of the day.

We can see practical reasons for which NIOSH might issue specific RELs associated with greater risk, but, in fact, it may not be necessary for NIOSH to establish a particular target level at all.

We have already discussed that

there are some substances for which we may have the four data points from a single animal study and other substances for which we may have a very extensive epidemiologic database.

So, for that reason alone, the database in one case may permit estimating concentrations that are associated with, let's say, a risk level 1 in 100,000; whereas, the more sparse database may lead to uncertainties at levels of risk that low that it would be essentially false precision to even assert that you know that if you control the such and such level, you are only going to have 1 in 100,000 risk or whatever.

And so for those substances, it might be reasonable to issue a REL that is at the risk level that the database offers you reasonable certainty that you are actually at that risk level.

And that, the availability of the scientific data alone might be the reason to have different levels for different

substances, but we do think it is very important that NIOSH assert in principle that one loses no right to protection by crossing the threshold of the workplace.

DR. SCHULTE: Other comments? Laurie?

DR. WELCH: Yes. Laurie Welch.

And if you were to say, "All right. A 1 in 1,000 working lifetime risk for developing an occupational cancer is an important threshold," people have exposures to multiple compounds, so -- both in mixtures or just over their lifetime use -- you know, there are categories of industrial products that are known to contain 2 or 3 specific carcinogens. So some industries you could just count on it.

So 1 in 1,000 really translates into, could translate into, 1 in 100 with the multiple exposures. So I think it is reasonable. And that, in a way, is why EPA uses such a low level. One of the rationales

is there are sensitive populations but also that people have multiple exposures over their lifetime.

I think it is another reason that 1 in 1,000 as a line seems too high, that because it can translate into as you add them up, if there are multiplicative risks, which we don't quite understand the biological effects of multiple exposures, but it may be more than additive, you could probably fairly quickly get up to something that is closer to 1 in 100 risk, which I think everyone would agree was unacceptable.

DR. SCHULTE: Other comments?

(No response.)

DR. SCHULTE: The area that Dr. Welch just brought up about multiple exposures is again that area that we talked about earlier. There is a growing literature coming out of the environmental field for the concept of cumulative risk assessment looking at the risks from a variety of sources and then

somehow trying to sum those.

It seems that science is moving ahead, albeit not rapidly, to a point where we have necessarily the tools to use adequately, but it might be the kind of scientific development and in the category of scientific developments that we want to consider. And maybe the guidance here is that a realistic appraisal of risks needs to include the universe or the environment that the worker is in, not just for a single exposure.

So any thoughts along those lines? Any concerns about an approach like that?

DR. WELCH: Laurie Welch again.

I mean, I always have concerns about models that are these mathematical models with risk assessment because, you know, the range of the variance around the estimate is very high, but, as the document goes forward and becomes part of some kind of public policy, usually the understanding that the -- it's just an estimate with a fairly

wide range kind of disappears.

So I would suggest approaching it in a more heuristic qualitative way to sort of, instead of saying, "Oh, well. If this person is exposed to styrene in the context of exposure to some other carcinogen, then you have to model it in," I think it would be more to understand that in the occupational environment, you can assume that there is going to be more than one exposure to a carcinogen in an industrial setting and use that as a guideline to use a lower or higher number, a lower risk, a higher number of zeros when you set a level.

DR. SCHULTE: Before we get to Bill, I just wanted to harken back to something, actually, Bill said earlier, Bill Kojola, that maybe a lower level of risk would be useful, such as 1 in 10,000.

Does anyone have any concerns if NIOSH started to develop RELs based on a level that would protect against a cancer risk of 1

in 10,000 or lower, about us doing that, the utility of that, implications of that?

(No response.)

DR. SCHULTE: Okay. I'm sorry. Bill? And then --

MR. KOJOLA: Yes. Actually, my comment kind of gets to that.

DR. SCHULTE: Okay.

MR. KOJOLA: I mean, I think there is utility in NIOSH using risk levels at something lower than 1 in 1,000, 1 in 10,000, 1 in 100,000, what have you, in that it establishes objectives for technology forcing control measures and risk management in the workplace that can have the effect of lowering worker exposures and lowering their risk.

And, you know, NIOSH is a public health agency. You were not charged with the responsibility of establishing legal limits that employers have to contend with. You, instead, have an opportunity here to push the envelope so that we begin to enhance the

protection of workers who are exposed to carcinogenic substances.

And to the extent that you do that by lowering risk levels, lowering risk targets in your REL, you will be advancing or at least have the opportunity to advance a higher level of protection for workers.

And when you do that, even if it is set apart from what OSHA is doing on the regulatory front, that is an important statement that workers and their unions and employers can use to say, "Well, we need to do something about this. We need to take steps in our workplace to lower exposures, to eliminate exposures. We need to use the best science that NIOSH has on our risk management techniques to do that in this workplace, irrespective of what may be happening on the regulatory front."

So I think this is one of the key values that that information will convey to those of us who are trying to grapple with

workers who are exposed to carcinogenic substances.

DR. SCHULTE: Thank you.

Up here?

MR. NAPIER: Dan Napier.

I guess, harkening back to some of the earlier points about the other discussions, my only concern is let's not get bogged down, but I thought I heard you say that you are referring to levels at different risks than 1 in 10,000 -- and that's part of your documentation. If it is, the discussion gets kind of moot as far as whether it is set at 1,000 for 1 item or 10,000 for another item. I just hate to see something saying, "Well, we are going to use this number, come heck or high water," and that's it.

I don't know that that truly provides a better level of protection. Sometimes we get to points where, no matter what I have, I can't detect it.

So you may publish a level that

says it has to be this but we can't get there anyway, we can't measure it in the field, we can't tell what it is. What have we done? We haven't served, we haven't truly served, the working people.

It is mythical. We have done something that doesn't serve the people, the person that is operating the equipment.

DR. SCHULTE: I think in a sense, those last two comments sort of show the poles of that discussion to some extent.

Over there?

MR. SCHWEITZER: John Schweitzer with ACMA.

Just a note. Your question was, does anybody object to an approach at 1 in 10,000? I would like just to -- pardon me I guess for the legal disclaimer. A lack of statement at this point doesn't imply an agreement with that, or disagreement. And wait for our written comments, please.

DR. SCHULTE: Yes. I appreciate

that. Thank you for that clarification.

DR. BURNS: I have a comment. Can you hear me?

DR. SCHULTE: Yes. Identify yourself, please.

DR. BURNS: My name is Dr. Kathleen Burns. I'm the Director of Sciencecorps in Lexington, Massachusetts. I have been working in risk assessment for about 30 years. I wrote a book on quantitative risk assessment in occupational and environmental health in 1985.

My comment is that to a great extent, we are not really talking about the benefits of taking a de minimis approach to the occupational risk, which might be in the 1 in a million or 1 in 10 million, as a target. And by recognizing that hazard, we satisfied many objectives of pushing towards greater safety, but also massively reducing the human harm, and also the attendant medical costs and other societal costs.

And I wonder if we can also include in how we think about the 1 in a million or 1 in 10 million the issue of substitution and also of medical monitoring.

If it is acceptable to impose a risk level that is 1,000 times greater than what we think of as acceptable for the general public, should there be a mandate at that point towards some kind of medical monitoring for workers and improved medical services programs associated with that in order to have an explicit recognition of the underlying costs that are being imposed by having people exposed to higher levels of a lot of these very well-established carcinogens?

DR. SCHULTE: Good. Thank you.

Yes?

DR. SIVIN: Darius Sivin, UAW.

We have some employers whose goal is mere compliance with the law and other employers who assert that they want to be world-class in occupational health.

We don't believe that you can be world-class if you merely comply with a law that allows 1 in 1,000-- or in some cases, under OSHA standards, more people than that-- to get fatal occupational cancers.

And it would certainly help us in pointing out to employers that you can't be world-class under those conditions if NIOSH had recommended exposure limits that represented considerably lower risks based on, as I stated before, in my opinion the available data for particular substances, rather, I think, than based on that there should be one single target, no matter what the data actually looked like.

DR. SCHULTE: Let me just read again from the OSH Act, section 20(a)(3), "NIOSH is mandated to describe the exposure levels that are safe for various periods of employment, including, but not limited to, exposure levels at which no employee will suffer impaired health or functional

capacities or diminished life expectancy as a result of his work experience."

So I think in that section, there is some appreciation that there could be some residual risk in a workplace setting. And I think that legislation is different than the environmental legislation. And, indeed, that is one of the differences we have had to deal with in occupational safety and health for many years.

And it may be that it is just the practicality of recommending a level that can't be measured, as this gentleman said, while it may have some technology forcing -- and I agree that we should be forcing the technology -- there has to be, it seems, or one might believe that there should be some sort of weighing of both the forcing nature of the recommendation as well as the practicality, or at least the likelihood that something can happen as a result of the classification and recommendation that will

better protect workers.

Does anyone have a thought about that?

DR. MELIUS: Jim Melius.

I would just like to go back to -- it's relevant to that point but also to something that Darius pointed out without getting into the next question as sort of what goes into extent -- to what extent is a given level feasible, but I think it is important to note that not only within a given industry are there large differences in how well people -- manufacturer, society, or employer -- decide to control exposures but between industries, there are significant differences.

And so in the regulatory arena, that tends to get lost for various reasons of legal interpretation, apparently, but in terms of what you are communicating, I think you need to keep that in mind. And so setting a risk level, taking into account feasibility, whatever goes on or whatever else you decide

to put in that risk level, that is sort of the lowest common denominator. What is the worst industry? What has the most difficulty meeting that situation or meeting that risk level is unfair and is not very helpful to all the other industries and workers, employees out there who -- where certainly feasibility may be at a much lower level of risk, and you should be driving them and encouraging people to do so, and not imply to them that they are doing too much. They don't really -- this is unnecessary.

DR. SCHULTE: I think it's appropriate that Dr. Melius opened it. And I think we were ready to transition anyway to that next question. We can continue talking about question 3, but we are now in question 4 in establishing NIOSH RELs. How should the phrase "to the extent feasible" be interpreted and applied?

Dr. Melius started that off. Any further comments on that?

Again, feasibility, large-scale feasibility, determinations have never been a critical part of NIOSH recommended exposure limits. We utilize the information that we have gained from health studies that would feed into setting the limit, but generally our assessment of feasibility has been a minimal one that identified if a facility could achieve it or come close to achieving it, that that would be sufficient. That is clearly not a full-scale appraisal of feasibility, nor does it address the comment that was just made that there is quite variable feasibility across industries.

Should we be thinking about the term "feasibility" more? Should we be doing more or is it really not a critical part of thinking of a health-based recommendation.

DR. LENTZ: Paul, this is T. J. Lentz with NIOSH.

I might also point out that we have made it a point in our criteria documents

and intelligence bulletins that NIOSH specifically not use the term "technical feasibility" because we recognize that OSHA has a very specific definition for "technical feasibility." And, in fact, we have actually used the term "technical achievability."

And, as Paul indicates, it is a much more generous term. And we have indicated that if it can be accomplished in as few as one facility, then that meets our definition of "technical achievability" in many cases. So I just wanted to point out that distinction.

DR. SCHULTE: Good clarification. Thank you.

Comments?

DR. WELCH: So I think NIOSH should keep up with that same approach of using what we might call a generous assessment of what is achievable. I think that the issue of whether the substance can be measured in the work environment at the level that you had set the REL is a more important issue than

whether it is possible to put in engineering controls that would hit that REL because it makes it difficult.

I am not saying you should always set one that is stuck with current technology, but obviously you have to think about it because as you want to give employers guidance how to reduce exposures to these hazards, the feasibility is part of that, you know, whether you think they can, examples, whatever it might be, but also being able to measure its importance.

And I hear from NIOSH that is something that is important to take into account. And you generally have.

DR. SCHULTE: Yes. Historically we valued, obviously, analytic feasibility, ability to measure it. You can't give guidance about triggering risk management activities if you don't have any faith, if you don't know anything about what the exposures are and you don't have any faith that you are

at or near some target level. So, indeed, analytic feasibility, I think, has to remain a paramount concern after looking at the health issues. So certainly we have focused on that.

In the back there?

MR. KOJOLA: Yes. I think that you just need to be careful about how you apply the term "feasible." And you don't want to create the impression or move in a direction of considering feasibility, in the ways that OSHA has to, when it establishes permissible exposure limits.

And I really like what NIOSH has done with regards to being mindful of the capabilities to analytically measure exposure. I think the most recent example of that is your draft document that has an REL for carbon nanotubes and carbon nanofibers. You pushed the envelope on the analytical piece because that is as much as you could take, but you also acknowledged that there was also potentially some significant risk that still

exists at that exposure level.

Well, here you have a situation I think where again this is acknowledging to the community here that maybe we ought to have some substantial work being done on pushing the analytical techniques in ways that can then cause NIOSH to reexamine its REL in lowering the risk levels that are attendant in that.

I think that is really important kind of work for NIOSH to do. It's an important kind of message for workers and employers in, sort of, that sphere.

DR. SCHULTE: Folks, I have a thought here that we will finish talking about this question. And we will get into the last question. I am thinking we could wrap this whole session up before lunch. We may go a little longer and then not come back in the afternoon.

But I am here. This is a public meeting. You are the public. We are here to

get your input. But if there is general agreement that we pretty well are exhausting the topics and everyone has had plenty of chance to speak, then we will still allow the people who wanted to make prepared statements do so. Does that seem like a reasonable way to proceed just to maybe wrap it up by 12:30 or so? I'm seeing heads nod, hands up.

So, okay. We will continue on talking here about the extent feasible. And then we could add in the other question, too, which gets into the whole question of the action level, its utility, and approaches to the action level.

So that area is open for discussion from anyone.

MR. ZUMWALDE: Can I? Let me add -- this is Ralph Zumwalde - as Paul had mentioned, analytical, what we call analytical feasibility, has always been important in terms of our RELs. And that has gone back, even into the '70s.

One of the things that happens, though, when we consider feasibility, especially analytical methods in this particular case, is that the REL that NIOSH may end up adopting or deriving may be set at some level that maybe it is not 1 in 1,000. Maybe it is a little bit higher risk. It is not a level that we probably would have proposed if we had an analytical method that could measure that particular agent in the workplace.

But what happens over time is that those RELs have stayed in place for a long period of time. And there is always this question about improvements in analytical methodology.

And so I guess from our standpoint, too, I guess there is the need for us to have at least some feedback in terms of if we take into account this issue of feasibility, whether it is analytical or engineering, what things should NIOSH have in

place in terms of looking at improvements, or doing improvements, in whatever needs to be done, whether it's analytical development or something that deals with controls. And how do we work that into a process in terms of where we're going back and considering revising that particular recommendation.

So I guess the point is that while that is important in terms of considering the issue of feasibility or achievability in developing an exposure limit, that particular limit may not be set at a level of risk that is health-protective.

And so how do we stay on top, or what needs to be done from NIOSH's perspective to make sure that, if that REL should be lower, what actions need to be done to improve the effort on achievability?

DR. SCHULTE: Up front here.

MR. NAPIER: Dan Napier again.

Well, following up on what Ralph was saying is that one of the things that can

be done is simply adding the caveat to use best available technology, and acknowledge those issues.

And, of course, the other thing I would ask is for NIOSH to give me a better method.

DR. SCHULTE: Other comments? In the back?

DR. MELIUS: Yes. Jim Melius from the Laborers again.

I think what would be important is that in your development of RELs or whatever it is, being as explicit as you can be about the basis for the different parts of the achievability, or feasibility determination that goes in.

In some cases, it may be based on analytic feasibility. In some cases, it may be you may want to take into account workplace achievability and so forth, even in cases where there may be a better analytical method. But I think it is important that you provide

as much information as you can, which I think you traditionally have done.

Though I am not always sure you -- I think you tend to focus on a number and communicate around that number, rather than, you know, giving a broader picture of what is achievable analytically, say, whatever.

But I think if you are going to have a process where you might update or things change over time, then having that as explicitly communicated is important because the analytical approaches change over time. What is feasible now, or may not be feasible now, becomes feasible.

There are also I think practical issues that come up in play in terms of what type of workplace you are trying to look at, and what is reasonable to expect from an employer. There may be some very sensitive methods that just aren't practical to put in place in the workplace.

The other thing, there may be

things like asbestos, where it ought to be that it's banned. It should be banned. So maybe you find information, another substance that would fit that categorization also and where, really, I don't know if you need to talk, then, about analytical feasibility. That shouldn't take place.

I think your overall REL needs to, you know, just take into account a number of factors but do it as explicitly as possible so it is communicated to people working in the field, as well as people exposed, and they understand what the basis of that is for. I think that also communicates better to OSHA and other regulatory agencies about why you selected that number.

MR. KOJOLA: Yes. This is Bill Kojola again.

Just one quick comment. Yes, I would agree with what Jim just said, that it is important for you to outline, you know, the underlying rationale for how you establish

your REL.

But one of the great values of NIOSH is, not only your expertise in your role in developing this policy and establishing recommended exposure levels, is: you are a research agency.

And when some of these research issues are clearly identified in the document that you used to establish an REL, you know, that helps to set, or should help to set, your research agenda. So that, for example, issues about analytical techniques being insufficient, that would help derive and drive your research agenda as well, not only for the agency, but for other researchers who are active in occupational safety and health.

DR. SCHULTE: Thank you. Any comments on the action level? Anyone have concerns about abandoning the action level approach or modifying it? Right now, as I said, it is generally formulaic, half the REL. But it may be that there are other ways to do

it, a tenth of a REL, or something that is based on the variability of the data in any -- the measurement data in any particular plant. So if you have any comments on that, we would love to hear them.

DR. SIVIN: Darius Sivin, UAW.

We find that except for our largest employers, who directly employ a lot of occupational health resources, many of our other employers simply don't understand the action level. That is to say, if they take a measurement and it is below what is legally required, they think they are done.

I would rather, I would much rather, see an approach where NIOSH would identify a level that is associated with whatever target risk we are talking about, and then choose a REL that would guarantee that, let's say, 95 percent of the time a measurement below that REL would guarantee that the average exposure was below the number that was associated with the target risk

because then you could approach that employer, which, let's say, they are very good business people but they have never had a stats class, they don't really understand variability and probability, and you just approach them and you say: here is the target level, and if you measure below this target level, you will know that most of the time, folks will be okay.

That would be a much more practical approach that we could actually use the numbers much more practically in dealing with your typical medium-sized employer.

DR. SCHULTE: Thank you.

Go ahead.

MR. ZUMWALDE: The action level concept historically has been important both for workers and employers to have the ability in their workplace, with minimum resources, to be able to make some kind of an identification as to whether or not -- I'll use the word "compliance," whether or not they're below the occupational exposure limit for a particular

substance.

The concern that NIOSH has, and as Paul explained, is that the whole concept of setting this action level at one-half the OEL goes back to the '70s, where the data sets that were used to develop the action level were based on a very limited exposure data set from a very small industry group.

And that particular data set indicated that the variability in exposure had a GSD that was somewhere between one and two. And so it allowed efforts to develop criteria for setting an action level at 50 percent that would give you 95 percent confidence in that only 5 percent of the samples would exceed the action level.

But since the '70s, there has been a lot more data that has been gathered from a lot of different occupational groups, industry sectors. And I think it is pretty clear that the exposures within any sector are highly variable, and that having an action level that

is set at 50 percent would really underestimate exposures. And that given this high exposure variability, that if you wanted to use that concept of an action level, with 95 percent confidence, you may be talking about having an action level that would be one-tenth of the occupational exposure limit.

So, what NIOSH is interested in is whether or not the concept of an action level, using the same kinds of criteria that were developed for setting an action level at 50 percent, is still reasonable; and that NIOSH should use that same approach in looking at exposure data sets and making an appropriate recommendation. Or, are there other risk management approaches that may accomplish the same thing, that would provide the worker and the employer with a way of looking at their particular workplace, given some limited amount of resources, and be able to make some kind of interpretation as to whether or not action needs to be taken?

DR. SIVIN: Darius Sivin, UAW again.

In terms of actually dealing with most employers, if OSHA sets an action level and a standard, that action level is enforceable. And so I can say, "You have measured above such and such. Therefore, here is the standard that requires you to do something."

I don't see a NIOSH action level per se as useful because the employer is not required to do anything. And the employer will just look at me and say, "Well, if there is a risk to their employers, why didn't NIOSH set the exposure limit lower?"

So I am thinking that you set your REL at ten percent of your target exposure if that is what your database actually supports in terms of the variability of the exposure. Because employers will understand that.

MR. ZUMWALDE: I agree. There is this misconception in terms of what the

purpose of an action level is. It is not a health-based number. It is a statistically derived number to give you some understanding and perspective of what your exposures are with respect to the OEL.

So I know there is that kind of confusion. And maybe that comes into play in terms of what NIOSH is looking for in terms of comments. So maybe there are other risk management approaches that may be a little clearer to implement. And it may be of more value than using an action level concept.

DR. SIVIN: Yes. Just once you use the term "statistically derived" or "GSD," the employer's eyes are glazed over in many cases. And you are lost.

DR. SCHULTE: But clearly we have to de- glaze any communications that we -

MR. NAPIER: Dan Napier again.

We are getting into the realm of-- one of the other things is a sampling criteria. And also what I would say is: why

don't we use or more clearly accentuate the 95 percent confidence interval and use that as a better method? Because as an industrial hygienist, I have been in my practice for 35 years, I have generated an awful lot of left-censored data. For people in the room who don't know what that is, that is non-detect data.

And so generally I find either non-detect data or identify a problem. But very seldom am I in a situation where somebody is just a little bit below the PEL and we don't do anything about it.

DR. SCHULTE: Thank you.

So we welcome further comments on this, and other questions to the docket. I will take a couple of more oral questions. Then we will go to the statements, the people who have registered to give statements. So Dr. Melius?

DR. MELIUS: In following up on your de- glazing approach here, could you just

clarify two of your questions? One is in question 5, you have, "In the absence of data, what uncertainties or assumptions are appropriate for use in the development of RELs?" I wasn't sure what you were trying to get at there.

And then you also have a complex mixture question at the end. I'm just not-- sort of searching for what you are searching for here. We sort of jump to action level and --

DR. SCHULTE: Right. I think that was a collection question for all the other things that we hadn't addressed. Certainly how we include, in our classification and REL development, how we include uncertainty in the evidence base, how we weigh that. For example, sometimes in risk assessments we will use uncertainty factors to address that.

So are there any particular thoughts that people have about including uncertain information in the classification or

REL development, was essentially the main driver?

And then on the risk, the issue of mixtures, I think we have talked about that a number of times.

DR. MELIUS: I didn't have any comments. I just wanted to try and understand what you were --

DR. SCHULTE: Right. Right. Yes. That was a little bit confusing. Thank you.

Okay, we have a number of people who have identified that they wanted to make statements. Now, they may have said most of that, and they are welcome to say that. And they can use the podium for this purpose. So I will just go down the list. Essentially we will talk about five minutes per person if you still want to speak.

The first one was Bill Kojola from AF of L.

OPEN PUBLIC COMMENT PERIOD

MR. KOJOLA: I don't have anything

more to add than I have already had the opportunity to do so.

DR. SCHULTE: Okay. Thank you.

And, again, you all have opportunities to further extend your remarks or add new remarks to the docket.

DR. LENTZ: Paul, before we go to those comments, too, do you want to see if anyone on the line wants to pose any other questions to us here?

DR. SCHULTE: Okay. Right. We have been open to anyone on the line, but is there anyone on the line who has further questions or comments?

Hearing none, we'll proceed. The next presenter who registered was Anna Fendley. You are welcome to use the podium or sit there, whatever you --

MS. FENDLEY: Anna Fendley with the Steelworkers.

I don't really have much else to add. My colleagues have said a lot of useful

things. Just we think that NIOSH has a real opportunity here to advance protections for workers. And we hope that they take it. And we look forward to a draft in the spring that outlines a very transparent process.

DR. SCHULTE: Thank you.

Next is Darius Sivin.

DR. SIVIN: I would just like to add two brief comments to what I have said before. One is that the National Research Council Science and Decisions: Advancing Risk Assessment, otherwise known as the Silver Book, has extensive discussions on dealing with uncertainty. And I think it would be good to consult those in developing NIOSH's carcinogen policy.

Also, on complex mixtures, which was asked about but we didn't have too much discussion today, some of the existing means of dealing with complex mixtures that I think NIOSH should consult, include the TLV mixture formula, the ACGIH reciprocal calculation

method for refined hydrocarbon solvent vapors. EPA's relative potency factor and toxic equivalency factors approaches are a couple of others.

Also, most of those methods have specific assumptions, which should be made clear if NIOSH applies them, such as toxicologic independence or toxicologic similarity. And so if you do analyses of complex mixtures, make those assumptions explicit.

Also, there are some heterogeneous mixtures, for which maybe none of those methods would be appropriate because the assumptions underlying the methods are not met. And I think NIOSH might be able to do some research in identifying some of the more common mixtures actually found in the workplace, and proposing methods to deal with those.

DR. SCHULTE: Thank you.

Next we have Kathleen Burns by

teleconference.

DR. BURNS: Yes. Amanda Hawes was going to be speaking on behalf of Worksafe and Sciencecorps. And I just notified her when you initially announced that you might accelerate the schedule to call in. She is calling in from California. So what I would request is that you allow us to speak last. And hopefully she will be on the line by then.

But if not, I can say something or if Ms. Dorothy Wigmore is on the line, she may want to speak. She is at Worksafe.

DR. SCHULTE: Okay. Hearing no one speak, we will put you last and hope Ms. Hawes calls in. And if she doesn't, she can certainly put her remarks in the docket. And you can speak in a wrap-up position and anyone else who represents that group.

Moving on, then, to John Schweitzer.

MR. SCHWEITZER: I'm going to come up to the podium.

DR. SCHULTE: Right. All right.

MR. SCHWEITZER: I am John Schweitzer with the American Composite Manufacturers Association. And we do really appreciate the opportunity NIOSH has provided to have input on this very important project. And we will be submitting some extensive written comments, but I wanted to use the opportunity today to take a step back and make perhaps some more philosophical observations and suggestions about NIOSH and its role in occupational safety and health.

Let me start off by saying that I represent an industry of about 3,000 predominantly small companies that use chemicals to make products. And there are some things that characterize small chemical processors, one of which is that they are relatively risk-averse. By that I mean that it is not uncommon to find that the owner, her family members, and her neighbors work in the plant. And the idea that we could somehow

trade off injury and illnesses to make money is anathema to these people. They would rather shut up-- shut the business and become real estate agents than hurt anyone. And so they are very serious as a group about safe and healthy workplaces.

Another thing that distinguishes this group is that guidelines, particularly those that are precautionary or progressive or technology-forcing in nature without consideration, without specific consideration, of practicality and affordability of control, are of no benefit. What does the small business owner do with this idea that, well, here is a target? And maybe someday somebody will invent a device that you can afford to put in your plant that would control to this level.

Well, this is like, well, yeah. I could put my plant on the moon, too, but of what use is that to me? In fact, it is worse than of no value because those sorts of

pronouncements by the government drive costs for liability insurance. They drive costs for worker's comp insurance. They drive these small business owners into court to deal with tort suits. All of that cost and burden without any real risk assessment.

And that's for small businesses and can be an enormous strain on their viability and can be an enormous impediment to employing people in this country.

The final point to make in terms of context setting, is that we don't, as an industry, have the resources to fight a battle on, or to work with -- let me not set that in a military metaphor-- but to work with multiple regulators on the same issue.

It is conceivable over the next few years that NIOSH, OSHA, and Cal-DOSH are all going to be doing rule-making activities on the same topic. That is insane. I told my board of directors that we were going to participate in a NIOSH activity on cancer. And

they said, "Aren't we in the middle of that with OSHA on GHS? Why are we doing that again?" I had a hard time explaining to them why a second occupational cancer activity is necessary.

And it is not just the regulatory agencies. We have some issues with combustible dust. And it is not enough for me to participate in OSHA's combustible dust activity. I also have to go to NFPA [National Fire Protection Association] and worry about that as well.

And so this is not efficient. And it strains our ability to bring our resources and our information to bear when there are multiple regulatory or regulatory-type agencies working the same issue.

So, having set the context for my perspective about this, let me get to my points here. So we thought about how NIOSH can profitably contribute to worker protection. And there are two things we came up with. One

is that we can reduce, that NIOSH could serve to reduce rule-making burdens based by OSHA.

My companies really need OSHA standards that are protective and reasonably affordable and achievable. That is what they depend on. And that is their best source of information for protecting their employees. And everything else that is out there becomes noise and is very hard for them to make good use of it.

So we need good and effective OSHA standards. And anything that NIOSH can do to help OSHA do more-- more productively and efficiently do rule-making-- we would be in favor of.

And the second idea that we came up with was that NIOSH may be able to do and conduct and manage productive programs that, while they are productive and helpful, may not fit in OSHA's traditional rule-making process. I have got some examples of both of those things.

In terms of reducing rule-making burdens faced by OSHA, undoubtedly, one of the most difficult things that OSHA has to consider are matters of practicality and affordability, particularly for small businesses.

I mentioned combustible dust. We have been helping our industry with combustible dust for a long time. And when OSHA introduced their national emphasis program on combustible dust and instituted a rule-making, I thought, well, this is going to run aground when they come to small businesses. And I understand, in fact, at this point the OSHA combustible dust process has come to a stop because OSHA has discovered things to do about combustible dust that fit in large companies, but for small companies are just wildly unaffordable or impractical. And what do we do about that?

So I think that if NIOSH could devote some of its considerable resources to

looking at affordability and practicality up front when we come to a hazard and do a lot of that work, collect information, do analysis, decide where the cost-benefit returns are for different industry segments. I think that could really give OSHA a head start in getting a rule- making out the door.

And I think more on that point is that -- and I alluded to this earlier -- for small businesses, any sort of guidance that's free of a meaningful consideration of affordability and practicality is very much a two-edged sword.

Yes, it can be a helpful target. But without knowing how to get there, and whether or not the cost is proportional to the actual risk reduction, makes that product of very limited usefulness to smaller companies.

Now, on the other idea about programs and activities that we think could be helpful and productive that may not fit into OSHA's rule- making process, our idea is that

NIOSH could facilitate and manage the operation of stakeholder groups working to prepare what I am un-artfully calling here a pre-rule-making document.

And I just have a couple of minutes here or less. And, really quickly, Cal-DOSH has a process for their PEL updates, where there is an expert panel that meets in public. So stakeholders can come and participate in those meetings. So it is extremely transparent.

And that process then produces a document that goes to the staff. And that is the beginning of the formal rule-making process.

So all of the stakeholder issues are on the table up front: matters of agreement and disagreement, data gaps that the agency is going to have to fill in are identified, et cetera, et cetera. So we think that is a process that gives the agency a head start.

And, actually, even though there is a commitment up front of perhaps a year to run the stakeholder group on a particular topic, we think it dramatically lessens the chance that stakeholder groups are busy trying to derail the thing at the end because they are unhappy with it, which ties things up and often results in things having to be done over again, which is highly inefficient.

So those are our two basic suggestions about how NIOSH might function to help OSHA get rules out the door quickly.

Thank you.

DR. SCHULTE: Thank you, Mr. Schweitzer.

Let me just note, too, that NIOSH is a research and guidance agency. We are not a regulatory agency, but I appreciate the comments. And we will take them to heart.

Next is Joel Tickner on teleconference. Joel Tickner? All right. We'll move on to Charlotte Brody on teleconference.

DR. SCHULTE: Okay. Moving on to Dana Casciotti on --

MS. CASCIOTTI: I don't have anything to add.

DR. SCHULTE: Okay. Thank you.

And Aaron Trippler? Aaron? I heard your name before. Aaron Trippler?

DR. SCHULTE: Okay. We're back to Dr. Burns.

DR. BURNS: I think the difficulty is that very few people can -- you know, I really respect the people who are here and are spending the day, but very few of us in the field can take an entire day to participate. So these other people, I know, did really want to be able to speak directly to those of you at the meeting. And I haven't heard anything from Mandy yet.

So, Mandy, are you on the line? I guess not.

I am just going to say a couple of really brief things. And I appreciated the

insight of Mr. Schweitzer as a small business representative there, because obviously we need to understand their thinking.

My only point that I want to just mention that I don't think was discussed in any detail is the issue of goals versus what you might consider regulations, or requirements or standards, in both the environmental realm in the U.S. and in other countries in both occupational and environmental health.

We see the establishment of goals. And, for example, the drinking water standards across the United States have goals that are zero for carcinogens. And, of course, that's I guess you might say a combination of a political, medical, and scientific statement that what we would like to have is no exposure to these, but in recognition of the reality, usability, practicality, affordability, and so on, there are standards that are set.

But what the goals do -- and right

now the chemicals for which the goals differ from the standards in that context aren't primarily the carcinogens -- is that they put people on notice: water purveyors, companies, the general public. And they give an alert, a head's up, that says, you know, here is where we should be, where we would like to be. We can't be there right now in every case, but this is our objective, this is our target. And I think it is a tremendous advantage to NIOSH doing something along those lines, which is, of course, what they have prior to the change in the way carcinogens were handled during the 1980s.

You know, there are implicit risks and costs associated with having exposure to carcinogens, you know whether we believe in the risk assessment calculations, which I think have a great deal of uncertainty, or we don't, there are clearly problems associated that can be enumerated, even if they are over a wide range.

In addition, most carcinogens to date are genotoxic. And genotoxic carcinogens impose birth defects that are heritable risks that are passed from generation to generation in many cases as well as cancer risks.

So there are a lot of co-benefits to controlling these, a lot of down sides to not controlling these. And having this information explicitly communicated by setting a goal that may be much lower than what you set as an REL has an advantage.

And I would argue that this might have more of an advantage for small businesses, where they need that up-front information, so that they have an opportunity to perhaps change the processes, change the chemicals that are used, change the personal protective gear, and so on. And they may deserve some special attention as far as being identified as reasonable locations for pilot projects to control some of these chemicals to get closer to that goal so that they can, in

effect, be setting the gold standards for other companies that may have more resources.

So my only comment is just that if NIOSH is able to look at living in the context of the 1 in 1,000 or feasibility or these other contexts that are covered in the Federal Register as an issue of goal versus regulation and, perhaps, putting out information on both of those, that it would be quite a service to the general public, and I believe also to the companies that are trying to do their best on these issues.

DR. SCHULTE: Well, thank you very much.

Is there anyone else, then, who wants to speak? Anyone on the phone in the teleconference? Dr. Melius back there?

DR. MELIUS: This is Jim Melius from the Laborers.

Just briefly two things. First of all, I would encourage you in your thinking of going forward in terms of process that when

you come up with your draft policy, that you also lay out, sort of, what your follow-up plans are for implementing that policy.

I am not sure how explicit that policy will be in terms of, for example, guidelines for classification, but I think that there are many from throughout the scientific occupational health community who I think would benefit. And you would benefit from input on that part of the process.

I think it also helps to educate the wider community on what your classification is, and what it is based on. But it is a little hard for us to comment on criteria without having more of a context for it and understanding better what your classifications would be and so forth.

DR. SCHULTE: Right. And we intend to do that. This meeting was to gather opinion and to build that. And we wanted to make sure we had at the front end the opinion of stakeholders.

But, then, I appreciate what you are saying, that we need to describe how it will be implemented, and that approach as well.

DR. MELIUS: And the second recommendation I would have is that you give serious consideration to developing as part of your policy-- when one goes to a multiple-level classification system, I think it also allows you to communicate to some extent about risk management.

It may not convey totally risk, but it conveys something about the hazard. And it ought to alert people as to what steps they should be taking in the workplace to address the potential, possible, or known risks from that particular substance or exposure. And I think having that explicitly at least outlined in your policy would be helpful to the wider community.

It is going to vary by substance to substance as you go into more detail. But

certainly when something goes from a suspect to a probable or a known carcinogen, I mean, that certainly ought to convey to the community something about how the exposures to that substance should be managed in the workplace.

And I think that, given how long it takes for rule-making, given how long it takes for developing RELs and so forth, that having some sort of a communication that is part of the overall policy in that area would help.

I believe that is feasible. I think that can be done fairly. There may be some exceptions to it, but I think it really would be an important part of what you do in this revised policy.

DR. SCHULTE: Thank you.

Comments?

DR. MacMAHON: This is Kathleen MacMahon with NIOSH.

I just wanted to mention that

NIOSH has assembled all of the background documents and policy statements that are related to this effort on one web page, on the NIOSH website.

If you go to the NIOSH home page, which is www.cdc.gov/niosh, it is a spotlight on the home page. And you will find there a compilation of many of the historical documents that Dr. Schulte mentioned this morning.

And as this work continues, that is where we will put draft documents and other resources related to this effort for those who are interested in keeping up with the topic.

CLOSING COMMENTS AND NEXT STEPS

DR. SCHULTE: And when we actually have the draft policy, we will put out a Federal Register notice announcing that and put it on the web for public comment, most likely followed by a public meeting to have people amplify their comments. After that, we will then reflect on all of those comments and

issue the final document.

So last call, then, for any comments?

We appreciate the time that people have spent coming here, the thoughtful comments that people have given. And we certainly look forward to any written comments that you want to submit to the docket, and then ultimately to your comments on the draft document.

So thank you once again for being here. And at this time, we will adjourn the meeting.

(Whereupon, the foregoing matter was concluded at 12:16 p.m.)