

**Docket H054A**  
**Ex. 45-1**

UNITED STATES DEPARTMENT OF LABOR  
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION  
WASHINGTON, DC

INFORMAL PUBLIC HEARING FOR THE  
PROPOSED RULE ON HEXAVALENT CHROMIUM

VOLUME 1 OF 2

Auditorium  
DOL Building  
200 Constitution Avenue  
Washington, D.C.

Tuesday,  
February 1, 2005

The hearing was convened, pursuant to  
notice, at 9:30 a.m., JOHN M. VITTONI, Administrative  
Law Judge, presiding.

APPEARANCES:

OFFICE OF THE SOLICITOR

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CLAUDIA THURBER, Esquire

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MAUREEN RUSKIN, Industrial Engineer, Office  
of Chemical Hazards - Metals

VAL SCHAEFFER, Ph.D., Toxicologist, Office of  
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OSHA EXPERT WITNESSES

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P R O C E E D I N G S

ADMINISTRATIVE LAW JUDGE VITTONI: The hearing will come to order. This is a public hearing on the Occupational Safety and Health Administration's proposed standard on the occupational exposure to hexavalent chromium.

The proposed rule for this proceeding was published in the Federal Register at Volume 69, page 59,306. I'm John Vittoni, the Chief Administrative Law Judge for the U.S. Department of Labor, and I will be presiding at these hearings today, and for the remainder of this session.

The purpose of these hearings is to receive the oral and written testimony of interested parties, as well as other information pertinent to the promulgation of the proposed rule. At the conclusion of these hearings, the record of the proceedings will be reviewed by the Department in determining what the content of the rules should be.

My participation as presiding judge will be limited to conducting these hearings to assure that a complete record is made, and that all concerned and interested parties receive a fair hearing and have an opportunity to submit their information.

The rules governing this hearing, as well as

1 the prehearing guidelines, are available in the  
2 auditorium, just outside the auditorium in the back on  
3 the table. There is also a list of witnesses  
4 available, designating their proposed order of  
5 appearance, and the time at which they may be  
6 appearing.

7 A few words here about the nature of these  
8 hearings. Despite the informal nature of these  
9 hearings, it is governed by some basic guidelines to  
10 assure that everyone has a fair opportunity to speak  
11 and to express their point of view. However, unduly  
12 repetitious testimony will not be allowed, and the  
13 presentation of witnesses will generally be limited in  
14 time and scope.

15 The written submissions will be a matter of  
16 record, and participants in these proceedings should in  
17 their testimony concentrate on presenting the  
18 highlights of their testimony, or clarifying their  
19 written submissions. Witnesses may, if they wish,  
20 identify and sponsor their written submissions and make  
21 themselves available for questioning by the other  
22 participants.

23 After a witness has completed his testimony,  
24 parties who have filed Notices of Intention to Appear  
25 may question the witness. Each participant is expected

1 to limit his questions to a period of about 15 minutes.  
2 When a witness' testimony is completed, I will ask for  
3 the identity of those individuals in the audience who  
4 wish to question the witness. I will then determine  
5 the order in which the participants in this proceeding  
6 will question the particular witness. That is purely  
7 arbitrary on my part how I do that.

8 Now, the guidelines for these hearings were  
9 set out in detail in the notice, in the Federal  
10 Register, and also in my order of January 10, 2005,  
11 setting forth the prehearing guidelines. Before I turn  
12 this over to Ms. Sherman, I would like to make one  
13 point.

14 If you have cell phones, don't use them in  
15 this room. If you need to use them, please step out in  
16 the hall. Please turn them off. I have turned mine  
17 off, and I promise not to use it here, either.

18 The proceedings are going to begin now. I'd  
19 like to call on Ms. Susan Sherman with the Office of  
20 the Solicitor, Department of Labor.

21 Ms. Sherman?

22 MS. SHERMAN: Hello. My name is Susan  
23 Sherman, and I'd like to welcome you on behalf of the  
24 Solicitor's Office. I'd like to briefly explain the  
25 role of our office in these hearings.

1                   It is basically to facilitate the development  
2 of a complete, accurate, and clear record, upon which  
3 the final rule will be based. We'll do that by asking  
4 questions and otherwise eliciting information on the  
5 various issues. I'll also try to help resolve any  
6 procedural issues that may arise.

7                   Now I'd like to introduce Dorothy Dougherty,  
8 the Acting Director of the Directorate of Standards and  
9 Guidance, who will present a welcoming statement and  
10 introduce the rest of the panel.

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1 be a very important step in its efforts to develop a  
2 scientifically sound, feasible, and health-protective  
3 final rule addressing exposure to chrome (VI). The  
4 development of a clear, accurate, and complete public  
5 record is a critical part of the rulemaking process.

6 Your participation and your contributions to  
7 the public record are greatly appreciated. Let me  
8 assure you that OSHA will fully consider your comments,  
9 testimony, and recommendations as the final standard is  
10 developed. We all share the same goal of protecting  
11 workers.

12 OSHA's present standards for workplace  
13 exposure to chrome (VI) were adopted in 1971, and were  
14 based on a 1943 American National Standards Institute,  
15 ANSI, recommendation originally established to control  
16 irritation and damage to nasal tissues. In July, 1993,  
17 OSHA was petitioned for an emergency temporary standard  
18 to reduce occupational exposures to chrome (VI)  
19 compounds.

20 The Oil, Chemical, and Atomic Workers  
21 International Union and Public Citizen's Health  
22 Research Group, citing evidence that occupational  
23 exposure to chrome (VI) increases workers' risk of lung  
24 cancer, petitioned OSHA to promulgate an emergency  
25 temporary standard to lower the permissible exposure

1 limit, PEL, for chrome (VI) compounds to 0.5 micrograms  
2 per meter cubed as an 8-hour time weighted average.

3           Upon review of the petition, OSHA agreed that  
4 there was evidence of increased cancer risk from  
5 exposure to chrome (VI) at the existing PEL, but found  
6 that the available data did not show the "grave danger"  
7 required to support an emergency temporary standard.  
8 The Agency denied the request for an emergency  
9 temporary standard, but initiated rulemaking pursuant  
10 to section 6(b)(5) of the OSH Act, and began performing  
11 preliminary analysis relevant to the rule.

12           In 1997, OSHA was sued by Public Citizen for  
13 unreasonable delay in issuing a chrome (VI) standard.  
14 The U.S. Court of Appeals for the Third Circuit ruled  
15 in OSHA's favor and the Agency continued its data  
16 collection and analytic efforts. OSHA was sued again  
17 in 2002 by Public Citizen for unreasonable delay in  
18 issuing a chrome (VI) standard.

19           On December 24, 2002, the Court ruled in favor  
20 of Public Citizen, ordering OSHA to proceed  
21 expeditiously with the development of a chrome (VI)  
22 standard. On April 2, 2003, the Court set a deadline  
23 of October 4, 2004 for publication of a proposed  
24 standard and January 18, 2006 for publication of a  
25 final standard.

1 OSHA published the proposal on October 4,  
2 2004, and it is that proposal which is the subject of  
3 this informal public hearing. Based on an analysis of  
4 the information available in the rulemaking record,  
5 OSHA has made a preliminary determination that  
6 employees exposed to chrome (VI) face a significant  
7 risk from lung cancer at the current PEL.

8 Occupational exposures to chrome (VI) may also  
9 result in asthma and damage to the nasal epithelia and  
10 skin. OSHA is therefore proposing to lower the PEL for  
11 all chrome (VI) compounds from 52 micrograms to one  
12 microgram of chrome (VI) per cubic meter of air, 1  
13 microgram per meter cubed, as an 8-hour time-weighted  
14 average.

15 Although significant risk is expected to  
16 remain, OSHA's preliminary analysis indicates that the  
17 proposed PEL is the lowest level that is both  
18 economically and technologically feasible. The Agency  
19 estimates that the lower PEL will result in between 44  
20 and 167 avoided cases of lung cancer annually.

21 OSHA is also proposing ancillary provisions  
22 for employee protection such as preferred methods for  
23 controlling exposure, respiratory protection,  
24 protective work clothing and equipment, hygiene areas  
25 and practices, medical surveillance, hazard

1 communication, and record keeping. Separate regulatory  
2 texts are proposed for general industry, construction,  
3 and shipyards in order to tailor requirements to the  
4 circumstances found in each of these sectors.

5           Since the beginning of its chrome (IV)  
6 rulemaking efforts, OSHA has made every effort possible  
7 to collect the best available data to support the  
8 proposed standard. These efforts included 39 site  
9 visits, numerous contacts with industry and health  
10 experts, solicitation of comments and data from  
11 affected and interested parties through a Request for  
12 Information published in the August 22, 2002 Federal  
13 Register, and conducting a Small Business Advocacy  
14 Panel under the requirements of the Small Business  
15 Regulatory Enforcement Fairness Act, SBREFA, that met  
16 with small business representatives and provided OSHA  
17 with recommendations on how to minimize the small  
18 business impacts of the rule.

19           OSHA continues to seek data and comment and  
20 strongly encourages those parties who believe that the  
21 Agency's findings do not reflect the best available  
22 information to submit data that they feel are more  
23 reflective of current industry conditions and the  
24 current state of scientific knowledge concerning chrome  
25 (VI) and its compounds.

1           In order to enhance the development of a more  
2 complete record, OSHA has asked experts in relevant  
3 areas to express their respective views in the areas of  
4 their expertise. The views they will be expressing  
5 will be their own and not necessarily those of OSHA.  
6 In addition, we are pleased to have a panel of experts  
7 from the National Institute for Occupational Safety and  
8 Health, NIOSH, presenting testimony.

9           The importance of the public participation  
10 phase of this rulemaking cannot be over-emphasized.  
11 The rule which we will be discussing over the coming  
12 days is still in the proposal stage. It should not be  
13 considered OSHA's "final" determination or position on  
14 the issues involved.

15           The proposal serves only to initiate the  
16 public rulemaking process by presenting OSHA's  
17 preliminary assessment of the content of an appropriate  
18 rule based on the information available to the Agency  
19 at the time the document was developed. OSHA is  
20 seeking to improve the rule. The purpose of this  
21 informal public hearing is to provide a forum for a  
22 thorough discussion of the proposed standard and to  
23 receive testimony and additional evidence to assist  
24 OSHA in developing a final standard that reflects the  
25 best available and most current information. Further

1 opportunities for hearing participants to introduce  
2 evidence will be provided during the post-hearing  
3 comment period.

4 Thank you for your attention. At this time,  
5 we will answer any questions you may have about the  
6 proposal.

7 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you.  
8 May I have a showing of hands, please? All right.  
9 We'll start with Mr. Kojola.

10 MR. KOJOLA: Thank you, Judge Vittone. My  
11 name is Bill Kojola, I'm with the Safety and Health  
12 Department of the AFL-CIO.

13 It is a pleasure to be here this morning. We  
14 are pleased that however OSHA got here, that it is  
15 regulating what we consider to be a serious health  
16 hazard for workers in this country. We are pleased  
17 that OSHA is moving forward expeditiously with that  
18 process.

19 Typically in OSHA's comprehensive health  
20 standards, there is a requirement for exposure  
21 assessment or exposure monitoring. Isn't that correct?  
22 I'll address this to whomever on the OSHA panel.

23 MS. EDENS: That's correct.

24 MR. KOJOLA: Okay. And there are many  
25 reasons for requiring exposure monitoring in OSHA's

1 comprehensive health standards. Those reasons include  
2 a variety of important considerations, such as  
3 compliance with the PELs, the employer complying with  
4 the 8-hour TWA or action level, or ceiling.

5 Some assessment of the efficacy of engineering  
6 controls, it is important to assess exposures and see  
7 whether engineering controls are working properly. It  
8 is also important to assess exposure when an employer  
9 is selecting the appropriate respiratory protection.

10 ADMINISTRATIVE LAW JUDGE VITTONI: Mr.  
11 Kojola?

12 MR. KOJOLA: Yes?

13 ADMINISTRATIVE LAW JUDGE VITTONI: Is there a  
14 question there?

15 MR. KOJOLA: Yes, there is. I'm getting to  
16 the question. Isn't that correct? These are all  
17 important parts of why OSHA requires exposure  
18 assessment in their standards, is that correct?

19 MS. EDENS: I think we've laid out some of  
20 those same principles in our preamble.

21 MR. KOJOLA: And those are all important for  
22 protecting workers, isn't that correct? All of those  
23 elements are important.

24 MS. EDENS: When it's feasible to do so, yes.

25 MR. KOJOLA: Okay. In fact, you really can't

1 determine the efficacy of engineering controls without  
2 performing some exposure monitoring, can you?

3 MS. EDENS: I think that would play a part of  
4 that determination, yes.

5 MR. KOJOLA: And you can't properly select  
6 appropriate respiratory protection without knowing the  
7 exposure levels that workers are exposed to, isn't that  
8 correct?

9 MS. EDENS: Knowing their exposure levels  
10 would aid in selecting the proper PPE, yes.

11 MR. KOJOLA: And in the absence of knowing  
12 what the exposure level is, an employer could select an  
13 inappropriate respirator that would potentially expose  
14 a worker to some adverse health consequences, isn't  
15 that right?

16 MS. EDENS: Yes.

17 MR. KOJOLA: So your proposed hex chrome  
18 standard includes requirements for exposure assessment  
19 for general industry, correct?

20 MS. EDENS: Yes.

21 MR. KOJOLA: And it is important to require  
22 exposure assessment for some of the reasons we just  
23 discussed, isn't it?

24 MS. EDENS: Yes.

25 MR. KOJOLA: But in shipyards and

1 construction, the Agency is proposing no requirement  
2 for exposure or assessment, isn't that correct?

3 MS. EDENS: That's partially correct, we have  
4 not proposed a specific scheme that exposure monitoring  
5 would be conducted in construction and shipyards. What  
6 we are leaving is a more performance-oriented type of,  
7 as we explained in the preamble, a performance-oriented  
8 approach to exposure monitoring.

9 The obligation is still on the employer to  
10 determine that he is in compliance with the permissible  
11 exposure limit. We have taken costs for exposure  
12 monitoring in those situations, because we know that  
13 they are going to have to do some exposure monitoring  
14 to assure themselves that they are below the PEL and  
15 are in fact following the Respiratory Protection  
16 Standard and picking respirators correctly.

17 So while there is not a specific scheme about  
18 triggering it by an action level every three months and  
19 every six months for periodic monitoring, there still  
20 will be monitoring the employer will have to conduct,  
21 and OSHA has taken costs for that, because they will  
22 have to be, just like for the air contaminant standard,  
23 there is not an exposure monitoring requirement, but we  
24 do expect that people have to do exposure monitoring to  
25 be in compliance with the PELs.

1                   MR. KOJOLA: Well, that's an interesting  
2 response, because when you read the plain language of  
3 the proposed standard for shipyards and construction,  
4 the plain language of the standard is completely silent  
5 on whether or not there is a requirement to conduct  
6 exposure assessment, unlike your proposal for general  
7 industry.

8                   So the regulated community in construction and  
9 shipyards when they look at the plain language of the  
10 standard, will --

11                   MS. EDENS: Well, we've tried to explain our  
12 rationale for this in the preamble, and it is a  
13 preliminary determination. If you have some comments  
14 or you believe that that is not an appropriate  
15 approach, then we'd be happy to listen to that and any  
16 data that you have about why it should be included in  
17 shipyards and construction.

18                   MR. KOJOLA: Well, if an employer in  
19 shipbuilding, for example, had exposure to its  
20 employees to hex chrome and failed to do any exposure  
21 assessment, they could select respiratory protection  
22 inappropriately that would not provide a sufficient  
23 level of protection to those workers, isn't that  
24 correct?

25                   MS. EDENS: But they still have the

1 obligation of the Respiratory Protection Standard.  
2 That standard requires them to make the proper  
3 determination when selecting respirators.

4 MR. KOJOLA: So you are using the Respiratory  
5 Protection Standard as the link to require an employer  
6 to do an exposure assessment? That's a roundabout way  
7 to get at the issue that I'm driving at here, is that  
8 from our point of view we see a major flaw in this  
9 proposal, that there are no requirements for exposure  
10 assessment in shipyards and construction as opposed to  
11 general industry, or any other comprehensive health  
12 standard that OSHA has promulgated.

13 MR. O'CONNOR: What I would do is compare  
14 this to the permissible exposure limits we have under  
15 our Air Contaminant Standard where we have PELs that  
16 are laid out, but no specific scheme that is required  
17 for an employer to determine exactly how they have to  
18 go about monitoring for exposures to those  
19 contaminants. That is a completely performance-  
20 oriented approach.

21 We still have the PEL, and an employer would  
22 still have to take some action to determine if they are  
23 in compliance with the PEL, and in doing so, would have  
24 enough information on that basis to determine what type  
25 of respiratory protection, for example, would be

1 necessary.

2 MR. KOJOLA: We are talking about here OSHA's  
3 comprehensive standard, not their exposure limits in  
4 the Z table. So we're talking about a whole set of  
5 requirements that an employer is supposed to follow,  
6 including typically in OSHA's comprehensive exposure  
7 health standards, a requirement for exposure  
8 assessment. It is missing in this.

9 MR. O'CONNOR: I'm sorry. It was OSHA's  
10 preliminary determination that there were certain  
11 problems with implementing that in the construction and  
12 shipyard environments. But we're certainly open to any  
13 comments you might have or any evidence that you might  
14 have that would indicate that that preliminary  
15 determination was not correct, and that we ought to  
16 revise it for the final rule.

17 MR. KOJOLA: We don't see any difficulties  
18 whatsoever. I mean, the construction industry or  
19 shipyards conduct exposure assessment for other  
20 regulated, comprehensively regulated --

21 MS. SHERMAN: Mr. Kojola, are you asking a  
22 question? We'd like to listen to you when it is time  
23 for you to testify. But do you have questions for the  
24 panel now?

25 MR. KOJOLA: I think I've asked all my

1 questions on this issue. Thank you.

2 ADMINISTRATIVE LAW JUDGE VITTON: Thank you,  
3 Mr. Kojola.

4 Please raise your hands again. The lady with  
5 her hand on the right. The lighting in here isn't the  
6 best, so I'll try to identify you as best I can.

7 MS. TREHAN: I hope I'm a lady. Good  
8 morning. Thank you for taking my questions. My name  
9 is Chris Trehan, I'm with the Building Construction  
10 Trades Department, and I have a few questions.

11 First of all, what number is OSHA relying on  
12 as the number of construction workers exposed to  
13 portland cement?

14 MR. BURT: I'd need to check again, but it is  
15 several hundred thousand.

16 MS. TREHAN: And is that number from the  
17 number of workers who are believed to be in continuous  
18 daily contact? Or is there a threshold of a percentage  
19 of time of construction workers contact during a day, a  
20 week, or a year, that that number is based on?

21 MR. BURT: The estimate that we have was  
22 based on occupations that we felt were likely to come  
23 in contact with portland cement in construction work.  
24 We don't know of and would very much appreciate data  
25 that could tell us how frequently various groups of

1 people come in contact with it.

2 MS. TREHAN: Can you identify the groups that  
3 you identified as likely to come in contact within the  
4 construction industry by describing them possibly?

5 MS. RUSKIN: This information is in our  
6 contractor report. These were based on BLS  
7 information, cement work, masonry. I would have to go  
8 back and get the full list.

9 MR. BURT: But it was basically cement  
10 workers and general laborers.

11 MS. TREHAN: Cement workers and general  
12 laborers?

13 MR. BURT: Yes.

14 MS. TREHAN: Has that number been updated  
15 since prior to the SBREFA panel? Or is that the same  
16 preliminary economic?

17 MR. BURT: No, we haven't.

18 MS. TREHAN: So it is the same report?

19 MR. BURT: Yes.

20 MS. TREHAN: Okay. The next question is  
21 where did OSHA obtain the \$119 cost per medical  
22 treatment episode for occupational dermatitis? Medical  
23 cost treatments.

24 MR. BURT: That was based on some data in a  
25 study by Dr. Ruttenberg, I believe.

1 MS. TREHAN: Maybe it is more a request, but  
2 is it possible for OSHA to provide how they arrived at  
3 that number? Because Dr. Ruttenberg doesn't know where  
4 that number came from. We can't find it in her  
5 reports.

6 MR. BURT: I believe it was documented in the  
7 economic analysis.

8 MS. TREHAN: Is that in the preamble? Or is  
9 that, again, in the SBREFA documents?

10 MR. BURT: No, that is a separate document in  
11 the docket.

12 MS. TREHAN: Okay, because we couldn't find  
13 that. In May, 2004, the OSHA Advisory Committee for  
14 Construction, Safety, and Health, ACCSH, both labor and  
15 management voted that portland cement should be  
16 included in the hexavalent chromium final rule for  
17 construction. They did lay out a series of shall we  
18 say alternates or requirements that should apply to  
19 hexavalent chromium exposure in construction with the  
20 intent that the burden on employers for complying with  
21 protective measures for construction workers would not  
22 be overwhelming, and it would address the items in  
23 there.

24 Is there a basis that can be explained why  
25 OSHA decided to not follow ACCSH's recommendation?

1 MS. DOUGHERTY: Thank you. I believe Amanda  
2 Edens is the best to respond to your question.

3 MS. EDENS: We listened carefully to what  
4 ACCSH had to give us in way of advice. We also were  
5 there when they had the vote, and there were a number  
6 of different opinions amongst the committee, but the  
7 majority vote was that OSHA would include portland  
8 cement.

9 We looked at that and in response to the  
10 proposal that they put on the table in terms of some  
11 different ways to look at it, we actually laid that out  
12 in the preamble to get comment on, but we have made the  
13 preliminary determination that we think that there are  
14 some difficulties with cement. More importantly, our  
15 preliminary determination is that the majority of the  
16 exposure is dermal in nature, and very little, if any,  
17 airborne exposure, and that some existing standards  
18 that OSHA already currently has on the books for  
19 hygiene, PPE, and hazard communication would be able to  
20 address those dermal risks. So we have made a  
21 preliminary determination at this point not to include  
22 portland cement workers in the scope of the standard.

23 However, this is an open issue, and we have  
24 highlighted it in our preamble, along with the  
25 recommendation that was made by ACCSH, and specifically

1 the sort of proposal that they put on the table for how  
2 it might be made less burdensome to construction  
3 employers if they were included under the standard. So  
4 we'd be really happy to know what people thought about  
5 ACCSH's advice on that issue.

6 MS. TREHAN: In ACCSH's recommendation, they  
7 laid out some recommendations that were less  
8 burdensome, as I said, for employers regarding portland  
9 cement, such as no exposure assessment, and other  
10 things that would normally be part of an expanded  
11 health standard.

12 Is that any reason why OSHA decided to exclude  
13 the requirement for exposure assessment in the  
14 construction reg?

15 MS. EDENS: I'm not sure I follow your  
16 question.

17 MS. TREHAN: The recommendations from ACCSH  
18 included that you don't have to do air monitoring for  
19 exposure to wet portland cement, and did OSHA take that  
20 recommendation and blanketly apply it to construction  
21 based on ACCSH's recommendation?

22 MS. EDENS: No. I mean, the portland cement  
23 issue was separate from the exposure monitoring for  
24 construction in general.

25 MS. TREHAN: Okay. As part of the

1 determination or the position that OSHA has as far as  
2 existing standards protecting construction workers from  
3 exposure to wet portland cement, was there research  
4 done into the level of, or the number of citations that  
5 were routinely issued of the sanitation standard for  
6 the lack of hand washing facilities where workers are  
7 exposed to wet portland cement, which is toxic and  
8 extremely caustic?

9 MR. O'CONNOR: We did check into that. I  
10 don't recall the specific numbers, but I remember them  
11 as being pretty small.

12 MS. TREHAN: I think this is my last one.  
13 I'm not sure. But as part of this rulemaking, OSHA  
14 stated that existing standards and additional guidance  
15 documents may be a more appropriate way to address the  
16 issue of wet portland cement.

17 Regarding the use of guidance documents, what  
18 data does the Agency rely on to suggest that guidance  
19 documents are more protective than a regulation?

20 MS. EDENS: I'm not altogether sure that  
21 there is a specific set of data that we would say  
22 shows that guidance is more protective than standards.  
23 We see the two of them, and sometimes guidance alone  
24 can be very effective in addressing hazards that  
25 workers face.

1           In the particular case of portland cement, we  
2           have standards on the books for PPE, and we have  
3           standards on there for hygiene. As ACCSH raised in  
4           their discussions, some questions were raised about  
5           whether or not another standard would make them follow  
6           PPE more, but rather maybe we need to have guidance to  
7           get people to show them how they could effectively  
8           follow a PPE standard, because there are some different  
9           ways.

10           The Center for the Protection of Workers'  
11           Rights has some information out, and so we thought if  
12           people are not following the existing standards that  
13           are out there, maybe it would be a good place for  
14           guidance to be used where we could help employers and  
15           employees know better how to apply the rules that we  
16           currently have in place. So we see that as a very good  
17           use of guidance, not to say that it alone is more  
18           effective than a standard, but it definitely has a  
19           place in worker protection.

20           MS. TREHAN:    Guidance documents do have a  
21           place, I agree with that. But I was really trying to  
22           get at if there was any evidence that showed that it  
23           was a more protective route than a regulation.

24           MS. EDENS:    Well, I don't think we've done  
25           the studies to determine that either one way or the

1 other, that the obverse is true either.

2 MS. TREHAN: Okay. Thank you very much.

3 ADMINISTRATIVE LAW JUDGE VITTON: Thank you.  
4 The gentleman with his hand up.

5 MR. YOHAY: Good morning. My name is Stephen  
6 Yohay of the Law Firm Arent Fox on behalf of the Edison  
7 Electric Institute. Some questions for the panel,  
8 please.

9 Was the electric utility industry considered  
10 and/or analyzed when OSHA prepared the proposed  
11 standard?

12 MR. BURT: I'm sorry. I didn't hear you.

13 MR. YOHAY: Was the electric utility industry  
14 considered and/or analyzed when OSHA prepared the  
15 proposed standard?

16 MR. BURT: Yes.

17 MR. YOHAY: And where would we find that  
18 analysis in the record?

19 MR. BURT: Throughout the economic analysis,  
20 the electric utility industry is considered. That is,  
21 we didn't organize our analysis into a chapter called  
22 Electric Utilities and a chapter called Electroplating.  
23 We organized it by headings such as Exposure Profiles,  
24 Technological Feasibility, et cetera.

25 MR. YOHAY: Where would we find any studies

1 referred to in the record that addressed whether  
2 electric power plant employees are exposed to unsafe  
3 levels of hexavalent chromium?

4 MR. BURT: The exposure profile would list  
5 what information we had on exposure in electric  
6 utilities. The principle one we examined there was  
7 welding.

8 MR. YOHAY: And you examined that in the  
9 context of the way that welding is performed in a power  
10 plant? Is that what you're telling me?

11 MR. BURT: I'm sorry?

12 MR. YOHAY: Are you saying that the record  
13 reflects that OSHA analyzed the way welding is  
14 performed in an electric utility power plant, and we'll  
15 find that in the record?

16 MR. BURT: No. I am saying that any data we  
17 had would appear in the context of the overall  
18 discussion of welding. We are not able in this  
19 analysis to look at welding in all of the hundreds of  
20 industries in which it appears specifically.

21 MR. YOHAY: I see. Did any of the  
22 contractors visit any electric utility facilities in  
23 the course of preparing their report and analysis?

24 MR. BURT: No.

25 MR. YOHAY: So I take it then that you don't

1 have any discreet studies that address the question of  
2 exposure to hexavalent chromium in the power plant  
3 environment. Am I right?

4 MR. BURT: I am reluctant to say absolutely  
5 yes, but I don't recall one.

6 MR. YOHAY: Okay.

7 MR. BURT: Because we relied on a wide  
8 variety of material in assembling the exposure profile,  
9 and I'd need to review it carefully. But I don't  
10 recall. We certainly don't have a site visit report on  
11 that.

12 MR. YOHAY: Is OSHA aware that some work  
13 performed in the course of doing maintenance in an  
14 electric utility power plant, as for example during a  
15 boiler outage, would be properly characterized as  
16 construction as defined by OSHA?

17 MR. BURT: Yes.

18 MR. YOHAY: And have you consulted  
19 specifically with the Construction Advisory Committee  
20 on the advisability of regulating construction in  
21 electric utility facilities?

22 MR. BURT: We consulted with the Construction  
23 Advisory Committee. I don't recall if we brought up  
24 that specific type of construction as distinct from  
25 other kinds of construction.

1                   MR. YOHAY:    So you have no recollection one  
2 way or the other whether the issue was raised at this  
3 point?

4                   MS. EDENS:    I don't think that it was raised  
5 specifically with any industry when we went to ACCSH.  
6 We gave them the materials that we shared with SBREFA,  
7 which included some of the exposure profile, some of  
8 the site visits, and they had access to a lot of that.  
9 So we didn't ever when we went to them to give them  
10 short briefings, we didn't pull out that industry or  
11 any other industry per se.

12                  MR. YOHAY:    Okay.  Is there any analysis in  
13 the record that perhaps I missed that explains OSHA's  
14 analysis of the economic feasibility of applying this  
15 standard as proposed in the electric power plant  
16 environment?

17                  MR. BURT:    The analysis missed a number of  
18 industries in which welding takes place.

19                  MR. YOHAY:    Is that --

20                  MR. BURT:    We looked at the industries in  
21 which there were the greatest numbers of welders, but  
22 you are correct, there are a number of industries that  
23 are not broken out, but simply treated, costed as part  
24 of welding as a whole.

25                  MR. YOHAY:    Is it your plan to separately

1 analyze some of those industries?

2 MR. BURT: I think we're going to need to,  
3 yes.

4 MR. YOHAY: And what opportunity will the  
5 electric utility and others who have been omitted have  
6 to comment on that analysis prior to the publication of  
7 the final rule?

8 MR. BURT: I'm looking to our solicitor for  
9 that.

10 MS. SHERMAN: I believe that if we do do the  
11 re-analysis, it will be available in the record, and be  
12 available in terms of a post-hearing comment for you.

13 MR. YOHAY: Okay. Thank you. Has OSHA  
14 considered how the obligations to conduct exposure  
15 monitoring, for example, on the proposed standard would  
16 be apportioned between a host employer, for example, an  
17 electric utility power plant, and the kinds of  
18 specialty contractors that come into a power plant, as  
19 for example during boiler maintenance?

20 MR. BURT: We have --

21 MR. YOHAY: And let me just finish, if I may  
22 add to the question.

23 MR. BURT: Okay.

24 MR. YOHAY: In general, have you considered  
25 how the obligations of a host employer to comply with

1 the standard will be harmonized with OSHA's  
2 multiemployer citation policy?

3 MR. BURT: We have in general treated the  
4 costs as costs, for example, to the contractor, and  
5 then discussed whether these costs, and then have a  
6 separate discussion of the extent to which these costs  
7 might be passed on to the employer or that contractor.

8 MR. YOHAY: You said that's reflected in the  
9 record?

10 MR. BURT: I'm sorry?

11 MR. YOHAY: That analysis is reflected in the  
12 record?

13 MR. BURT: The discussion is in the  
14 preliminary economic analysis.

15 MR. YOHAY: Okay. As you perhaps noticed in  
16 EEI's comments, there is some concern that compliance  
17 with this standard and a nuclear power plant may result  
18 in an increased exposure to radiation. Has OSHA  
19 consulted at all with the Nuclear Regulatory Commission  
20 about the potential impact of this rule in that  
21 environment?

22 MS. EDENS: No.

23 MR. YOHAY: Okay. Will you consider doing  
24 so?

25 MS. EDENS: Yes.

1 MR. YOHAY: Good. That's all I have. Thank  
2 you very much.

3 ADMINISTRATIVE LAW JUDGE VITTON: Thank you,  
4 Mr. Yohay.

5 Can I see some more hands, please? I see this  
6 gentleman back here. You're going to have to come up  
7 here and talk, sir. State your name and who you are  
8 representing, please.

9 MR. SESSIONS: I'm Stuart Sessions. I'm a  
10 consultant representing the Surface Finishing Industry  
11 Council, basically the electroplating industry. I have  
12 just a preliminary question.

13 Are the members of the panel going to make  
14 individual statements? In which case I will ask my  
15 questions after the appropriate statements, or is this  
16 the opportunity to question the individuals on the  
17 panel?

18 MS. SHERMAN: Mr. Sessions, Ms. Dougherty  
19 made the statement for the panel. She will be  
20 directing any of the questions to various relevant  
21 members of the panel. But we do not have separate  
22 statements to make.

23 MR. SESSIONS: Okay. The Surface Finishing  
24 Industry Council submitted as part of its written  
25 comments Appendix G, which included 28 different issues

1 where we believe that the economic analysis estimating  
2 the number of exposed individuals, the number of  
3 affected facilities, the costs, the economic benefits,  
4 the health risks, et cetera, for the electroplaters was  
5 inadequately explained.

6 In essence, we could not follow the  
7 computations sufficiently in the economic impact  
8 analysis to replicate the conclusions, the intermediate  
9 steps and the conclusions that the Agency drew in the  
10 economic impact analysis. Thus, we submitted 28, as I  
11 say, questions covering 24 pages.

12 ADMINISTRATIVE LAW JUDGE VITTON: Sir, you  
13 have limited time. Do you have a question?

14 MR. SESSIONS: My question is in what forum  
15 could we get answers to these questions, such that we  
16 can effectively comment on the Agency's analysis?

17 MS. SHERMAN: We believe that the statement  
18 speaks for itself. However, if you have specific  
19 questions on any aspect of it, I would invite you to  
20 ask the questions now, and we will try to provide  
21 whatever answers we can.

22 MR. SESSIONS: Okay. I guess I can't  
23 effectively ask 28 pages worth of questions at this  
24 point, but I would like to submit for the record again  
25 our list of questions.

1                   In general, they request clarification of the  
2 analysis, including identification of data sources,  
3 explanation of steps in the calculations, explanations  
4 of assumptions that are not accompanied by  
5 justifications, explanations of internal  
6 inconsistencies --

7                   ADMINISTRATIVE LAW JUDGE VITTON:    Mr.  
8 Sessions?

9                   MR. SESSIONS:     Yes?

10                  ADMINISTRATIVE LAW JUDGE VITTON:    Are these  
11 already in the record?  Have you already submitted  
12 these questions?

13                  MR. SESSIONS:     Yes, they are, sir.

14                  ADMINISTRATIVE LAW JUDGE VITTON:    Okay.  
15 Well, I don't see a need to resubmit them then if they  
16 are already in the record.  You brought it back to the  
17 attention of the panel.  It is up to them now to deal  
18 with it.

19                  MS. SHERMAN:    Mr. Sessions, I would again  
20 invite you to select perhaps the more pressing  
21 questions and ask them now, because after today's  
22 presentation, the OSHA panel will no longer be  
23 available to answer questions.

24                  I would assure you that we will give full  
25 consideration to your questions, but you have live

1 witnesses in front of you, including the people who did  
2 the economic analysis. So perhaps this would be a time  
3 to ask your more important questions.

4 MR. SESSIONS: I repeat that I don't feel  
5 that we can comment effectively on the rule, either in  
6 a written testimony thus far, or in our oral testimony  
7 that we're going to present without the questions being  
8 answered.

9 OSHA's analysis is a long series of  
10 computations with data taken from numerous sources and  
11 numerous assumptions made. Any of the estimates that  
12 you generate in terms of number of affected facilities,  
13 cost, numbers of workers exposed, et cetera, are the  
14 sum of a numerous set of data steps and assumptions.

15 ADMINISTRATIVE LAW JUDGE VITTONI: Mr.  
16 Sessions, you are going to have an opportunity to  
17 testify, sir.

18 MR. SESSIONS: Okay.

19 ADMINISTRATIVE LAW JUDGE VITTONI: Okay?

20 MS. SHERMAN: Mr. Sessions?

21 ADMINISTRATIVE LAW JUDGE VITTONI: So if you  
22 do have some questions right now.

23 MS. SHERMAN: Would there be some questions  
24 now that you would like to ask?

25 MR. SESSIONS: Sure. I'll start with the

1 first one. In one portion of the economic analysis,  
2 OSHA estimates the number of electroplating facilities  
3 that will be affected by the rule. The estimate,  
4 according to the footnote in Table 2-1 derives from  
5 Table 2-4, and Table 2-4 is basically data from the EPA  
6 on the number of electroplating facilities that are  
7 estimated to conduct hard chrome, decorative chrome, or  
8 chromium anodizing operations. That's the number that  
9 appears in Table 2-4.

10 In Table 2-1 where the Agency estimates the  
11 number of affected facilities, which according to the  
12 footnote derives from Table 2-4, the number is  
13 different and less than the number that was in 2-4.  
14 Could you explain that?

15 MR. BURT: Let me ask Ms. Ruskin to speak to  
16 that.

17 MS. RUSKIN: The number that was used from  
18 EPA would be the number of processes. Some facilities  
19 would have more than one type of electroplating in one  
20 facility. We attempted to then estimate the number of  
21 facilities by using an estimator.

22 I'm trying to remember the society that we  
23 received the information from, but it is documented in  
24 our supporting documents. The number of facilities  
25 that would have both hard chrome, decorative chrome,

1 and anodizing processes in one facility. So that is  
2 why the total number of facilities is lower than EPA's.

3 MR. BURT: Which was a number of processes.  
4 Let me add just a couple of general points. Some of  
5 these issues, I believe including that one, the  
6 preliminary economic analysis is not a standalone  
7 document, but in turn depends on the contractor report  
8 in the docket as 35-390.

9 That is, we did not write the preliminary  
10 economic analysis in such a way that every number can  
11 be traced. We believe that almost all of the numbers  
12 can be fully traced when it is used in coordination  
13 with the contractor report it constantly references.

14 MR. SESSIONS: I believe we have read all the  
15 materials in the docket, including the contractor  
16 reports, and our list of questions is based upon the  
17 sum of all of them. I don't believe this particular  
18 question or the others we asked are answered in the  
19 preliminary materials.

20 MS. SHERMAN: Do you have another question  
21 for Mr. Burt or Ms. Dougherty to assign?

22 MR. SESSIONS: If I could follow up on that,  
23 on your answer. Tables 2-2 and 2-3 go through the  
24 process by which operations as EPA estimates the  
25 numbers, are converted to establishments, and then

1 Table 2-4 is establishments.

2 Table 2-4 estimates that there are 3,999  
3 establishments, that being your term, that conduct any  
4 of these three chromium using processes. Table 2-1,  
5 which derives from that table, adds to a total of sums  
6 500 less establishments.

7 Elsewhere in the materials, there is a further  
8 different number of the number of electroplating  
9 establishments that are affected. The reason I'm  
10 concerned about this is we as an industry believe that  
11 you have sharply underestimated the number of affected  
12 facilities. At a minimum, you have counted only the  
13 facilities that conduct one of these three processes.

14 MS. SHERMAN: Do you have a question?

15 ADMINISTRATIVE LAW JUDGE VITTONI: Ms.  
16 Sherman?

17 MS. SHERMAN: Yes?

18 ADMINISTRATIVE LAW JUDGE VITTONI: Calm down.

19 MR. BURT: You are correct in thinking that  
20 we only considered those three processes. I read your  
21 comments, and that is a correct understanding.

22 MR. SESSIONS: Okay. And do you know why  
23 your estimate is 500 less than the number that  
24 conducted those three processes?

25 MR. BURT: I would need to look more

1 carefully at that. As I said, there are a series of  
2 complex distinctions that we perhaps are not explaining  
3 clearly and distinguishing between processes,  
4 establishments, businesses, and firms, which is still a  
5 different number. I would need to check more  
6 carefully.

7 We appreciate your very detailed comment, and  
8 it is of course part of the record and something that  
9 we will be using to respond, and we'll need to respond  
10 to as part of the development of a final standard.

11 MR. SESSIONS: Am I correct that you intended  
12 to count only as affected only establishments that  
13 conduct one of these three particular chromium using  
14 processes?

15 MR. BURT: That is what we did in the  
16 preliminary analysis. I have seen comments from a  
17 number of people who suggested that wasn't the right  
18 approach who were very interested in more data on other  
19 kinds of electroplating facilities.

20 MR. SESSIONS: Why did you not count as  
21 potentially affected facilities that also use  
22 hexavalent chromium in electroplating via other  
23 processes?

24 MR. BURT: We initially understood that  
25 hexavalent chromium exposures that would be significant

1 would occur only in these processes. We have seen  
2 suggestions that the preliminary estimate was  
3 incorrect. We welcome evidence on that point.

4 MR. SESSIONS: Thank you. Let me ask further  
5 in Table 2-1, the other half of the table is estimates  
6 of the number of affected workers. I understand that  
7 the number of affected workers was derived from Bureau  
8 of Labor Statistics data on the number of "platers" in  
9 effect in the industry. Is that correct?

10 MR. BURT: That's correct.

11 MR. SESSIONS: Do you know if you limited  
12 that to the number of platers who deal with hexavalent  
13 chrome?

14 MR. BURT: No, those numbers would not have  
15 been limited only to hexavalent chromium. We would  
16 have needed to derive that figure.

17 MR. SESSIONS: Do you believe that workers,  
18 in addition to platers, may be exposed in  
19 electroplating shops to hexavalent chromium?

20 MR. BURT: It's possible.

21 MR. SESSIONS: So the number may be incorrect  
22 in not counting workers who are in hexavalent chromium  
23 shops who may be exposed to chrome, and it may be  
24 incorrect in the other direction by counting all  
25 platers whether or not they are working with hexavalent

1 chrome?

2 MR. BURT: It is an estimate. There are, as  
3 you probably know, some issues and problems here with  
4 respect to the fact that especially for captive  
5 plating, there is no generalized data source that gives  
6 you either how many captive platers there are, how many  
7 employees they have, and certainly not the exact  
8 numbers of hard chromium platers.

9 We welcome data on these issues. We have seen  
10 some of the data--alternative estimates provided in the  
11 comments--and we'll be considering those carefully.

12 MR. SESSIONS: Does it appear to you that  
13 your estimate of the number of facilities bears some  
14 relation to the number that conduct these three  
15 chromium using processes, but the number of workers is  
16 the total number of platers, whether or not they deal  
17 with cadmium? Chromium, sorry.

18 The point I'm getting at, is there a mismatch  
19 between your number of facilities, which arguably has  
20 something to do with those who conduct these three  
21 chromium processes, and the number of employees, which  
22 appears to be "platers," independent of whether they  
23 deal with this chemical or not?

24 MR. BURT: I don't believe that's the case,  
25 but I'm not in a position to trace through each of the

1 steps in our analysis sitting here right now.

2 MR. SESSIONS: Okay. We believe it is the  
3 case that in effect the number of affected employees is  
4 estimated in an entirely different and incompatible way  
5 with the number of affected facilities. The impact of  
6 that ripples through your analysis at various points.  
7 You make some assumptions having to do with the number  
8 of people per facility, some of your costs are  
9 estimated in that basis.

10 ADMINISTRATIVE LAW JUDGE VITTONI: Mr.  
11 Sessions, you are testifying again. Come on. Ask your  
12 question.

13 MR. SESSIONS: I guess the question is I have  
14 I would guess eight hours worth of such questions in  
15 order to be able to understand your analysis. I would  
16 hope that there would be some means by which we could  
17 get these questions answered in a fashion such that we  
18 could testify with the benefit of being able to  
19 understand OSHA's analysis.

20 ADMINISTRATIVE LAW JUDGE VITTONI: Ms.  
21 Dougherty, do you want to respond to that? Does  
22 anybody want to respond to that?

23 MS. SHERMAN: Mr. Sessions, you have an  
24 opportunity to ask questions now. You think that there  
25 are eight hours worth of questions. I have no way of

1 judging whether in fact you have eight hours worth of  
2 questions. I would invite you to ask the most pressing  
3 questions to your mind.

4 We have a requirement that the final rule is  
5 going to be based on the record as a whole. You will  
6 have an opportunity to testify. You will have an  
7 opportunity to submit post-hearing comments.

8 Are there any other questions at this point  
9 that we can help you with in terms of the answer?

10 MR. SESSIONS: Yes, there are a lot of them.  
11 I have gotten 1/3 of the way through page one.

12 MS. SHERMAN: Can I invite you to ask your  
13 most pressing questions?

14 ADMINISTRATIVE LAW JUDGE VITTONI: Well, Ms.  
15 Sherman, right now he -- you've gone past your 15  
16 minutes.

17 MR. SESSIONS: Okay.

18 ADMINISTRATIVE LAW JUDGE VITTONI: You'll  
19 have an opportunity to ask additional questions later  
20 on as people go on. You'll have an opportunity to  
21 testify, okay?

22 MR. SESSIONS: Okay.

23 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you  
24 very much.

25 MR. SESSIONS: Thank you.

1 ADMINISTRATIVE LAW JUDGE VITTON: Let's see.  
2 Any other hands? The lady sitting here with -- yes,  
3 you.

4 MS. MCMAHON: Thank you, Your Honor. Ms.  
5 Dougherty, I have just two questions. I think it is  
6 Mr. Burt who they most appropriately are directed to.

7 ADMINISTRATIVE LAW JUDGE VITTON: Could you  
8 identify yourself?

9 MS. MCMAHON: I'm sorry. I'm Kate McMahon  
10 with Collier, Shannon & Scott appearing on behalf of  
11 the Chrome Coalition and the steel industry.

12 ADMINISTRATIVE LAW JUDGE VITTON: Okay.

13 MS. MCMAHON: Mr. Burt, I have a question  
14 regarding the use of median exposure values in your  
15 book, The Economic and Technical Feasibility Analysis.  
16 Did OSHA rely on median exposure values to make  
17 determinations about what control technologies needed  
18 to be implemented to achieve the proposed PEL? And if  
19 so, did that analysis then get carried through to the  
20 cost analysis that was conducted by the Agency?

21 MR. BURT: The use of medians is fairly  
22 complicated here. Let me outline how we proceeded on  
23 this analysis. We looked at various kinds of controls  
24 and various kinds of facilities and what they could  
25 achieve.

1                   From this, we made some use of medians in  
2                   estimating what certain kinds of controls might  
3                   achieve. This is not to make the feasibility  
4                   determination, but to address the issue. We only  
5                   visited a limited number of facilities. We wanted to  
6                   use a complete exposure profile using all the exposure  
7                   data we had.

8                   The question now arose, suppose you see  
9                   someone at an exposure point that has say an exposure  
10                  of 20 micrograms per cubic meter. We need to ask  
11                  ourselves in order to make a cost estimate, what kinds  
12                  of controls might they already have in place in order  
13                  to estimate how much more they will need.

14                  It is there that we made use of medians to say  
15                  oh, people with a median of 20 typically have these  
16                  kinds of controls. We will assume that this facility  
17                  had those kinds of controls, and therefore needs these  
18                  additional controls to get down to five or one. So the  
19                  use of medians was chiefly to try to see how to  
20                  characterize a diversity of exposure data as to what  
21                  controls they might currently have in place.

22                  MS. MCMAHON: And when you say diversity of  
23                  exposure data, do you mean by operation or by employee,  
24                  based on the site visit?

25                  MR. BURT: By employee, by job category.

1 MS. MCMAHON: So, for instance, just to make  
2 sure I'm clear. If you had say seven data points for a  
3 furnace operator at a particular type of facility, and  
4 those data points ranged from well below the proposed  
5 PEL to well above the proposed PEL, you calculated the  
6 median, and then you made a determination as to what  
7 control technology was necessary to bring that  
8 particular job into compliance with the proposed PEL  
9 from the median number, whatever that was, to one, or  
10 .5, if you were looking at the actual level.

11 MR. BURT: As I said, we need to make an  
12 estimate of what controls they might have in place.  
13 For that purpose, we use the median. We then ask what  
14 further controls would be necessary to reduce it to one  
15 or .5, based on an estimate of what controls they had  
16 in place now based on the median, and as compared to  
17 the median of other places with similar controls.

18 I want to emphasize the median is not the  
19 basis for deciding technological feasibility. Its use  
20 in this context is to try to estimate what further  
21 controls are needed at the given job category, and at a  
22 given facility.

23 MS. MCMAHON: Do you know whether OSHA ever  
24 calculated, and whether it is in the record, what  
25 control technologies would be necessary for the highest

1 exposures that were identified in OSHA's database?

2 Exposure value database.

3 MR. BURT: I think we fairly consistently  
4 list in the full set of data, the economic analysis and  
5 the contractor report, what kinds of controls are  
6 necessary to get people who are above 20, which I think  
7 was the highest level we considered, to a level of 20  
8 micrograms.

9 MS. MCMAHON: Okay. I guess what I'm asking  
10 is whether OSHA ever considered the highest data points  
11 that you found for exposures. For instance, for a  
12 furnace operator, let's say you found an exposure of  
13 13. Did you ever identify what control technologies  
14 would be necessary to go from the high data point, 13,  
15 to the proposed PEL of whatever number you are looking  
16 at.

17 MR. BURT: Yes, we did. The respect in which  
18 we used medians is in talking about multiple data for a  
19 single job category in a facility. We took account of  
20 different facilities and different data points.

21 Suppose the only thing we knew about a furnace operator  
22 in a given facility is that he was at 13 micrograms.

23 Then what we did was cost it to go from 13  
24 micrograms to one. Now, if we had two measures  
25 actually somewhere between 10 and 20, sort of banded

1 the controls. Now, the only place we would have used a  
2 median is for that furnace operator in that facility.  
3 We had two data points, 13 and 5, we would have said  
4 well, the median is 9, so they probably have the kind  
5 of controls in place that elsewhere would get a median  
6 of 9, and then costed it to get from 1, the additional  
7 controls, according to the parallel that this was  
8 similar to other places that get a median of 9.

9 MS. MCMAHON: Okay. So for purposes of  
10 costing out the control technologies that would be  
11 implemented, if you had multiple data points for a  
12 single job category, that is where you would use the  
13 median value?

14 MR. BURT: We would use the median in  
15 comparison to the median achieved by similar controls  
16 elsewhere. In other words, it is used to make an  
17 assessment where we don't have data on the controls,  
18 but do have data on the exposure, what kinds of  
19 controls are already in place.

20 MS. MCMAHON: Okay. Thank you. The second  
21 topic that I wanted to ask you about is where you got  
22 data on the success of the control technologies that  
23 you identify in your technological feasibility  
24 documents.

25 That is how do you know that the control

1 technologies you've identified can bring the exposures  
2 from whatever the database shows, whether it be median  
3 or actual values, to the proposed PEL?

4 MR. BURT: This varies throughout the report,  
5 and it depends on the industry. I think we outline  
6 fairly carefully on an industry by industry basis the  
7 basis for these judgments.

8 In many cases, it is simply yes, we observed  
9 this being done in a facility that is reasonably  
10 typical of this industry as a whole. In other cases,  
11 it relies on professional judgement, which I think is  
12 fairly explicitly laid out why they think these further  
13 controls could achieve the level in question.

14 In some cases it is something parallel in  
15 another industry could do this. In some cases it is  
16 professional judgment of some very experienced people.

17

18 MS. MCMAHON: Okay. Thank you.

19 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you,  
20 Ms. McMahon.

21 Who else had their hand up? Mr. Tyson?

22 MR. TYSON: Good morning, Judge Vittone.

23 ADMINISTRATIVE LAW JUDGE VITTONI: Mr. Tyson.  
24 It is good to see you again.

25 MR. TYSON: I apologize for being a little

1 bit late. Delta didn't cooperate too well this  
2 morning.

3 I have a very specific series of questions  
4 with respect to a very specific provision, so I won't  
5 take very long.

6 ADMINISTRATIVE LAW JUDGE VITTON: Mr. Tyson,  
7 who do you represent?

8 MR. TYSON: I'm sorry, Your Honor. It is  
9 Patrick Tyson representing the 3M Corporation.

10 Specifically I want to address the provisions  
11 in the proposed standard dealing with what the OSHA  
12 folks call the PLHCP, which I won't even attempt to --  
13 well, I will. Physicians and other Licensed Health  
14 Care Professionals. That section is on 59488.

15 In particular, I want to request the Agency's  
16 position with respect to the issue of the purpose of  
17 that provision. I would ask if it is not correct, that  
18 the reason for the requirement that PLHCP have a  
19 license granted by a state is to ensure that the PLHCP  
20 is in fact competent to perform the type of analysis  
21 which is required in the standard.

22 MS. EDENS: The purpose of that definition is  
23 to give employers more flexibility in picking a health  
24 care provider to do the portions, the medical  
25 surveillance portions, of the standard. So OSHA does

1 not want to be in the position of dictating what  
2 particular kind of professional has to do the test.  
3 All that OSHA cares is that the person doing that is  
4 operating within the legal scope of their practice.

5 MR. TYSON: Well, in that case, I pose the  
6 question again. But isn't the concern of the Agency to  
7 make sure that the person is in fact competent to  
8 perform the types of analysis that the standards  
9 require, as opposed to the Agency putting itself in the  
10 position of enforcing the state licensing laws?

11 MS. EDENS: I think the way we've laid it out  
12 is, we've specifically said we want someone who is  
13 operating within the legal scope of their practice, and  
14 that's our position in the proposal.

15 MR. TYSON: But does the Agency have the  
16 authority to enforce state licensing laws?

17 MS. EDENS: No.

18 MR. TYSON: So would it be a violation, for  
19 example, if the corporate medical director of a large  
20 corporation with operations in many states who happened  
21 to be in the State of New York and was licensed there  
22 in the State of New York conducted the medical  
23 evaluation for employees who were in the neighboring  
24 state of New Jersey?

25 MS. EDENS: I believe that in your testimony

1 you attached a letter of interpretation which addresses  
2 a particular issue like that. I don't necessarily know  
3 that this table is prepared to make enforcement calls  
4 at this point. You might want to talk to the Director  
5 of Enforcement on that.

6 But in that particular case, the letter you  
7 referenced, the individual was a medical physician I  
8 believe in the State of Texas.

9 MR. TYSON: That's correct.

10 MS. EDENS: And they had a mobile crew that  
11 was going around different states who were not licensed  
12 health care professionals, they were technicians doing  
13 PFTs. They brought that information back to Texas  
14 where that individual did the diagnosis.

15 The letter of interpretation says that that  
16 individual needed to be licensed in all the states in  
17 which they were giving a medical diagnosis. We would  
18 stand by that letter of interpretation.

19 MR. TYSON: I still don't understand the  
20 issue with respect to the example I gave with the New  
21 York physician overseeing the program in the State of  
22 New Jersey.

23 MS. EDENS: Well, yes, we would still like to  
24 consult with our enforcement people, but our general  
25 sense is there is nothing to prevent a Medical Director

1 say overseeing an entire program as long as they are  
2 not the one that is doing the hands-on diagnosis.  
3 That's allowed by state law. If one state doesn't care  
4 if a physician that is licensed in another state does  
5 that, as long as it is legal to do that, OSHA wouldn't  
6 have an opinion on that one way or the other.

7 MR. TYSON: But doesn't OSHA have to base any  
8 type of either in the standard or in enforcement of the  
9 standard, on an employee health and safety  
10 consideration?

11 MS. EDENS: Yes.

12 MR. TYSON: But in this case, it sounds like  
13 what you are describing is the Agency enforcing a state  
14 licensing requirement, as opposed to looking at the  
15 issue of employee safety and health.

16 MS. EDENS: We wouldn't enforce state medical  
17 law, but we hope that, our intent of this provision  
18 which we've laid out, and if we haven't laid it out and  
19 you have some particular concerns, we'll be willing to  
20 listen to your testimony on that. But what we've laid  
21 out is that we want someone who is operating within  
22 their legal scope of practice, and we hope that  
23 physicians are doing that.

24 But no, we wouldn't enforce, if they were  
25 breaking medical law, we probably wouldn't enforce

1 them. We might refer that to the state agency.

2 MR. TYSON: Very good. Thank you very much.  
3 That's all my questions, Your Honor.

4 ADMINISTRATIVE LAW JUDGE VITTON: Thank you,  
5 Mr. Tyson.

6 I saw some other hands. The gentleman here in  
7 the middle.

8 DR. LURIE: Good morning. I'm Peter Lurie  
9 with the Public Citizens Health Research Group here in  
10 Washington.

11 I want to start off with some of the bigger  
12 questions, just with regard to the science upon which  
13 the Agency relied in making this proposed rule. I'd  
14 like to get the assessment of the panel about the  
15 general quality of the studies that have been put  
16 forth. How did these compare in general quality to the  
17 kinds of studies often at the hands of the Agency when  
18 they have to make a rulemaking. Here I'm talking about  
19 the epidemiological studies.

20 MS. DOUGHERTY: Okay. Thank you for your  
21 question.

22 Dr. Schaeffer?

23 DR. SCHAEFFER: Yes, Mr. Lurie. The studies  
24 we relied on we felt were very strong data sets for  
25 exposure response. They had very large cohort size,

1 they had long follow ups, sufficient follow up, they  
2 had a large number of lung cancer mortality to work  
3 with, and most importantly, they had extensive  
4 concurrent exposure information on individual workers  
5 in those cohorts.

6 DR. LURIE: So it is fair to say that in  
7 previous rulemakings you have ruled upon, you have  
8 relied upon studies that are perhaps weaker than these?

9 DR. SCHAEFFER: I am not prepared to say  
10 that.

11 DR. LURIE: Okay. But there is certainly  
12 nothing wrong with the standard of the studies that you  
13 are putting forth here, upon which you base this?

14 DR. SCHAEFFER: That's correct.

15 DR. LURIE: Okay. And is it true that as a  
16 general matter with respect to the regulation of  
17 carcinogens, that the Agency generally takes the  
18 approach that there is no effect level, that there is  
19 no threshold? Is that the general approach that the  
20 Agency takes? In the absence of clear evidence to the  
21 contrary.

22 DR. SCHAEFFER: For genotoxic agents that  
23 cause cancer, that has been the approach of choice.

24 DR. LURIE: Right. That's the Agency's  
25 longstanding policy, is that correct?

1 DR. SCHAEFFER: Again, I don't know if it is  
2 officially a policy of the Agency, but that has been  
3 what we have done in the past.

4 DR. LURIE: Well, I'll just point you then to  
5 page 344 of the Federal Register, or 59,344 in which  
6 that is described indeed as the Agency's "longstanding  
7 cancer policy."

8 Okay. Now, I am wondering in terms of this  
9 threshold effect, in looking at the dermal effects of  
10 hexavalent chromium, did you find any evidence of the  
11 threshold effect there?

12 DR. SCHAEFFER: With regard to dermal effects  
13 did you say?

14 DR. LURIE: Yes, that's the question.

15 DR. SCHAEFFER: No, we did not.

16 DR. LURIE: Okay. And with respect to the  
17 animal studies that were conducted, did you find any  
18 evidence of a threshold effect? Animal carcinogenicity  
19 studies.

20 DR. SCHAEFFER: No. No convincing evidence  
21 of a threshold.

22 DR. LURIE: Okay. And when the mechanistic  
23 studies were done, I'm using your term, was there any  
24 evidence of a threshold effect in the mechanistic  
25 studies of hexavalent chromium?

1 DR. SCHAEFFER: The mode of action study  
2 suggested that hexavalent chromium was a genotoxic  
3 agent, and that would lead us to believe it would not  
4 have a threshold in that case.

5 DR. LURIE: Okay. Based on the mechanistic  
6 studies?

7 DR. SCHAEFFER: Those kinds.

8 DR. LURIE: And based on the primary  
9 epidemiological studies upon which you relied, was  
10 there any evidence of a threshold effect?

11 DR. SCHAEFFER: Again, epidemiological  
12 evidence is generally not sufficient to establish  
13 whether there is a threshold.

14 DR. LURIE: Okay. So you didn't establish  
15 that there was one?

16 DR. SCHAEFFER: No.

17 DR. LURIE: Okay. Let me step into a  
18 different area then and ask you about the issues raised  
19 by Mr. Kojola.

20 I'm curious, when looking at other standards  
21 of this magnitude, comprehensive standards that involve  
22 not simply exposure monitoring, but also medical  
23 removal, hygiene, et cetera, et cetera, all the things  
24 in this lengthy Federal Register document, we're  
25 looking at standards of that magnitude.

1                   Has the Agency ever before had a standard in  
2                   which there was no requirement for either baseline or  
3                   follow up exposure monitoring? Has that ever happened  
4                   before?

5                   MS. EDENS:    Yes, the air contaminant  
6                   standard.

7                   DR. LURIE:    All right. Is that a standard of  
8                   the kind, would you say, here? That has the same  
9                   levels of complexity as this? Or is that just simply a  
10                  level that is established in the law?

11                  MS. EDENS:    It is a standard which covers a  
12                  number of different chemicals and sets permissible  
13                  exposure limits.

14                  DR. LURIE:    Okay. It is unusual though, is  
15                  that fair to say? I mean, one looks at lead, asbestos,  
16                  and so forth, it is rather common to have comprehensive  
17                  requirements for monitoring both the baseline and  
18                  follow up, right?

19                  MS. EDENS:    You are talking about for  
20                  construction? Or are you just talking about in the  
21                  general industry?

22                  DR. LURIE:    I'm talking in general when the  
23                  Agency regulates.

24                  MS. EDENS:    In the past, we have included  
25                  those provisions in our general industry standards.

1 DR. LURIE: Yes, you have. Okay. So, for  
2 example, in construction, for example, in the past it  
3 has been possible to require workplaces to monitor for  
4 lead, is that not correct?

5 MS. EDENS: We have an exposure monitoring  
6 requirement for lead.

7 DR. LURIE: In the construction standard?

8 MS. EDENS: In the construction standard.

9 DR. LURIE: Right. Yet you don't have that  
10 here as a requirement in --

11 MS. EDENS: We've made a preliminary  
12 determination not to require exposure monitoring in  
13 construction and shipyards, that's correct.

14 DR. LURIE: Right. But at least for some  
15 other metals, it was possible to do so, is that  
16 correct? Meaning lead.

17 MS. EDENS: Yes.

18 DR. LURIE: Okay. It's said that an employer  
19 can be exempted not only of follow up testing, but also  
20 even a baseline testing if they can produce "historical  
21 or objective data." I'm wondering what that means.

22 MS. EDENS: Historical or objective data?

23 DR. LURIE: Yes. I find that the Federal  
24 Register seems to be --

25 MS. EDENS: One is historical data. When

1 this standard comes into play, people may have already  
2 done exposure monitoring. If those exposure  
3 monitorings can pass, can accurately determine what the  
4 exposure is of the employees they have now, then the  
5 Agency would give them the latitude to use some of that  
6 information that has already been developed.

7 Objective data is data that may not be  
8 strictly, it can be data that has been developed say by  
9 a trade association that might say that this is  
10 reflective of the different kind of processes they  
11 might be able to do, some paperwork or analysis about  
12 their understanding of the chemistry involved in the  
13 processes to say that they could predict what the  
14 exposure levels were.

15 David, did you want to add something to that?

16 MR. O'CONNOR: No, I didn't really have much  
17 to add to that. Just that the historical monitoring  
18 was simply limited to the previous 12 months so that if  
19 an employer had done monitoring that was appropriate to  
20 characterize the exposures of individuals at the time  
21 this standard went into place, it wouldn't be necessary  
22 to immediately repeat that simply because the standard  
23 came into place.

24 DR. LURIE: If it used a different technique  
25 for measuring, for example, might the Agency accept

1 that?

2 MR. O'CONNOR: We weren't specifying a  
3 specific technique to be used, specific sampling and  
4 analytical method that would have to be used, so it is  
5 not necessarily something that would specify that  
6 nature of the exposure monitoring.

7 But we did have fairly specifically laid out  
8 criteria that would have to be met in order for  
9 previous monitoring to be considered sufficient to  
10 characterize exposures and be considered historical  
11 data.

12 DR. LURIE: I didn't see it specifically laid  
13 out, which is why I'm asking these questions. The lack  
14 of specificity seems to include using different  
15 monitoring tests, isn't that right? That might be  
16 acceptable to the Agency, is that correct?

17 MR. O'CONNOR: Well, our proposed  
18 requirements for exposure monitoring do not specify a  
19 particular test.

20 DR. LURIE: Right.

21 MR. O'CONNOR: We do indicate certain  
22 parameters that would have to be met in order for that  
23 particular analytical method to be considered  
24 appropriate. In order for the data to be accepted as  
25 historical exposure data, it would have to fall within

1 those parameters.

2 DR. LURIE: Okay. Let me ask you more about  
3 exposure assessment for a moment. It seems at least  
4 possible that if one were to take serial measurements  
5 in a workplace that you could get significant  
6 fluctuation within a workplace. That's after all why  
7 we do time weighted averages, right?

8 And so without reiterating the whole  
9 complexity of the Agency's plan for the action level  
10 and all that stuff, you all know that very well, I  
11 won't go through it. But it seems clear that if there  
12 is enough fluctuation in the measurements in a plant  
13 from say day to day or week to week, you could just  
14 through random fluctuation of the levels eventually hit  
15 a situation where you hit the action level, and then  
16 with repeat testing, evade all testing in perpetuity.

17 So my question then is has the Agency looked  
18 in any way at within company fluctuations to the point  
19 that they can tell us that these fluctuations are so  
20 small that simply random variations wouldn't after a  
21 time exempt certain industries or certain companies  
22 from monitoring whatsoever?

23 MR. O'CONNOR: Well, the action level itself  
24 is something that is based on OSHA's long experience  
25 with determining what an appropriate level would be in

1 order for the monitoring to indicate taking into  
2 account those day to day variations that you had  
3 mentioned, that if an exposure was measured to be below  
4 the action level, it could be reasonably believed that  
5 on other days, it would not exceed a PEL.

6 DR. LURIE: But what is that reason? I mean,  
7 why is it, and I understand the action level is half of  
8 what the PEL is, but how do we know that there is just  
9 not enough up and down that even if the average had  
10 been let's say above the PEL, that you might easily get  
11 a couple in a row that were under the action level, and  
12 that would be the end of testing?

13 MR. O'CONNOR: It is really based upon OSHA's  
14 long experience. There was a lot of information that  
15 went into that. But if there were some issue with the  
16 propriety of that proposed action level, we are  
17 certainly open to any alternative evidence that would  
18 point us in the direction of some other appropriate  
19 level.

20 MS. EDENS: I'm sorry. It is a longstanding  
21 OSHA policy to pick half the PEL, the action level.  
22 But it has been established in the industrial hygiene  
23 community, I mean, we can cite to some studies where  
24 they have done sampling. Basically they have chosen  
25 that level because of a statistical significance, and

1 that most industrial hygienists have applied this for  
2 many years in trying to determine when they can  
3 reasonably believe they're going to be below the PEL.  
4 They use half of whatever level they are concerned  
5 about.

6 DR. LURIE: The point that I'm making though  
7 is would it not be superior to have data specifically  
8 for hexavalent chromium and for specifically the  
9 affected industries? It is one thing to say that as a  
10 general matter, we know something about the fluctuation  
11 of chemicals in America, in occupational places.

12 My question is narrow, with respect to  
13 hexavalent chromium, might there not be enough  
14 variability from day to day that you might kick off the  
15 action level, even though a significant number of later  
16 measurements, which now no longer need to be taken,  
17 could in fact exceed even the PEL, let alone the action  
18 level?

19 MR. O'CONNOR: Certainly it's a possibility,  
20 but we don't have any information to indicate that that  
21 is actually the case.

22 DR. LURIE: Don't you think you should get  
23 it?

24 MR. O'CONNOR: Well, we would certainly  
25 welcome it if you have it to offer.

1 DR. LURIE: I certainly don't have it. You  
2 know that.

3 MR. O'CONNOR: We based our initial proposed  
4 action level upon our long experience, and I was going  
5 to mention as well some work that had been by Leidel  
6 and his associates at NIOSH I believe back in the 70s  
7 that those original action levels of half of a PEL were  
8 based upon.

9 Now, we have simply not seen anything to  
10 indicate that with regard to specific substances, such  
11 as hexavalent chromium compounds, that there is any  
12 difference between them and any other hazardous  
13 chemicals that we see in the workplace.

14 DR. LURIE: It almost has to be though,  
15 right? I mean, it all depends not only on the  
16 chemical, but upon the nature of the exposures, right?  
17 I mean, it just has to be different.

18 MS. EDENS: Well, I think we've laid out our  
19 position on the action level. It is well described in  
20 the preamble. If you have some suggestions about how  
21 we need to improve that, or what data we need to make  
22 the decisions that you feel are more appropriate, we'd  
23 be more than happy to listen to them and consider them  
24 for the final.

25 DR. LURIE: Right. Okay. That's the move on

1 answer. Very well, and so I will. Does the Agency  
2 have a basis for separately regulating different forms  
3 of hexavalent chromium? Or is the Agency's conclusion  
4 that for the purposes of this rulemaking, they can be  
5 considered to be equally carcinogenic?

6 MS. DOUGHERTY: Dr. Schaeffer?

7 DR. SCHAEFFER: There is data to suggest that  
8 there is a difference in carcinogenic potency among  
9 different chromates. But our risk assessments relied  
10 on workers exposed to highly soluble chromates that  
11 appear to be less potent than some chromates, and at  
12 least not more potent than others.

13 DR. LURIE: Right. So it is possible that  
14 the risk assessment upon which OSHA has relied are in  
15 fact conservative, is that fair to say?

16 DR. SCHAEFFER: Excuse me? Say that again.

17 DR. LURIE: That they in fact are  
18 conservative, in that they rely on the less  
19 carcinogenic chromates? It is certainly what the  
20 Federal Register seems to say.

21 DR. SCHAEFFER: Our preliminary determination  
22 is that workers exposed to other chromates and similar  
23 chromates in other industries would be of similar  
24 magnitude to the risks we predict, yes.

25 DR. LURIE: Yes, but could be larger?

1 DR. SCHAEFFER: It could be larger possibly  
2 for some chromates, yes, in some situations.

3 DR. LURIE: Okay. Thank you. Let me ask you  
4 about medical surveillance for a moment.

5 ADMINISTRATIVE LAW JUDGE VITTONI: Mr. Lurie,  
6 this will be your last question, sir.

7 DR. LURIE: Okay, then let me ask you a  
8 different question. As I read the Federal Register  
9 notice, what I hear is a situation in which by the  
10 Agency's own admission, "clearly significant risk  
11 remains, even at the PEL that is being exposed."  
12 Correct me if I'm wrong about that, and that the  
13 obstacle to going still lower are technical and  
14 economic issues.

15 What I see too is that on the economic level  
16 where the Federal Register is clearer, the fraction of  
17 workers exposed to hexavalent chromium for whom this  
18 would be an economic hardship, defined either as  
19 greater than 10 percent of profits, or 1 percent of  
20 income is actually very small.

21 So my question then is why, this really has  
22 two parts, why is this small number of workers and the  
23 small number of industries with a small number of  
24 processes used as a kind of lowest common denominator  
25 to set the PEL at one, when in fact the alternative

1 might be to go still lower, eliminate some of the, in  
2 the Agency's words, "clearly significant risk," and  
3 then treat those processes or industries separately  
4 under a SECAL?

5 MS. DOUGHERTY: Bob?

6 MR. BURT: Let me explain that the primary  
7 basis for going to one is an issue of technological  
8 feasibility, that it is specifically with respect to  
9 the estimate that when you get to .5, you are not going  
10 to have most operations most of the time able to meet  
11 the standard without the use of respirators in hard  
12 chrome electroplating, and in a number of kinds of  
13 welding.

14 These are two of the largest and most  
15 important sectors we are regulating. That was the  
16 basis for saying it is not technologically feasible.

17 DR. LURIE: May I ask what fraction of  
18 workers that is while you're on that.

19 MR. BURT: Yes?

20 DR. LURIE: May I ask what fraction of  
21 workers overall fall into the category that you say is  
22 not technologically feasible?

23 MR. BURT: That is given in the preamble. I  
24 can look it up and read it for you, but there is a  
25 question of how you measure a fraction. Because there

1 is the total number of employees, the total number of  
2 employees that actually have detectible exposure, there  
3 is total numbers that are currently above the various  
4 PELs. So it is a relatively small percentage of all  
5 exposed workers, but it is a very significant  
6 percentage of all the people who are exposed above one,  
7 and above .5 are in those sectors where we saw a  
8 technological feasibility problem.

9 Now, there remains the policy issue you  
10 brought up of how OSHA should react to that issue,  
11 whether it should have separate PELs, whether we should  
12 have SECALs for specific industries. These are both  
13 approaches OSHA has used in the past.

14 We preliminarily came forward with a standard  
15 that had a PEL of one because these were, in our view,  
16 important sectors, and for the administrative  
17 simplicity of having one PEL across all industries.  
18 But this is an area in which we have explicitly sought  
19 comment and welcomed comment on all sides as to how  
20 best to approach the very difficult issue of we have  
21 some important areas where it is not technologically  
22 feasible, and we have significant risk at that level.

23 DR. LURIE: I'm just curious what process the  
24 Agency might use to determine this. I mean, clearly if  
25 90 percent of people were working in areas with high

1 | exposures of where it was technologically infeasible,  
2 | one can understand the usefulness of having a single  
3 | standard in some way putting the 10 percent of people  
4 | aside.

5 |           But when in fact it is a minority of workers,  
6 | I'm curious what approach the agency might use in  
7 | establishing that a SECAL might be the way to go, the  
8 | way it was in cadmium, for example.

9 |           MR. BURT: Well, I think we are looking at a  
10 | much higher percentage of the workers who were actually  
11 | exposed at levels above .5 and above one in these than  
12 | we were in cadmium, where we picked off very specific  
13 | operations and said it might not be feasible here.

14 |           Here we are looking at some entire and  
15 | important sectors which form a considerable portion of  
16 | those exposed at significant levels of hexavalent  
17 | chromium. That was our preliminary reasoning on this.

18 |           ADMINISTRATIVE LAW JUDGE VITTON: Thank you,  
19 | Mr. Lurie.

20 |           The gentleman here with his hand up. Did  
21 | anybody else have their hands up to ask questions? Can  
22 | I see a show of hands?

23 |           MR. SCHNEIDER: Thank you very much. My name  
24 | is Scott Schneider, and I'm with the Labors' Health and  
25 | Safety Fund of North America.

1 ADMINISTRATIVE LAW JUDGE VITTONI: Okay.

2 MR. SCHNEIDER: I had a couple of questions.  
3 In the preamble on page 59,437, you talk about the cost  
4 of adding wet cement to the scope of standard at \$33  
5 million per year.

6 How was that cost derived? Was that cost  
7 based on the proposal that the ACCSH had developed as  
8 to which provisions would be applicable and which ones  
9 would not?

10 MS. DOUGHERTY: Mr. Burt?

11 MR. BURT: I believe that estimate, though  
12 I'd need to check, is based on needing to comply with  
13 the major provisions of the standard. I don't think we  
14 did a process of exempting some of them. We said some  
15 of them might be very small because you don't need  
16 exposure assessment, for example.

17 MR. SCHNEIDER: So you did not look at the  
18 ACCSH proposal and use that to develop your estimates?  
19 Is that what you're saying?

20 MR. BURT: I believe we used the proposal we  
21 had and developed it from there.

22 MR. SCHNEIDER: Okay. You also here state  
23 that the cost of addressing the problem through  
24 existing standards would be \$80 to \$300 million, or  
25 about three to nine times higher than adding it to the

1 standard. So how did you balance that out?

2 MR. BURT: I'm sorry. We seem to have been  
3 confusing there. The \$33 million is the additional  
4 cost. The \$80 to \$300 are the costs that are incurred  
5 to give everybody in the industry the protective  
6 clothing they need.

7 The \$33 million is the additional cost of  
8 having this standard in place and having to do things  
9 that aren't directly related to providing the proper  
10 protective equipment.

11 MR. SCHNEIDER: I'm really confused, because  
12 it says, "The cost of addressing the problem through  
13 existing standards," in other words, standards that  
14 already exist on the books like the hygiene standard,  
15 et cetera, "are from \$80 to \$300 million a year."

16 What you are saying is this would be \$33  
17 million on top of that, right?

18 MR. BURT: Yes, that's correct.

19 MR. SCHNEIDER: Okay. But that didn't follow  
20 the ACCSH proposal I guess. Okay.

21 The second question I have is you say that  
22 there is a discussion here about the addition of  
23 ferrous sulfate to cement, and how that could  
24 conceivably address the problem.

25 Did you consider that in your regulatory

1 analysis as to what the cost of that would be, and the  
2 amount of benefits that would save?

3 DR. SCHAEFFER: No, we did not. We discussed  
4 it as a possibility, but did not attempt to cost it out  
5 and determine its benefits. We discussed also what  
6 some of the European experience has been, where it  
7 seems to have had some effect, I believe about 10  
8 percent or so, 10 to 20 percent lowering of dermatitis  
9 cases. But we cite some specific European studies, but  
10 we didn't try to quantify that in the context of our  
11 analysis.

12 MR. SCHNEIDER: Okay. Thank you very much.

13 ADMINISTRATIVE LAW JUDGE VITTON: Thank you.  
14 Ladies and gentlemen, we're going to take a short break  
15 here for about 10 minutes.

16 But before we do that, I have been asked to  
17 make some housekeeping comments. First of all, please  
18 pay attention to the doors that have emergency exit  
19 signs over them in case we need to use them. Hopefully  
20 we won't. They're located in the back and the front.

21 Cafeteria when we break for lunch is up on the  
22 sixth floor. The bathrooms I think are back in that  
23 direction down the hallways, but I'm not absolutely  
24 sure. But they're back there, you'll find them.

25 We are going to take a short break. We'll be

1 back at 11:15.

2 **(Whereupon, a brief recess was taken.)**

3 ADMINISTRATIVE LAW JUDGE VITTON: Ladies and  
4 gentlemen, if you could take your seats, please.

5 Ladies and gentlemen, I think I got through everybody  
6 who had their hands up, but let me make sure. Anybody  
7 else want to do some questioning? This lady over here.  
8 Is there anyone else? Go ahead up to the podium? Is  
9 there anyone else?

10 MS. DRUMMOND: Thank you, Your Honor.

11 ADMINISTRATIVE LAW JUDGE VITTON: Just a  
12 second.

13 MS. DRUMMOND: Oh, I'm sorry.

14 ADMINISTRATIVE LAW JUDGE VITTON: I'm sorry.  
15 I didn't realize all of the panel was not here. All  
16 right. Go ahead.

17 MS. DRUMMOND: I'm Anita Drummond with  
18 Associated Builders and Contractors. I just had a  
19 couple of practical questions. This has to do with the  
20 construction regulation in 1926.

21 The work and engineering controls are provided  
22 for in order to come under the PEL if possible,  
23 supplemented by respirator, if necessary. In most  
24 standards, and I'm challenging my brain to think of  
25 another, but like in lead, rotation is a normal

1 practice, particularly in construction where  
2 engineering controls are very difficult to contained  
3 air space. We were trying to determine why rotation  
4 was prohibited in the hexavalent chromium rulemaking.

5 MR. O'CONNOR: Worker rotation is prohibited  
6 as a means of achieving the PEL. It is a situation  
7 where we don't want people to rotate workers simply to  
8 avoid implementing the engineering work practice or PPE  
9 controls that would be necessary in order to protect  
10 those workers.

11 Because in the case of a carcinogen like  
12 hexavalent chromium, all you would be doing is  
13 spreading the risk in more workers in doing so. We are  
14 not looking to prohibit worker rotation when it is  
15 implemented for any other reason.

16 MS. DRUMMOND: Let me ask this. If you  
17 envisioned a schematic where engineering controls were  
18 not feasible, and this is particularly true in  
19 construction where you don't have a static workplace,  
20 you can't control the air like you would say in a  
21 regulated area, so the next step is to use respirators,  
22 or you are going to use PPE, but you're going to rotate  
23 workers in order to minimize their exposure to PEL.

24 What you've just said is you don't want to  
25 expose more workers. So instead of exposing one worker

1 to intensive hex chrome, you are kind of balancing  
2 against four workers, I'm just using, that would be  
3 exposed to hex chrome, but they all would be under the  
4 PEL.

5 MR. O'CONNOR: What we are saying is that it  
6 is not appropriate to try to get under the PEL by doing  
7 that worker rotation, because even if you got to a  
8 level below the PEL through worker rotation, you  
9 wouldn't be eliminating the risk through that. You  
10 would still have these people who were exposed possibly  
11 below the PEL, but still at risk of cancer.

12 Spreading that among many people rather than  
13 concentrating it in a single individual really negates  
14 the benefit of the rule.

15 MS. DRUMMOND: I understand what you're  
16 saying. But what if engineering controls are not  
17 possible to control it and you are using other means?  
18 I mean, your objective is still to get these folks  
19 under the PEL.

20 MS. EDENS: In the example that you just laid  
21 out, I believe I understood you to say that they were  
22 in excess of the PEL and were requiring respiratory  
23 protection.

24 MS. DRUMMOND: Right.

25 MS. EDENS: So this rotation is meant to be

1 prohibited where people are trying to get under the  
2 PEL.

3 MS. DRUMMOND: And they are not using a  
4 respirator, for instance.

5 MS. EDENS: Exactly.

6 MS. DRUMMOND: Okay.

7 MS. EDENS: Because what we're saying in the  
8 preamble as we laid it out, the PEL has been set at a  
9 feasible level, and that under the PEL there are still  
10 remaining risks. So we wouldn't want people to try to  
11 put people in who are just about at the PEL and then  
12 take them out and then put somebody else in so that  
13 their 8-hour time weighted average is under the PEL.  
14 That is what we don't want to happen.

15 If people are doing rotation because there is  
16 a certain batch process, or they have certain business  
17 needs to rotate people out because people get sick or  
18 whatever --

19 MS. DRUMMOND: Or it might be the practice of  
20 the work because you don't want a welder in for eight  
21 hours. You want a welder in for two hours for some  
22 other conditional reason, or they have other workers.

23 MS. EDENS: As long as it is not to achieve  
24 the PEL.

25 MS. DRUMMOND: Okay. And the second question

1 is really for Bob Burt. Did you take into  
2 consideration in the economic analysis, and we were  
3 talking back in the back, no one could determine  
4 whether there was a calculation. We didn't recall  
5 seeing a calculation for welder's respirators, which  
6 are significantly more expensive than normal  
7 respirators.

8 A welder does not use the same type of  
9 respirator generally. It can cost upward of \$200 or  
10 \$300.

11 MR. BURT: I don't recall if we did that. I  
12 don't think we did, and we would welcome comments on  
13 that issue.

14 MS. DRUMMOND: Okay. Thank you.

15 ADMINISTRATIVE LAW JUDGE VITONE: Thank you,  
16 Ms. Drummond. Last time. Anybody else who has not  
17 asked questions? Okay. Well, we have some extra time,  
18 so why don't we make use of it? Those people who have  
19 already asked questions but did not get all of their  
20 questions in, would they like to come forward and ask  
21 some additional questions up until the time we break  
22 for lunch? Can I see a show of hands?

23 With the understanding, Mr. Sessions, we don't  
24 have eight hours. Okay. I see one, two, Mr. Lurie,  
25 okay. All right. Anyone else? Because I'm going to

1 divide the time up with people who have just raised  
2 their hands. Three people, so I'll give each of you  
3 about ten minutes. I might make it a little less,  
4 depending upon where we are. Okay. We'll start with  
5 Mr. Lurie. Now you can ask your doctor question.

6 DR. LURIE: And I will. The question is  
7 about medical surveillance. As I understand this  
8 correctly, were a worker in the general industry to  
9 exceed the PEL, they would become subject to medical  
10 surveillance. That's right, isn't it?

11 MS. EDENS: More than 30 days above PEL.

12 DR. LURIE: For more than 30 days. Right,  
13 exactly. Yet if the same thing happened to somebody in  
14 the shipyard or in construction, there would be no  
15 requirement for that, is that correct?

16 MS. EDENS: That's correct.

17 DR. LURIE: Can you explain that to me? Same  
18 exposure, same risk, same chemical, different medical  
19 surveillance. Why would that be?

20 MS. EDENS: In the preamble, the discussion,  
21 I'm sure you've read it. What we said there was we  
22 have not required exposure monitoring in construction  
23 and shipyards. Therefore, one of the problems with  
24 trying to enforce a value above the PEL of 30 days, it  
25 would almost force them back into doing exposure

1 monitoring.

2 We were trying to relieve the burden of  
3 exposure monitoring in these two industry sectors. So  
4 that if an employer had to go back and calculate the  
5 employees who had 30 days, you basically would be  
6 forced back into doing exposure monitoring, which would  
7 be different from somebody who is just doing general  
8 exposure monitoring to make sure they are below the  
9 PEL. This would have to be done per person to figure  
10 out which ones were above it. So that was the  
11 rationale we laid out in the preamble.

12 DR. LURIE: So the rationale then is not  
13 based upon any medical need, because after all, the  
14 medical needs are the same. The rationale is rather  
15 based on the agency's desire to not conduct exposure  
16 monitoring in shipyards and construction.

17 MS. EDENS: That's right.

18 DR. LURIE: Okay. That's all. Thanks.

19 ADMINISTRATIVE LAW JUDGE VITTONE: Thank you,  
20 Mr. Lurie.

21 Ms. McMahon?

22 MS. MCMAHON: Thank you, Your Honor.

23 ADMINISTRATIVE LAW JUDGE VITTONE: You're  
24 welcome.

25 MS. MCMAHON: I have two questions. One

1 relates to the solubility of hexavalent chromium  
2 compounds issue, and the other relates to feasibility  
3 and enforcement. So why don't I ask the latter first.

4 Ms. Sherman, in terms of enforcement of the  
5 standard ultimately, what I'm wondering about is what  
6 happens when OSHA goes to a work site to determine  
7 whether they are in compliance with the standard and  
8 the engineering controls that have been identified in  
9 the feasibility analysis here are not in place. They  
10 have been determined already to be feasible under this  
11 rulemaking, but this company can demonstrate on an  
12 individual basis that they would not be economically  
13 feasible to implement at that one site for a variety of  
14 reasons that could be demonstrated at that point.

15 What would OSHA's position be in terms of  
16 whether the company had properly taken all steps to  
17 comply with the engineering control requirements to the  
18 extent feasible and then rely on respirators to bring  
19 the exposures under the PEL?

20 MS. SHERMAN: Okay. I will try to answer  
21 this question. First of all, I'm not going to put  
22 words in the compliance officer's mouths or heads.  
23 Generally speaking, we make a showing of feasibility  
24 for the industry as a whole, industry sectors as a  
25 whole as part of the rulemaking.

1                   However, when the CSHO, or Compliance Safety  
2 and Health Officer, comes to a work site, he or she  
3 looks at the particular situation at the work site and  
4 makes a determination on that work site as to what is  
5 feasible and what is not feasible.

6                   MS. MCMAHON: I'm sorry. Is that from both a  
7 technological as well as an economic feasibility  
8 standpoint?

9                   MS. SHERMAN: I believe that they can take  
10 both into consideration. However, the employer has an  
11 opportunity in the closing conference and at other  
12 points in the proceeding to talk to the compliance  
13 officer about what is or is not going on.

14                   It can also be raised later on, if the  
15 compliance officer is not convinced, as an affirmative  
16 defense in the particular citation proceeding. Just a  
17 minute, let me further gather my thoughts.

18                   Also any individual employer has an ability to  
19 apply for a variance at any point after a final  
20 standard would go into effect. There may be other  
21 methods that the particular employer could consider in  
22 meeting the requirements of the standard.

23                   MS. MCMAHON: I guess what I'm trying to get  
24 at, and I don't want to belabor this, and I'll move on  
25 shortly. But what I'm trying to get at is let's assume

1 that it is possible that the feasibility analysis  
2 conducted by OSHA in this rulemaking is in error for at  
3 least a particular industry.

4 So determinations that that industry could  
5 comply with the proposed standard are feasible, are  
6 actually incorrect, either technologically or  
7 economically. This particular industry meets the  
8 feasibility standard that OSHA has set out, or has been  
9 set out in the case law.

10 The rule is implemented nevertheless and  
11 promulgated. Later on from an enforcement standpoint,  
12 I'm wondering if that company, an individual company in  
13 that industry can rely on a feasibility argument to  
14 defend against implementing the engineering controls  
15 that are identified in the feasibility analysis.

16 MS. SHERMAN: The general feasibility finding  
17 is not subject to review by a review commission judge  
18 based on an industry sector. However, in terms of the  
19 individual work site visited, there can be feasibility  
20 concerns taken into consideration in the context of the  
21 individual citation. But you do not raise the total  
22 feasibility determination of the entire standard in  
23 front of a Review Commission judge.

24 In other words, we have a general duty to  
25 defend the feasibility of a standard if somebody should

1 challenge a final rule in the Court of Appeals. Once  
2 the court has passed on this argument and the standard  
3 would be allowed to go into effect, an individual  
4 employer in the context of an individual inspection  
5 might have an opportunity to raise a feasibility issue  
6 just for his own work site.

7 MS. MCMAHON: In defense of failure to  
8 comply?

9 MS. SHERMAN: In defense of failure to  
10 comply. I think Ms. Thurber would like to add  
11 something.

12 MS. THURBER: Let me just add one thing. I  
13 think an employer who relies at that stage on making  
14 that employer's own determination on feasibility is  
15 probably doing so at his or her peril.

16 I think the challenges that have come up on  
17 feasibility have come up in the Court of Appeals in the  
18 lawsuits against the major standards. The time to  
19 bring up feasibility issues is now. Bob Burt is  
20 collecting a great deal of material, and I know, Ms.  
21 McMahan, you have worked for at least the last couple  
22 of years in trying to help us find more material.

23 Once OSHA passes the standard, makes its  
24 feasibility determinations, if you have technological  
25 infeasibility truly, then your route is a variance. To

1 get that is rather complicated, time is ticking, and it  
2 has a whole set of rules attached to it. The time for  
3 economic feasibility is now. This is not an  
4 enforcement panel.

5 MS. EDENS: It has come up in a number of  
6 other -- I mean, I'm sure that there have been a number  
7 of final rules that OSHA has passed that maybe someone  
8 didn't agree with the final analysis, but the  
9 opportunity to decide site by site during inspections  
10 has always been there. The variance process is in  
11 place for just that. We don't anticipate that the  
12 process for chromium would be any different than what  
13 we have for other final standards that the Agency has  
14 issued.

15 MS. MCMAHON: And Ms. Edens, would you see  
16 that the variance process would be available on an  
17 economic feasibility argument?

18 MS. EDENS: I'm not a variance expert, so I  
19 really couldn't answer that question.

20 MS. MCMAHON: Ms. Sherman?

21 MS. SHERMAN: I believe that the Act speaks  
22 for itself. I believe that the Act talks about the  
23 burden being that what you are doing is "as safe as."  
24 I'm talking about a permanent variance and not a  
25 temporary variance, which is a different standard of

1 review.

2 MS. MCMAHON: Thank you. On the issue of the  
3 solubility of hexavalent chromium compounds, Dr.  
4 Schaeffer, as I'm sure you're aware, in the preamble  
5 there is some recognition that there are various  
6 carcinogenic potentials associated with different  
7 hexavalent chromium compounds. The Agency seems to  
8 recognize, and maybe I'm putting words in the Agency's  
9 mouth, and I don't mean to do that, but it seems to  
10 recognize that there might be some basis to regulate on  
11 that basis.

12 My question is twofold. One, what is the  
13 Agency's view of the strength and soundness of the  
14 scientific work on the distinction between the  
15 hexavalent chromium compound's carcinogenic potential  
16 first?

17 DR. SCHAEFFER: We do think that there is  
18 animal evidence in which these highly soluble chromium  
19 compounds cause less tumors than other chromates under  
20 the same dosing regime. We do believe on a qualitative  
21 basis that it appears that those chromates are more  
22 potent than the highly soluble chromates.

23 MS. MCMAHON: So aside from there possibly  
24 being a time restriction, would there be any reason to  
25 not regulate on the basis of the various hexavalent

1 chromium compounds?

2 I recognize the time restrictions you all are  
3 under, and it sounded from what was said in the  
4 preamble as if that might be at least part of what may  
5 be going on here.

6 MS. EDENS: I think we laid out in the  
7 proposal, as Dr. Schaeffer mentioned, that there are a  
8 fair amount of studies that one, establish that all of  
9 the compounds we believe are credible, that they are  
10 carcinogenic. There are also individual studies that  
11 show that there seems to be some differences in those  
12 potencies.

13 The difficulty is that the types of studies  
14 that you need to develop separate PELs for all those  
15 different compounds simply doesn't exist. So if we had  
16 10 more years to do all of the bioassays on all of the  
17 different compounds, perhaps the Agency might be able  
18 to do that.

19 But we believe based on the analysis that  
20 we've done that we have a very credible, at least we've  
21 made a credible preliminary determination that would  
22 support having all of the chromate compounds treated  
23 under one PEL at this point.

24 MS. SHERMAN: I think it's important to  
25 emphasize in Ms. Edens answer that we are basing our

1 analysis on the evidence that exists now.

2 MS. MCMAHON: The Agency would be open to  
3 further support for the presumption that there ought to  
4 be a regulatory distinction between the various  
5 compounds of hexavalent chromium?

6 MS. EDENS: We've laid out our position that  
7 one PEL should cover all. We realize that some people  
8 have made some different suggestions, and we're taking  
9 those seriously and looking for the data that people  
10 think that we could use to make those sorts of  
11 determinations and defend a final standard on it.

12 MS. MCMAHON: And do you believe that the  
13 data that you would need, would animal studies be  
14 sufficient?

15 MS. EDENS: Well, I don't know that I can sit  
16 here right now and lay out a research perspective about  
17 what I would need to do that. I think at this point we  
18 have decided that we don't have sufficient information  
19 to do it now.

20 If you wanted us to sit down and do that, it  
21 would take awhile to figure out what would be the  
22 appropriate studies to do in the way that we could  
23 legally defend separate PELs for separate compounds.  
24 Accordingly, we would then have to do separate economic  
25 analyses on the different ones, because obviously we

1 haven't necessarily fractioned out our economic  
2 analysis on the feasibility of I don't know how many  
3 different chromic compounds there are, but there are  
4 multiple compounds.

5 MS. MCMAHON: Thank you. Your Honor, just  
6 one housekeeping question. I was under the impression  
7 there would be a report or a transcript. Is that  
8 occurring?

9 ADMINISTRATIVE LAW JUDGE VITTONI: Yes, it  
10 is.

11 MS. MCMAHON: Okay.

12 ADMINISTRATIVE LAW JUDGE VITTONI: The  
13 reporter is in the glass booth in the back making a  
14 transcript. The transcript will be available.

15 MS. MCMAHON: Thank you.

16 ADMINISTRATIVE LAW JUDGE VITTONI: You're  
17 welcome. I'm sorry, I should have said that.  
18 Everything is being transcribed. Even though the  
19 reporter is not up here, she's back there recording it.

20 MS. SHERMAN: In answer to your earlier  
21 question, Ms. McMahon, I would refer you to Section 7D  
22 of the Act on variances.

23 ADMINISTRATIVE LAW JUDGE VITTONI: Okay. Mr.  
24 Sessions?

25 MR. SESSIONS: Thank you. I am sorry to

1 | pursue a number of additional smaller issues.

2 |           OSHA does an analysis of impacts on small  
3 | entities and small facilities, as is required by  
4 | SBREFA. I wonder how OSHA considered the different  
5 | financial characteristics and ability to pay of smaller  
6 | entities in the electroplating sector relative to  
7 | larger entities.

8 |           MR. BURT:   Basically we did three things.  
9 | First, we analyzed the industry as a whole in terms of  
10 | cost as a percentage of the profits, and as a  
11 | percentage of revenues.

12 |           We then also broke out the small firms as  
13 | defined by SBA, and then further broke out and did the  
14 | same kind of analysis of firms of establishments with  
15 | less than 20 people.

16 |           In each case, we did first a screening  
17 | analysis which just looked at the cost as a percentage  
18 | of revenues and profits, and in cases where these were  
19 | relatively small, that was the end of the argument. In  
20 | the case of electroplating, this was not the case, at  
21 | least in portions of the electroplating sector. There,  
22 | we considered some of the variations that have taken  
23 | place over time in costs of various kinds of  
24 | electroplating services and concluded that this was  
25 | within the range of the kinds of experiences the

1 industry has had with costs, with fluctuations in  
2 costs, and changes in costs such that it wouldn't  
3 change the competitive structure of the industry.

4 As to a specific differential between small  
5 and large firms that they I believe had a somewhat  
6 higher percentage of costs as a percentage of profits  
7 and revenues, we did not go further than that.

8 MR. SESSIONS: I recollect that you assumed  
9 that both revenues and profits were proportional to  
10 employment. If you had twice as many employees, you  
11 had twice as many revenues or costs. I believe that  
12 the result of that was that you ended up projecting the  
13 same amount of revenues per employee for small  
14 businesses as for large, and you projected the same  
15 level of profits as a share of revenues for small  
16 businesses as large, is that correct?

17 MR. BURT: The profit as a percentage of  
18 revenues I'm pretty sure we did not distinguish between  
19 large and small. The data is very tricky there, and it  
20 seemed best to use an industry average.

21 The projection of revenues for small firms I  
22 would need to check. I thought we made use of some of  
23 the SBA data and only used employment when we got to  
24 distinguishing very small firms against small  
25 businesses in general.

1                   MR. SESSIONS: I think the outcome was that  
2 you projected that profits as a share of revenues were  
3 6.3 percent for both large businesses and identically  
4 so for small businesses. I wonder if you checked those  
5 estimates for both large and small businesses against  
6 generally available data from places like Dunn and  
7 Bradstreet or Risk Management Associate statement  
8 studies, and how does that 6.3 percent profit margin  
9 for both large and small businesses compare with  
10 figures in generally available sources?

11                   MR. BURT: I believe in that section we used  
12 data from IRS, and we did not compare it to other  
13 sources. We would welcome such a comparison if you  
14 would like to introduce it for the record, or the  
15 suggestion that we make a further comparison.

16                   MR. SESSIONS: Okay.

17                   MR. BURT: As you may know, profit to data is  
18 quite difficult and quite different from data source to  
19 data source. We chose the IRS because it is the most  
20 complete and thorough as against Dunn and Bradstreet,  
21 which has a very small and very arbitrary sample of  
22 firms involved.

23                   MR. SESSIONS: We can talk about that. Let's  
24 see. I would be interested in knowing specifically  
25 which IRS, there are many lines of data in the IRS

1 source you cited, which particular definition of  
2 profits you chose, and for which particular industry  
3 you chose the data with which to represent the  
4 electroplaters.

5 The job shop electroplaters are a six digit  
6 NAICS code, and I don't believe the IRS data goes to  
7 the six digit level.

8 MR. BURT: This is another problem that you  
9 have to project downward from larger sectors to the  
10 sectors we sometimes want to use.

11 MR. SESSIONS: Okay.

12 MR. BURT: This is always an issue in these  
13 rulemakings. For example, we certainly don't have hard  
14 chrome separated from other kinds of electroplaters.  
15 It is a difficulty that we need to extrapolate the  
16 profits data from the best available data we can find.  
17 If there is better data introduced into the record,  
18 we'd be delighted to use it.

19 MR. SESSIONS: Okay. And I'm happy to  
20 introduce better data. But to do that, I need to  
21 understand exactly where you got your data. Exactly  
22 which line of the IRS data you chose, and which  
23 industry you chose to represent electroplaters with.  
24 Those facts are not present in the economic analysis,  
25 or in the support material.

1 ADMINISTRATIVE LAW JUDGE VITTON: Question,  
2 Mr. Sessions?

3 MR. SESSIONS: Yes. Which exact line of the  
4 IRS data did you choose to represent profit?

5 DR. BLICKSILVER: This is Dr. Blicksilver.

6 MR. SESSIONS: And which particular industry  
7 did you pull the data from?

8 DR. BLICKSILVER: Okay. The data were taken  
9 from the IRS Corporation source book, and the lines we  
10 used were total receipts for revenues and net income  
11 for profit. Both are pre-tax.

12 MR. SESSIONS: Okay. And which industry did  
13 you pull the data from with which you represented  
14 electroplaters?

15 DR. BLICKSILVER: The NAICS codes are 331,  
16 332, 333, 336, 339. There were some larger categories  
17 as well that included other NAICS codes. Where those  
18 were taken, they were scaled down according to the  
19 number of employees estimated within those refined or  
20 narrower NAICS codes.

21 MR. SESSIONS: So if electroplaters  
22 constituted 5 percent of the employment in those summed  
23 NAICS codes you recited, you attributed to  
24 electroplaters 5 percent of the revenues and profits?

25 DR. BLICKSILVER: Where a six-digit NAICS was

1 a certain percentage of the larger NAICS, of a three or  
2 four digit, then it was scaled down, yes, according to  
3 the percentage of employment.

4 MR. SESSIONS: So where I'm going with this  
5 set of questions is is your projection for both large  
6 and small electroplaters was identical, and it was that  
7 they earned 6.3 percent of annual revenues as profits  
8 in a typical year. That's the basis on which you did  
9 your economic analysis.

10 There are easily available data from census  
11 and other places to the effect that small businesses in  
12 the electroplating sector earn far less in the way of  
13 revenues per employee than do large businesses, and far  
14 less in terms of profits per share of revenue.

15 ADMINISTRATIVE LAW JUDGE VITTONI: Mr.  
16 Sessions, you're running out of time. So if there is a  
17 question, I'd like for you to get to it.

18 MR. SESSIONS: Okay. What level of impact in  
19 terms of annualized compliance cost as a share of  
20 revenues and as a share of profits would give you worry  
21 about economic feasibility?

22 MR. BURT: We don't have a hard and fast  
23 line, because it requires analysis of the individual  
24 industry. We use for purposes of regulatory  
25 flexibility analysis a rule that more than 5 percent of

1 profits or 1 percent of revenues deserves further  
2 attention and analysis. But we then don't have a  
3 cutoff that says oh, at 20 there is a problem or at 30  
4 there is a problem. Instead, it then becomes a matter  
5 of looking at the available data about that industry,  
6 and what has happened to the industry, what might be  
7 their ability to pass costs on, what has been their  
8 historical experience in that respect.

9 So there isn't a hard and fast line.  
10 Certainly as an increase in the percentage of costs as  
11 a percentage of profits or revenues raises increasing  
12 issues.

13 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you,  
14 Mr. Sessions.

15 MR. SESSIONS: Thank you.

16 ADMINISTRATIVE LAW JUDGE VITTONI: I just  
17 want to make sure nobody else has their hand up. Okay.

18 Ladies and gentlemen, we're going to break for  
19 lunch and return at 1:00. This afternoon we have two  
20 experts from OSHA, Mr. Gibb and Mr. Clewell. We will  
21 resume at 1:00 in this room. Thank you very much.

22 MS. SHERMAN: Your Honor, I would like to  
23 introduce Ms. Dougherty's statement as 44-3.

24 ADMINISTRATIVE LAW JUDGE VITTONI: Okay.  
25 That will be received into the record in this

1 proceeding. All right.

2 (Whereupon, Exhibit Number 44-3 was marked for  
3 identification and admitted into the record.)

4 (Whereupon, a lunch recess was taken.)

5 ADMINISTRATIVE LAW JUDGE VITTONI: We resume  
6 our hearings this afternoon. Our first witness is Mr.  
7 Herman Gibb. Dr. Gibb is from Science International  
8 Incorporated. Thank you, Dr. Gibb. Do you have a  
9 prepared statement you're going to make first?

10 DR. GIBB: I was just going to describe the  
11 study. I have submitted a statement that everybody  
12 has.

13 ADMINISTRATIVE LAW JUDGE VITTONI: Okay. It  
14 is in the record.

15 DR. GIBB: I was just going to sort of do a  
16 cursory review of that.

17 ADMINISTRATIVE LAW JUDGE VITTONI: That would  
18 be appreciated. Thank you.

19 DR. GIBB: Thank you.

20 ADMINISTRATIVE LAW JUDGE VITTONI: Ms.  
21 Sherman, do you have anything before we get started  
22 that you need to raise?

23 MS. SHERMAN: No, I don't, Your Honor.

24 ADMINISTRATIVE LAW JUDGE VITTONI: Okay. All  
25 right. Dr. Gibb, you may begin.

1                                    **DIRECT STATEMENT OF OSHA EXPERT WITNESS**

2                    **By Dr. Gibb, Sciences International, Incorporated**

3                    DR. GIBB:    Okay.    I am Herman Gibb, I'm the  
4 author of one of the primary studies that is being used  
5 by OSHA for this proposed PEL.    The study was a study  
6 of chromate production workers at a plant in Baltimore,  
7 Maryland.

8                    We had extensive exposure measurements and we  
9 found certainly a significantly elevated risk of lung  
10 cancer in the plant, and we found an exposure response  
11 among the workers there for lung cancer.

12                    To give you an idea of what my background is,  
13 I currently work at Sciences International, which is a  
14 consulting company in Alexandria, Virginia.    I began  
15 there in January of 2004.    Prior to that, I spent over  
16 25 years at the U.S. Environmental Protection Agency  
17 where I was a risk assessor.    I was at the National  
18 Center for Environmental Assessment at EPA.    I was the  
19 Associate Director for Health at the National Center  
20 for Environmental Assessment, and held other positions  
21 as Assistant Center Director, I was a staff  
22 epidemiologist.

23                    I have a Ph.D. in epidemiology, I have a  
24 Master's Degree in environmental health.    I have  
25 considerable background in metals, risk assessment,

1 particularly chromium, arsenic, nickel, copper,  
2 mercury, that I did for the Agency.

3 I have had considerable experiences in risk  
4 assessment I think internationally and nationally as a  
5 consultant in serving on a number of international  
6 committees, particularly with the World Health  
7 Organization. I have been a consultant to foreign  
8 governments on metal exposures.

9 So let me tell you a bit about the study.  
10 Again, there is a prepared statement which I noticed  
11 was on the table outside. I'll briefly review the  
12 study and what we did.

13 When I was at EPA, I was part of the  
14 assessment of chromium. I think it was probably in the  
15 late 1980s. At that time, we relied on the Mancuso  
16 study of chromate production workers at Painesville,  
17 Ohio. That was the best data that we had available.  
18 But when we did the assessment, there were a number of  
19 comments made by industry regarding our assessment.

20 One is that these workers were believed to  
21 have smoked a lot, and we had no information on the  
22 smoking at the Painesville plant. Another was that  
23 they believed that the exposures were much greater at  
24 Painesville. Mancuso had used some industrial hygiene  
25 data from 1949 to estimate what the exposures were.

1 This cohort in Painesville, Mancuso's cohort, began  
2 between '31 and '37, so we didn't know how -- if the  
3 exposures were much greater.

4 We made some assumptions, and then we  
5 discovered that there was some data, exposure  
6 information for a plant in Baltimore. There had been a  
7 study of the Baltimore plant, an epidemiology study,  
8 and that was by Hayes, et al., but they didn't have  
9 exposure information. So we began to explore around  
10 and discovered there was a considerable amount of  
11 exposure information. Not only was there a lot of  
12 exposure information, but there was also smoking  
13 information for the cohort.

14 So what we did was we used essentially Hayes'  
15 cohort, but we modified it. We modified it so that we  
16 only included workers that started there after I  
17 believe it was August 1, 1950. On that date, there was  
18 a new plant begun, and it was sort of a state-of-the-  
19 art plant, and I wanted to get only workers starting in  
20 the new plant.

21 The company, and this is a considerable  
22 advantage to this study, the company at that time  
23 wanted to get exposures that were representative of  
24 what a worker did. A lot of times industrial hygiene  
25 is done so that you look at hot spots, where the

1 problems are. But in this particular plant, they  
2 wanted to get what was a typical exposure. So they  
3 began to take a considerable amount of exposure data.

4 They also did time and motion studies, so they  
5 knew that if a worker had a particular job, that that  
6 worker would spend so much of his time in this part of  
7 the plant, and then would move to another part of the  
8 plant. So if you spent 80 percent of your time in this  
9 area, and 20 percent in this area, then your exposure  
10 was weighted by how much time you spent in each area.

11 Another considerable advantage to this study  
12 is that the exposure measurements here, unlike the  
13 Mancuso study, here we had exposure measurements that  
14 were through the entire time that the cohort worked  
15 there. So we didn't have to guess at what might have  
16 been the exposures at a previous time.

17 We had over 70,000 exposure measurements.  
18 Actually it was considerably more than that, but there  
19 was at least 70,000 exposure measurements which were  
20 taken over the course of the time that the workers were  
21 there. The plant closed in 1985, and so we followed,  
22 we updated all of the work histories that Hayes had up  
23 through 1985.

24 When we did the analysis of the data, we broke  
25 the group into for the paper that was published in the

1 American Journal of Industrial Medicine in 2000, we  
2 divided the cohort up into four exposure groups. More  
3 to be descriptive than anything, but there was a clear  
4 exposure response with the four exposure groups.

5 We then used a regression model where we  
6 included the smoking information, and did an analysis  
7 with that and found that hexavalent chromium,  
8 cumulative hexavalent chromium exposure was certainly  
9 significantly associated with lung cancer risk.

10 One of the things that we did after we began  
11 the study was we went back to the plant and we took  
12 dust measurements from all areas of the plant, or for  
13 almost all of the areas of the plant. What we wanted  
14 to do was look at hexavalent and trivalent chromium.

15 So we took the dust measurements and took the  
16 ratios of those, and we used that to estimate what the  
17 airborne hexavalent and trivalent chromium would have  
18 been. One of the claims by Mancuso was that both  
19 hexavalent and trivalent chromium were carcinogenic,  
20 and we wanted to evaluate that.

21 One other advantage that we had to this study  
22 is that we had area samples, that is what constituted  
23 most of the exposure information, but we also for a  
24 time period had personal samplers. So we could compare  
25 the personal samples to the area samples. When we did

1 that, for 2/3 of the jobs, we found that they  
2 correlated very well. For about 1/3, the area sample,  
3 or the personal sample was higher than the area sample,  
4 so we adjusted for those jobs for the cohort.

5 I know there have been several quantitative  
6 assessments made using our study to estimate what the  
7 risk is. I think one thing that is noteworthy is that  
8 the quantitative assessment from our study is  
9 remarkably similar to the quantitative assessment using  
10 the Mancuso data. It is also remarkably similar to the  
11 quantitative assessment using the Luippold data.

12 What is incredible and as a risk assessor I  
13 spent considerable time doing risk assessment, three  
14 different studies showing remarkably similar  
15 quantitative estimates. I mean, it is just very  
16 unusual. Especially with human data where there is a  
17 lot of concerns about follow up and so forth. So  
18 that's rather remarkable.

19 Another comment that I want to make is that if  
20 you take the proposed PEL of 1 microgram per cubic  
21 meter, and if you assume that a worker works for 45  
22 years as OSHA does, and that exposure, that cumulative  
23 exposure, 1 microgram times 45 would put you into the  
24 fourth quartile of our study, which means that that  
25 proposed PEL is within the range of observation.

1           The current PEL and the proposed PEL are both  
2 within the fourth quartile which is statistically  
3 significant. In a sense, you don't even need risk  
4 models. I mean, you are in the range of observation,  
5 and that was statistically significant.

6           I want to respond to a couple of the comments,  
7 some of the public comments. I did in the statement,  
8 which is on the table outside, but let me comment on  
9 them again.

10           One comment that was made was that there were  
11 RAC samplers in this plant. RAC samplers stands for  
12 Research Appliance Corporation. The comment was made  
13 that the RAC samplers would have underestimated  
14 exposure. Actually, I was surprised at the comment  
15 because it is clearly stated in the paper that we had  
16 the personal samplers and the area samplers, and we  
17 used the personal samplers to adjust the area samples.  
18 So that was already dealt with in the paper, and I was  
19 rather surprised at the comment.

20           Another comment that was made was that we use  
21 Maryland rates to estimate the expected lung cancer  
22 risk. We did use Maryland rates. We could have used  
23 U.S. rates, we could have used Baltimore City rates.  
24 We decided to use Maryland rates because about 55  
25 percent of the cohort died outside of the City of

1 Baltimore. Maryland rates are pretty much driven by  
2 Baltimore City rates. Maryland rates are some of the  
3 highest lung cancer rates in the country.

4 So therefore, we thought it reasonable to use  
5 the Maryland rates. But it doesn't matter if we use  
6 Maryland rates or Baltimore City rates or U.S. rates.  
7 There still was an excess lung cancer risk, and there  
8 still was an exposure response. So I think the choice  
9 of what rates you use is sort of rather irrelevant to  
10 the overall picture.

11 Another comment was that at a particular  
12 exposure, particular cumulative exposure, or below a  
13 particular cumulative exposure I should say, that no  
14 lung cancer risk was observed. The argument was made  
15 that, well, this suggests that there may have been a  
16 threshold.

17 Having been a risk assessor for a number of  
18 years, and having dealt with that argument many times,  
19 there is always some point at which you cannot  
20 statistically detect an excess risk. I mean, it  
21 relates to the power of the size of the group to be  
22 able to see that risk.

23 If there is true threshold, I mean, I'm not  
24 exactly sure what that means, but a threshold I think  
25 might be, and has to be based on biological argument.

1 There has to be the data to support it. So saying that  
2 below a particular cumulative exposure means that there  
3 wasn't a statistically significant excess risk, doesn't  
4 mean that a risk does not exist. The risk can still be  
5 there, although you may not be able to detect it.

6 Finally, there was a clear exposure response  
7 in the study. So with that, I think I'll take any  
8 questions.

9 ADMINISTRATIVE LAW JUDGE VITTON: Thank you,  
10 Dr. Gibb.

11 May I have a showing of hands, please? I only  
12 see one hand. This gentleman right here. Two hands.

13 DR. MARR: Dr. Gibb, I am by no means --

14 ADMINISTRATIVE LAW JUDGE VITTON: Name,  
15 please.

16 DR. MARR: Oh, I'm sorry. Peter Marr, M-A-R-  
17 R, and I'm associated with the Color Pigment  
18 Manufacturers Association.

19 Dr. Gibb, I am by no means an expert on this,  
20 but I saw your abstract and was rather interested by  
21 it. So I looked up a couple of things, and that led me  
22 to a couple of questions.

23 One is I found a website, I believe it is the  
24 National Cancer Institute's website, and it is quite  
25 flexible. It allows you to look at cancer rates in

1 various ways. I asked it for a report, and this was on  
2 death rate report by state, lung and bronchus, white  
3 males, all ages, sorted by rate. It lists the United  
4 States average at the top, and then goes down the  
5 states with the highest at the top and the lowest lung  
6 cancer rate at the bottom.

7 I was surprised to find that you had indicated  
8 that Maryland had a very high rate. On this listing,  
9 Maryland is pretty much in the center. It is almost  
10 exactly the U.S. average, but maybe we're looking at  
11 different numbers or something, I don't know.

12 What really surprised me was when I looked at  
13 the rate in the lowest state and the rate in the  
14 highest state, and they differ by a factor of 3.5. It  
15 seems to me that that is sort of the order of magnitude  
16 that you are looking at as an increase in the plant  
17 that you've been studying.

18 It sort of seems to me that with a difference  
19 like this in the different states somehow implies noise  
20 in --

21 ADMINISTRATIVE LAW JUDGE VITTON: Implies  
22 what, sir?

23 DR. MARR: Noise.

24 ADMINISTRATIVE LAW JUDGE VITTON: So what is  
25 your question?

1 DR. MARR: Something we don't really  
2 understand.

3 ADMINISTRATIVE LAW JUDGE VITTONI: Okay. So  
4 what is your question?

5 DR. MARR: Well, my question really is why  
6 does that noise not cause you a problem in doing the  
7 study?

8 DR. GIBB: Because there was an exposure  
9 response. So if you had taken any one of those rates,  
10 you know, you can take any state in the United States  
11 and apply it. You're still going to see an exposure  
12 response.

13 I mean, there is going to be noise. There is  
14 certainly going to be noise. There is going to be  
15 noise with information regarding how much they may have  
16 smoked, if there was exposure misclassification, there  
17 is going to be some noise. But it is not going to  
18 affect the overall, there was a clear exposure  
19 response.

20 I think what is particularly strong about this  
21 database is that we have two other studies showing  
22 risks that are almost exactly the same, which is  
23 uncanny really in risk assessment.

24 DR. MARR: If there aren't a lot of other  
25 questioners, could I just have a couple of follow-up

1 questions.

2 ADMINISTRATIVE LAW JUDGE VITTON: You still  
3 have some time.

4 DR. MARR: Okay. Thank you. Just getting  
5 back to the similarity of those three studies. On page  
6 five of your paper that is available outside, in the  
7 middle of the page it starts off, "Despite the greater  
8 confidence," and it says these three studies that you  
9 named, your own, Mancuso and Luippold, you say they are  
10 remarkably similar. And then you say within a factor  
11 of three.

12 DR. GIBB: Right.

13 DR. MARR: I don't think there are many areas  
14 where remarkably similar would mean within a factor of  
15 three.

16 DR. GIBB: When you have done risk assessment  
17 for a long time, you get within an order of magnitude,  
18 you feel you're doing pretty well. So within a factor  
19 of three given that there are differences in the  
20 studies, you know, there were, for example, we didn't  
21 have terrific exposure. Well, we had exposure  
22 information with Mancuso, but we didn't have airborne  
23 hexavalent chromium measurements, we had to estimate  
24 it.

25 In the Luippold study, there wasn't smoking

1 information. There was smoking information for maybe  
2 1/3 of the cohort. My understanding is there were no  
3 data on the race of the workers. So to derive  
4 expected, they had to just use what the lung cancer  
5 risk was for males. So there could have been  
6 differences there with regard to the race.

7 So there are a variety of factors, little  
8 things that you wish you had the details but you don't.  
9 Those things can make a fair amount of difference. But  
10 still, coming up with this within threefold, threefold  
11 is very good. I think if you talk to people in the  
12 risk assessment community and take three different  
13 epidemiology studies done by three different people of  
14 three different cohorts and then have different people  
15 do the quantitative assessments and they come out so  
16 close, it is pretty remarkable.

17 DR. MARR: Okay. Thank you. And you've  
18 talked about dose response a couple of times. In the  
19 Federal Register publication on page 59,364, there is a  
20 table that is listed as VII-1, dose response data from  
21 Gibb et al. observed an expected number of lung cancer  
22 deaths grouped by age and four cumulative hexavalent  
23 chromium exposure categories. I'm sure you remember  
24 that table.

25 DR. GIBB: I don't have it here. Maybe I do

1 have it here. All right.

2 DR. MARR: Now, that table has quite a number  
3 of lines for each exposure group. It starts off the  
4 observed, the expected, person-years, and mean  
5 exposure. But what it doesn't give is a number that I  
6 often find in studies like this, which is the ratio of  
7 observed-to-expected.

8 Now, you can't put everything in a table, so  
9 that's okay. But I did extract those numbers, and  
10 calculated the observed-to-expected ratios. Now, if  
11 you look at the first three columns of age, from 20 to  
12 29, 30 to 39, 40 to 49, the numbers there are  
13 relatively small, so we could pretty well ignore those  
14 columns.

15 Similarly, if you look at the left two  
16 columns, 70 to 79 and 80 plus, again, the numbers in  
17 there are quite small, so we might ignore those at  
18 least for the moment. So you could say that the  
19 important columns were the 50 to 59 and the 60 to 69,  
20 where most of the deaths occur.

21 If you look at the observed-to-expected ratios  
22 in column 60 to 69, it makes quite, I haven't graphed  
23 it, but I would say it is a fairly smooth line with  
24 people at the lowest exposure rate having a ratio of  
25 .74, and then it seems to move fairly smoothly up to

1 those with the greatest exposure rate at 2.68. My  
2 understanding is, and I think you've implied this, is  
3 that that is the mark of a good study of this sort. Is  
4 that a fair statement?

5 DR. GIBB: I'm not sure what -- would you  
6 state the point again?

7 DR. MARR: Well, as the exposure increases,  
8 you would expect that the observed-to-expected ratio  
9 would increase as well?

10 DR. GIBB: Yes.

11 DR. MARR: With no exposure, you'd expect a  
12 ratio of one. With a high exposure, you'd expect a  
13 high ratio?

14 DR. GIBB: Right.

15 DR. MARR: Okay. Now, if you look at the  
16 column next to it, the 50 to 59, and if you calculate  
17 the same ratios, they don't make that same smooth  
18 upward line. In fact, they either go down a little  
19 bit, which if taken literally would mean that chromate  
20 was good for you, or they more likely just stay the  
21 same. I wondered if you had an explanation for that.

22 DR. GIBB: There is going to be some  
23 variability about this. Overall, as indicated, there  
24 are, and there could have been an interaction of  
25 smoking, an exposure which we don't know about. There

1 could have been exposure misclassification, we may have  
2 misassigned the people with unknown race to the wrong  
3 race category. There are a number of things that can  
4 cause the variability of the rate.

5           If the rate isn't exactly, you know, what you  
6 would expect based on the comments you just made, it  
7 doesn't necessarily imply that there is a fault in the  
8 data. I think there is enough variability about these  
9 things that overall, I mean, the increase is  
10 statistically significant as you go across the various  
11 age categories.

12           It is a question of numbers, it is a question  
13 of obtaining all of the data. Doing any kind of a  
14 study of humans involves variation in lifestyles,  
15 variation in a number of factors which we can't  
16 control, for which we don't have information on. So we  
17 do the best we can with the information that we have.

18           For this study, again, as the senior author, I  
19 probably have some right to I suppose brag about it.  
20 But it is unusual to get this much exposure  
21 information. It is very rare to get smoking  
22 information on a cohort. It is just rare. We had  
23 smoking information for 91 percent of the cohort, and  
24 exposure measurements taken at the time that the  
25 workers were exposed.

1                   So, again, there are things that we don't  
2 know, lifestyles, other things and so forth that can  
3 cause variability in the rates. There may be ethnic  
4 differences and so forth. But still, even with all of  
5 that, you still see a very clear exposure response.  
6 That is statistically significant.

7                   I know I have probably tried to, I mean, the  
8 simple answer is that there is going to be variability  
9 in the rates, okay? Just because something dips here  
10 in one age category and goes up over there in another  
11 age category, you can't take too much out of that. You  
12 have to look at the overall picture is what I'm trying  
13 to tell you.

14                  DR. MARR: Well, I've heard references to  
15 your papers over a great number of years, Dr. Gibb. It  
16 has been a pleasure for me to listen to you in person  
17 and be able to have these questions. Thank you very  
18 much.

19                  DR. GIBB: Thank you.

20                  ADMINISTRATIVE LAW JUDGE VITTONI: Thank you,  
21 Mr. Marr.

22                  Mr. Lurie, did you have your hand up? Who  
23 else? Who else has their hands up? One, two. Okay.

24                  DR. LURIE: Good afternoon.

25                  ADMINISTRATIVE LAW JUDGE VITTONI: Mr. Lurie,

1 I'm sorry. You're going to have to identify yourself  
2 each time you come up.

3 DR. LURIE: Peter Lurie with Public Citizen's  
4 Health Research Group.

5 Dr. Gibb, I have two sets of questions for  
6 you. The first are questions about your own study, and  
7 the second are questions about your study and the  
8 Luippold study.

9 My first question is you have tried to be  
10 modest in describing your study while pointing out what  
11 is good about it. But it is true you have won some  
12 awards for this study, haven't you?

13 DR. GIBB: I did, yes.

14 DR. LURIE: Can you tell me about those?

15 DR. GIBB: Well, EPA gives a Science and  
16 Technology Achievement award for primary research. I  
17 received that award.

18 DR. LURIE: That is one per year?

19 DR. GIBB: Pardon?

20 DR. LURIE: One award per year?

21 DR. GIBB: No, no. There are several awards.  
22 It is a cash award, so I received some money for it.

23 DR. LURIE: Okay. Well, congratulations.  
24 Tell me if I have this correct. If I read your data  
25 correctly, at the PEL being proposed by the Agency,

1 they would remain in excess of 9.1 lung cancer deaths  
2 per 1,000 workers exposed over a 45-year period. Does  
3 that sound right?

4 DR. GIBB: The current -- I'm sorry.

5 DR. LURIE: No, at the proposed PEL.

6 DR. GIBB: At the proposed PEL, there would  
7 be a risk of 9.1.

8 DR. LURIE: An excess risk of 9.1.

9 DR. GIBB: Let me see. I haven't figured  
10 that out, but if you --

11 DR. LURIE: I'm taking this from --

12 DR. GIBB: Pardon?

13 DR. LURIE: I was saying the Federal Register  
14 characterizes your study that way.

15 DR. GIBB: Okay. All right.

16 DR. LURIE: Okay. Let's assume for a moment  
17 that that is right. Does that seem to you in your  
18 experience as a risk assessor, and someone who has done  
19 work in other carcinogens in the occupational setting,  
20 does that seem to you like a large risk? How does that  
21 compare to the kinds of levels of risk to which you'd  
22 like to reduce to?

23 DR. GIBB: My experience has been with the  
24 Environmental Protection Agency. At EPA, we are  
25 usually looking at lower risks than that, but we are

1 also dealing with much lower exposures. I think in the  
2 occupational setting, not being as familiar with the  
3 occupational setting, I think the risks may be somewhat  
4 higher. But I don't know.

5 DR. LURIE: Well, typically as I understand  
6 it, the Agency tries to get the risk down to about 1 in  
7 1,000 on a lifetime basis, given exposure.

8 DR. GIBB: OSHA does.

9 DR. LURIE: Yes, that's right. So what you  
10 are calculating, based on the PEL, would be nine times  
11 higher than that? Assuming that I'm characterizing the  
12 OSHA's characterization of you correctly. So there  
13 would be a lot of risk remaining, okay.

14 You did talk about threshold. Let me see if I  
15 can just get you to restate it. In simple terms, did  
16 you find one in the study that you looked at? The  
17 study that you conducted.

18 DR. GIBB: We weren't really looking for a  
19 threshold.

20 DR. LURIE: Okay. But you probably noticed  
21 one.

22 DR. GIBB: Well, I can't accept that there  
23 was a threshold.

24 DR. LURIE: You can't accept that?

25 DR. GIBB: I mean, I don't believe there was

1 a threshold. I mean, if somebody said to me there was  
2 a threshold, I would say I'm sorry, I don't think there  
3 is.

4 DR. LURIE: And in fact a number of other  
5 people have re-analyzed your data, and they have come  
6 to just the same conclusion, haven't they?

7 DR. GIBB: That there was no -- well, I don't  
8 know that other people have said that, other people  
9 have said there is no threshold. I haven't seen an  
10 argument advanced for why there was a threshold that I  
11 would consider credible.

12 DR. LURIE: Okay. And similarly a related  
13 matter, there is the question of whether the linear  
14 dose response relationship adequately characterizes  
15 your data.

16 Now, it is my understanding based on the risk  
17 assessment that you did with others and published in  
18 Risk Analysis last year that in fact you conclude that  
19 linear dose response relationship is probably the best  
20 way to characterize the data, is that true?

21 DR. GIBB: That's right.

22 DR. LURIE: Okay. And that would be  
23 inconsistent with a threshold?

24 DR. GIBB: That would be inconsistent with a  
25 threshold. But again, I think that aside from the

1 models, various models, you can debate different  
2 models. But as I indicated before, I think one of the  
3 advantages of this study was the exposure was low. I  
4 mean, these were typical exposures.

5 It was a new plant in 1950, and they were  
6 employing state-of-the-art hygiene measurements.  
7 Again, if you accept the 45-year working lifetime, and  
8 if the proposed PEL is 1 microgram per cubic meter, you  
9 are within the range of observation. You almost don't  
10 even need the models.

11 DR. LURIE: Right. Because it is all within  
12 the range, and there is no need to extrapolate.

13 DR. GIBB: You're already there. You're  
14 already there.

15 DR. LURIE: There is no extrapolation at all,  
16 right?

17 DR. GIBB: No.

18 DR. LURIE: Necessary, to get down to one.

19 DR. GIBB: Right. If you accept the 45-year  
20 working lifetime.

21 DR. LURIE: Right. Now, the data are the  
22 data, right, without extrapolating?

23 DR. GIBB: The data are the data. You don't  
24 need them.

25 DR. LURIE: Right. Okay. Your study has

1 | been criticized for including too many, or many at  
2 | least, short-term workers.

3 | DR. GIBB: Right.

4 | DR. LURIE: I suspect you don't find that so  
5 | much a problem. Can you respond to that criticism?

6 | DR. GIBB: Well, the party that made the  
7 | criticism to OSHA, in their initial criticism later on  
8 | did an analysis to find out it didn't make any  
9 | difference if you included the short term. So the  
10 | commentor sort of answered their own concern.

11 | Secondly though, even if you include the  
12 | short-term workers, you still get a similar risk to  
13 | what you get doing dose exposure response. These are  
14 | human studies. Doing exposure response with Luippold  
15 | or Mancuso.

16 | If they were short-term workers, and the  
17 | argument was advanced that short-term workers tend to  
18 | have a riskier lifestyle and so forth, they are  
19 | probably more likely to get lung cancer, that only  
20 | would have sort of muted the exposure response, because  
21 | they are in the lower category.

22 | DR. LURIE: Right.

23 | DR. GIBB: So you wouldn't have seen as clear  
24 | of an exposure response.

25 | DR. LURIE: It would have added noise to the

1 whole analysis.

2 DR. GIBB: It would have added more noise.

3 DR. LURIE: It would have made it more  
4 difficult to find something.

5 DR. GIBB: And in the proportional hazards  
6 model, we were using that group as sort of the  
7 baseline. And so we still see a significant exposure  
8 response.

9 DR. LURIE: Now, you were also criticized for  
10 not adjusting for smoking in your SMR calculations.  
11 Isn't it not true that in your multivariate analysis,  
12 you did include smoking, and that the risk remained  
13 even after doing so?

14 DR. GIBB: You wouldn't correct for smoking  
15 in the SMR analysis. You have to make too many  
16 assumptions. Why would you do that? We did it in the  
17 regression model. That is where it should have been  
18 done. You don't have to make assumptions about what  
19 the background rate is, background mortality rate is  
20 for smokers and so forth.

21 DR. LURIE: Because you have individualized  
22 data on particular people.

23 DR. GIBB: We did a regression analysis.  
24 That's the appropriate place to do it, and it was done.  
25 It is not that we didn't correct for smoking. If we

1 had so much smoking data, why wouldn't we have used it?

2 We did use it, of course.

3 ADMINISTRATIVE LAW JUDGE VITTONE: Gentlemen,  
4 if you both talk at the same time, I think it makes it  
5 hard for the transcript.

6 DR. LURIE: Okay. Let me turn to the  
7 Luippold study. You're familiar with that, I take it?  
8 You have read that study?

9 DR. GIBB: Yes.

10 DR. LURIE: Let me ask you a little bit about  
11 the way in which it compares to yours. In terms of the  
12 number of workers that you studied in your collection,  
13 did you have more workers than in the Luippold study?  
14 Or fewer?

15 DR. GIBB: We had more. We had 2,357,  
16 Luippold had around about 500, I believe.

17 DR. LURIE: So about five times more. And in  
18 terms of the number of the number of person-years as a  
19 of follow up?

20 DR. GIBB: Yes. Person-years, we had 70,000.  
21 I can't remember what Luippold had.

22 DR. LURIE: Considerably less than that. I  
23 have 14,000 in my notes.

24 DR. GIBB: 14,000, okay.

25 DR. LURIE: So in terms of the way

1 epidemiological studies are typically done, I mean,  
2 yours is an unusually large study I think it's fair to  
3 say, with an unusually long period of follow up.

4 DR. GIBB: It's true. However, one thing  
5 isn't in the Luippold study. You have to note that  
6 they included people if you had worked a year or more.  
7 We didn't. So I'm not sure what the size of our cohort  
8 had been if we had excluded people who worked less than  
9 a year.

10 DR. LURIE: But that's the study we have,  
11 right?

12 DR. GIBB: Right.

13 DR. LURIE: As you say, you go to work with  
14 the study you have.

15 DR. GIBB: Yes.

16 DR. LURIE: Or something like that the  
17 President said. In terms of the number of lung cancer  
18 deaths, you had quite a number more than them as well,  
19 didn't you?

20 DR. GIBB: We had 122, and they had about 40  
21 percent of that, about 50 --

22 DR. LURIE: One. That's fine. It doesn't  
23 have to be that precise.

24 DR. GIBB: It was about 40 percent of what we  
25 had in terms of lung cancer deaths.

1 DR. LURIE: And could you compare the ways in  
2 which you collected your exposure measurements compared  
3 to the way they did in terms of the sampling pattern?

4 DR. GIBB: Well, theirs were done in surveys  
5 is my understanding. So they went in I think at  
6 numerous times and did surveys, whereas ours was pretty  
7 much continuous. There were some gaps that we had in  
8 years, but we were able to extrapolate or interpolate  
9 for an area. We weren't making large interpolations, I  
10 mean, these weren't like jumping up an order of  
11 magnitude.

12 These were very, where there were data gaps,  
13 we were able to make very good estimates, looking at  
14 what we would predict, and then comparing it to  
15 observed. It was a paper actually that one of my co-  
16 authors, Peter Lees, had presented at the International  
17 Agency for Research in Cancer meeting. We were very  
18 comfortable with when we didn't have an exposure  
19 measurement that we were able to predict it.

20 So there were differences. My understanding  
21 is they did it at different times and surveys, ours I  
22 think were generally continuous. As I indicated, there  
23 were some data gaps.

24 DR. LURIE: So one might say that the kind of  
25 measuring that was conducted in your study is akin to

1 the kind of measuring that a workplace subject to the  
2 new hexavalent chromium standard might do? The same  
3 kind of continuous monitoring, independent of  
4 particular events, right?

5 DR. GIBB: I don't know what OSHA would  
6 request. I guess I would hope that people would do  
7 continuous.

8 DR. LURIE: As opposed to responding to an  
9 accident, for example?

10 DR. GIBB: Right.

11 DR. LURIE: Which might have been some of the  
12 data in Luippold study.

13 DR. GIBB: I think the important thing is to  
14 look at what a typical exposure is, and that is what I  
15 think is one of the advantages to our study. A lot of  
16 occupational studies.

17 DR. LURIE: In terms of the number of  
18 measurements, you had quite a fair number more than  
19 them, didn't you?

20 DR. GIBB: We had 70,00 measurements. I  
21 believe they had 800 and something, 890 or something  
22 like that.

23 DR. LURIE: What I take out of this is that  
24 in almost any respect that one would measure, your  
25 study seems to be stronger. Whereas it is possible to

1 do risk assessment based on the Luippold study, but  
2 really everything that you have said appears to suggest  
3 that yours is almost an order of magnitude different,  
4 higher, in terms of quality.

5 DR. GIBB: I think when you are doing studies  
6 like this, I wouldn't want to denigrate anybody's  
7 study, because I think you work with what you have. I  
8 think that we had an advantage. I mean, we had an  
9 information advantage, I think that's true. That  
10 doesn't mean to say that other authors didn't do what  
11 they did well, but I think, I mean, I know we had an  
12 information advantage because we had considerable  
13 exposure information, we had a larger workgroup, we had  
14 smoking information.

15 Luippold, as I read it, didn't even have race  
16 information. So lung cancer rates among blacks can be  
17 20 to 50 percent higher than it can be among whites,  
18 white males. So there was, yes, I think there is a  
19 considerable advantage to our study. I think it is the  
20 best study.

21 DR. LURIE: Based on that, this study, is  
22 there any question in your mind that hexavalent  
23 chromium is a lung carcinogen?

24 DR. GIBB: No, none whatsoever.

25 DR. LURIE: Is there any question in your

1 mind that the risk of lung cancer from hexavalent  
2 chromium might extend below even those quartiles in  
3 which you found statistical significance?

4 DR. GIBB: Sure. I think that's quite  
5 possible. I mean, the lowest quartile covered zero up  
6 to whatever the end of the quartile was. So it is not  
7 going to go below zero.

8 DR. LURIE: Right.

9 DR. GIBB: But yes, I think that we would  
10 have to assume given the data that we had that the lung  
11 cancer risk, that some concentration of hexavalent  
12 chromium is going to present a carcinogenic risk.

13 DR. LURIE: Including levels below the PEL  
14 that OSHA has proposed?

15 DR. GIBB: I think that you could say that  
16 there is going to be a lung cancer risk below the PEL.  
17 But I also know having come from a regulatory agency, I  
18 have to say this, that there is of course, as everybody  
19 knows, there is a balancing of the costs and the risks.  
20 But I think that yes, there could be certainly a risk  
21 below the --

22 DR. LURIE: Well, again, you don't actually  
23 have to extrapolate as you point out, because at a PEL  
24 of .25, one of the levels considered by the Agency,  
25 that falls within the third quartile of your exposures.

1 That too was statistically significant, wasn't it?

2 DR. GIBB: Right.

3 DR. LURIE: Then it must be true that even  
4 below the PEL, there certainly would be not only some  
5 risk of hexavalent chromium carcinogenesis, but in fact  
6 enough to be statistically significant.

7 DR. GIBB: Yes, I think that's true. I mean,  
8 if you take the lower exposures, within our study it  
9 would have been statistically significant. Of course  
10 you can change the background. If you change it to  
11 Baltimore, then Baltimore City in some instances it is  
12 not statistically significant. But again, statistical  
13 significance depends somewhat on the background rate  
14 you are using, the size of the group, and so forth. So  
15 yes, there is a risk. I mean, there is a risk I would  
16 say below what would be proposed.

17 DR. LURIE: Okay. Thank you.

18 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you,  
19 Mr. Lurie.

20 Somebody had their hand up over here. Okay.  
21 Right here.

22 MS. PROCTOR: Thank you. I'm Deborah  
23 Proctor. Pardon my voice, I seem to be losing it.

24 ADMINISTRATIVE LAW JUDGE VITTONI: Who do you  
25 represent, Ms. Proctor?

1 MS. PROCTOR: I work for Exponent, a  
2 consulting firm. I have done work for a number of  
3 trade associations with chromium exposed workers. I'm  
4 also co-author of the Luippold et al. study. I have  
5 some relatively simple questions, I guess.

6 Dr. Gibb, I notice in the risk assessment,  
7 which was published in Risk Analysis in December, the  
8 Park et al. paper, you had a quantitative analysis of  
9 the lung cancer risk. That analysis is somewhat  
10 different than the analysis that OSHA did using the  
11 Baltimore cohort, using different reference rates and  
12 using the quantitative smoking information.

13 I was just wondering if you could reflect on  
14 the advantages or disadvantages of the methodologies  
15 used in your published paper as compared to the  
16 analysis that OSHA used for the rulemaking.

17 DR. GIBB: You are asking the advantages and  
18 disadvantages of the paper published in Risk Analysis  
19 compared to the OSHA? Is that what you're asking?

20 MS. PROCTOR: Right. Compared to the  
21 quantitative risk assessment.

22 DR. GIBB: The quantitative risk assessment.

23 MS. PROCTOR: Like the Park paper presents a  
24 risk assessment, and OSHA has prepared a risk  
25 assessment. Quantitatively, they are relatively

1 similar, they are different by about 25 percent. But  
2 qualitatively, there is differences, and I was just  
3 wondering if you could reflect on that at all.

4 DR. GIBB: I can't at this time. I can get  
5 back to you. I guess there is an opportunity in post-  
6 meeting comments. I couldn't address it at this time.

7 MS. PROCTOR: Okay. All right. When you  
8 talked about the remarkable similarities in the lung  
9 cancer risks for the Luippold cohort, the Mancuso  
10 cohort, the Hayes cohort and your cohort, and that's  
11 certainly true. They are all cohorts of chromate  
12 production workers.

13 In OSHA's quantitative risk assessment, they  
14 looked at six different studies, the four that I just  
15 named, four chromate production worker studies, and  
16 then two other studies. A study of aerospace workers,  
17 and a study of welders.

18 In both the welder study and the aerospace  
19 worker study, there was not a positive relationship  
20 between dose and response in those studies. In fact,  
21 in the aerospace study, there was an inverse  
22 relationship. I mean, what are your comments on  
23 whether or not you can extrapolate lung cancer risks in  
24 the chromate production industry to other industries?

25 DR. GIBB: What were the two studies you just

1 mentioned? The aircraft and the?

2 MS. PROCTOR: The aircraft worker study is  
3 Alexander et al.

4 DR. GIBB: Right.

5 MS. PROCTOR: And the welders is Guerin et  
6 al., 1983. If you look in I think it is Table 8 of the  
7 proposed rule, it summarizes all of the risk estimates.  
8 That is on page 59,379.

9 DR. GIBB: Right.

10 MS. PROCTOR: I mean, I'm just wondering more  
11 from a philosophical point of view. You have a lot of  
12 experience with risk assessment, what your thoughts are  
13 on the extrapolation of risk from this one industry to  
14 others.

15 DR. GIBB: Let me give you a comment on the  
16 example of the Alexander study. The Alexander study,  
17 my understanding is that the cases were only  
18 ascertained from the Fred Hutchinson Cancer Center in  
19 Seattle. So they didn't have any information. If you  
20 didn't die at Fred Hutchinson, you weren't there, you  
21 weren't part of it.

22 The follow up was only 75 percent. The age at  
23 the end of the follow up, the average age was 42 years  
24 old, I mean, remarkably young. There were only 15 lung  
25 cancer deaths in the cohort. It is pretty hard to say

1 that there wasn't a risk there, because it just wasn't  
2 a study that was adequate enough to be able to detect a  
3 risk. I mean, too many limitations in the study.

4 MS. PROCTOR: So do you think that the  
5 Alexander study should be used for quantitative risk  
6 assessment?

7 DR. GIBB: I don't think so. There are too  
8 many limitations on it. You might use it to set some  
9 kind of an upper bound or something on risk, but I  
10 wouldn't put that into the -- my own opinion is that I  
11 wouldn't include that, because there is just too many  
12 limitations to the study.

13 MS. PROCTOR: Okay.

14 DR. GIBB: The other one, the Guerin study,  
15 the Guerin study, there is some suggestion of a risk in  
16 that. It doesn't appear to be an exposure response,  
17 but the expected number of lung cancer deaths was  
18 rather small. Expected sort of gives you an idea of  
19 what the ability of the study is to be able to detect a  
20 risk.

21 A number of these studies that I have seen and  
22 people have quoted that there is this study, there is  
23 the Cooper study, there is the Kano study, a variety of  
24 different studies. But if you look at what the  
25 expected number of lung cancer deaths were, they are

1 very small. So you really don't have a lot of ability  
2 to be able to detect a risk.

3 A lot of the studies don't have any exposure  
4 information. So that exposure information, were they  
5 even exposed?

6 MS. PROCTOR: So would you characterize the  
7 epidemiological literature for hexavalent chromium to  
8 pretty much be based on the chromate production  
9 industry? I mean, that is where the majority of the  
10 risk assessment data comes from, if not all of the  
11 usable risk assessment data.

12 DR. GIBB: Well, there are studies of platers  
13 that have shown increased lung cancer risk. There are  
14 studies of pigment workers that show increased lung  
15 cancer risk. There are certainly other chromium  
16 occupations. I don't think it is limited to chromate  
17 production.

18 MS. PROCTOR: Right. I agree with you there.  
19 But as far as quantifying the risk and the dose  
20 response relationship, would you basically say you're  
21 down to the chromate production industry?

22 DR. GIBB: I wouldn't say you're down to the  
23 chromate production industry. I think you could do  
24 something probably with the chrome plating industry,  
25 because there is some information from chrome plating.

1 I'm not sure about chrome pigment, but I think there is  
2 from plating.

3 MS. PROCTOR: Okay. And then I just have one  
4 more question about the study, more specifically about  
5 the Gibb et al. study. That is on the exposure.

6 You talked about the RAC samplers and how  
7 there was a period of time I think starting from the  
8 mid 1960s to 1978 approximately where only the RAC  
9 samplers were used for collecting samples. Then after  
10 I think it is approximately '78, personal monitoring  
11 samples were used.

12 You look at the exposure profile in your  
13 second paper, in the clinical findings paper, which is  
14 only granted for three job categories, it looks like  
15 the exposures are kind of high before 1965, and then  
16 they are relatively low until '78, and then they kind  
17 of shoot back up. Granted this is only for three  
18 groups.

19 But I was just wondering when you use the  
20 personal monitoring data to correct the RAC samples for  
21 the 1/3 of the jobs for which there wouldn't have been  
22 some underestimation, if you did that only from '78  
23 forward, or if you went back in time and corrected the  
24 data from '78 to '65?

25 DR. GIBB: I want to confirm this with

1 industrial hygienists on this, but we did go back in  
2 time to correct, yes. I'm pretty sure that is what was  
3 done.

4 MS. PROCTOR: Okay. All right. Well, that's  
5 all my questions. But just for the record, for the  
6 Luippold et al. study, we did have race information.  
7 It was just that --

8 MS. SHERMAN: You are going to testify later.

9 MS. PROCTOR: No, actually I'm not. I have  
10 withdrawn. I just wanted to mention that we did have  
11 race data, and they were virtually all white, 97  
12 percent.

13 DR. GIBB: Oh, there was? Because in the  
14 paper that I read, it states, I mean in the Luippold  
15 paper.

16 MS. PROCTOR: We have limited information.

17 ADMINISTRATIVE LAW JUDGE VITTONI: Well,  
18 whichever is in the paper is in the paper.

19 MS. PROCTOR: Okay.

20 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you  
21 very much. Somebody in the back. Ms. Drummond, did  
22 you have your hand up?

23 MS. DRUMMOND: Anita Drummond with Associated  
24 Builders and Contractors. I just have a few  
25 clarifying questions in reading the summary materials,

1 because I do not in any way have an expertise in this  
2 area.

3 One of the points that is in the Federal  
4 Register is that for the total cohorts, a significant  
5 exposure response training was observed such as the  
6 lung cancer mortality increased with the increasing  
7 cumulative exposure to hexavalent chromium.

8 The definition of the cumulative exposure, did  
9 that come about because a worker was there for a longer  
10 period of time, or was consistently in a point source  
11 of contamination? I mean, how did you know that  
12 subject matter, or how did you define had an increase  
13 in cumulative exposure to the hex chrome?

14 DR. GIBB: Well, the cumulative exposure was,  
15 if you are exposed to a certain concentration, if you  
16 are exposed to that concentration for a year, let's  
17 say.

18 MS. DRUMMOND: Okay. And that was a  
19 variable. Okay. So it was based on individuals'  
20 exposure in concentration and time. So those were the  
21 two factors, concentration and time?

22 DR. GIBB: Right.

23 MS. DRUMMOND: Okay. Do you know if the  
24 point source of contamination were any kind of confined  
25 spaces, or separate from the other workplace? Or what

1 was point sources of contamination? How was that  
2 defined?

3 DR. GIBB: Well, I mean, I think you are  
4 probably referring to the fact that we had some higher,  
5 at least when we looked at the personal samples as  
6 compared to the area samples. We said there were point  
7 sources, but there were certain areas of the plant  
8 where the exposures were much higher, like chromic acid  
9 packing was a notoriously high exposure.

10 I mean, there was exposure in milling and  
11 roasting and different places in the plant. I didn't  
12 mean to say that there was only certain points.

13 MS. DRUMMOND: Right. And I was trying to  
14 determine what that terminology meant. So basically  
15 that was more driven by the data you were getting from  
16 personal sampling of that, and then therefore maybe  
17 classifying that person based on their title.

18 DR. GIBB: Right. Well, we knew that there  
19 was, I mean, it was known that there were certain areas  
20 of the plant where you are going to have more exposure  
21 than in other areas of the plant.

22 MS. DRUMMOND: Okay. And do you know if any  
23 of those areas were confined spaces? I don't mean that  
24 in the OSHA legal term, I mean more like smaller rooms  
25 than the rest of the plant, or isolated?

1 DR. GIBB: I can't answer that, no.

2 MS. DRUMMOND: That's okay. I just had a few  
3 other questions.

4 ADMINISTRATIVE LAW JUDGE VITTON: Excuse me  
5 a second.

6 MS. DRUMMOND: I'm sorry, Your Honor.

7 ADMINISTRATIVE LAW JUDGE VITTON: We're  
8 going to take about a 5-minute break here, and you can  
9 look over your questions.

10 MS. DRUMMOND: Okay. Thank you, Your Honor.

11 **(Whereupon, a brief recess was taken.)**

12 ADMINISTRATIVE LAW JUDGE VITTON: Can  
13 everybody take their seats, please. Thank you. Let me  
14 ask again for a showing of hands after Ms. Drummond who  
15 has questions. I see one hand. Don't be bashful. It  
16 is not like church or school. Okay. All right.

17 Ms. Drummond, go ahead.

18 MS. DRUMMOND: Thank you, Your Honor.

19 In the air samples that were taken, were they  
20 specifically and only for hexavalent chromium and  
21 similar? Are there any other carcinogens that were  
22 tested in the air samples?

23 DR. GIBB: They were collected on a filter,  
24 it is my understanding, in the early 50s there I think  
25 on impingers, but they were analyzing for hexavalent

1 chromium. There were hexavalent chromium, it wasn't  
2 total chromium.

3 MS. DRUMMOND: Okay. And do you know if  
4 there was smoking in the workplace?

5 DR. GIBB: My understanding is there was not.  
6 I want to confirm that, but my understanding is there  
7 was not smoking in the workplace.

8 MS. DRUMMOND: Do you know what the  
9 percentage of smokers were in the general population at  
10 that point? The reason I ask is you can make reference  
11 to there is an assumption that blue collar workers  
12 smoke more. Of your sample that you knew, it looked  
13 like 86 percent were smokers, and that does seem high,  
14 but it was a time period where people smoked more. Was  
15 there any comparison to the general population?

16 DR. GIBB: There was actually in a  
17 presentation that I made several years ago. When you  
18 are born of course has some effect on if you were born  
19 say between 1900 and 1910, there was a certain  
20 prevalence of smoking among that group, and 1910 to  
21 1920 there is a certain prevalence of smoking there.

22 What we found in that analysis is that when we  
23 broke our group down into whites and non-whites and  
24 looked at prevalence of smoking, prevalence of smoking  
25 was about the same for the white population as it was

1 to the general population. For non-whites, it was  
2 greater.

3 MS. DRUMMOND: Okay. Thank you. Those were  
4 my questions.

5 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you,  
6 Ms. Drummond.

7 The gentleman up here. Okay. One last time.  
8 Does anybody else have anything? I see no hands.  
9 OSHA, do you have any questions?

10 MS. SHERMAN: Yes, Your Honor.

11 ADMINISTRATIVE LAW JUDGE VITTONI: Okay. Go  
12 ahead.

13 DR. SCHAEFFER: Dr. Gibb, I just have a  
14 couple of questions. In your study, did you see  
15 prevalence of upper respiratory damage, nasal damage in  
16 the workers?

17 DR. GIBB: Well, we had two published  
18 studies, both in the American Journal of Industrial  
19 Medicine. One looked at clinical findings. There was  
20 nasal irritation, nasal perforation, skin irritation,  
21 eardrum perforation, so there were a number of signs of  
22 irritation.

23 DR. SCHAEFFER: In your study, did you  
24 investigate the correlation between that respiratory  
25 damage and lung cancer, and whether that respiratory

1 damage would be predictive of lung cancer in these  
2 workers?

3 DR. GIBB: We did as part of the analysis in  
4 the lung cancer paper. I mean, I was curious to see if  
5 irritation might be predictive of lung cancer. We did  
6 univariate analyses and found that a number of them  
7 were. But whenever you looked at, when you put it into  
8 the regression model, none of them were. In other  
9 words, irritation was not predictive of the lung cancer  
10 response.

11 DR. SCHAEFFER: Thank you. One other  
12 question. Just to clarify. In regards to that Table  
13 7-1 in the preamble on 59,364 which is really your dose  
14 response data stratified across cumulative exposures  
15 and age, when you analyze that data, does it show a  
16 dose response, despite all the uncertainties you  
17 mentioned in terms of measuring exposure, et cetera, et  
18 cetera?

19 DR. GIBB: Yes, there is an exposure  
20 response, of course.

21 DR. SCHAEFFER: Significant?

22 DR. GIBB: There was a significant exposure  
23 response, yes.

24 DR. SCHAEFFER: Thank you. That's all.

25 MS. TUMMINO: Dr. Gibb, am I correct in

1 recalling that in your paper, the regression analyses  
2 you performed was internally standardized?

3 DR. GIBB: Well, we would have used the  
4 lowest exposure.

5 MS. TUMMINO: So then you were comparing  
6 workers within the study with one another?

7 DR. GIBB: Right.

8 MS. TUMMINO: Would this sort of analysis  
9 have been affected by the sort of geographical  
10 variation in lung cancer rates?

11 DR. GIBB: No.

12 MS. TUMMINO: That we were talking about  
13 today?

14 DR. GIBB: No, of course not.

15 MS. TUMMINO: Okay. Thank you. I also want  
16 to note that OSHA received some comments that we might  
17 be able to look at, the studies on lead chromate  
18 workers Davies, Cooper and Kano to better understand  
19 the risk of lung cancer associated with lead chromate  
20 that we might be able to do a risk analysis of these  
21 studies.

22 Based on your knowledge of them, would risk  
23 assessment using these three studies provide useful  
24 information about the risks associated with lead  
25 chromate?

1 DR. GIBB: When you say a risk assessment,  
2 are you talking about a quantitative risk assessment?

3 MS. TUMMINO: A quantitative risk assessment.

4 DR. GIBB: As I recall, Davies didn't have  
5 any exposure information. Cooper didn't either, and I  
6 don't think Kano did either. So you couldn't do a dose  
7 response, or exposure response. These are human  
8 studies. You couldn't do an exposure response without  
9 exposure information.

10 MS. TUMMINO: Good point. In your opinion,  
11 did these studies show evidence that there wasn't  
12 excess cancer risk associated with chromium? Workers  
13 were exposed to chromium.

14 DR. GIBB: I think there is equivocal  
15 evidence. The studies are very limited. I think in  
16 the Davies study, there were three plants, A, B, and C,  
17 and C had only lead chromate exposure. But I think the  
18 expected was something like about 6.5, and they  
19 observed seven cases. I mean, there is very little  
20 ability to detect anything.

21 The other studies, the ability to detect  
22 something in those studies was very limited. Without  
23 exposure information, it is really hard to say whether  
24 you would have been able to detect anything. But even  
25 aside from that, just because they are small and the

1 number expected is not great, they are not going to  
2 shed a whole lot of light on evaluation of hexavalent  
3 chromium as a lung carcinogen.

4 MS. TUMMINO: Thank you very much.

5 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you,  
6 Doctor.

7 DR. MARR: Excuse me, sir. Could I ask  
8 another question after OSHA?

9 ADMINISTRATIVE LAW JUDGE VITTONI: All right.  
10 Just one.

11 DR. MARR: Dr. Gibb, in the --

12 ADMINISTRATIVE LAW JUDGE VITTONI: Mr. Marr,  
13 right?

14 DR. MARR: I'm sorry. Peter Marr, yes, with  
15 the CPMA. Was there anything in those three studies  
16 that we were just discussing to indicate that lead  
17 chromate is a lung carcinogen?

18 DR. GIBB: The simple answer is no, I can't  
19 see anything in the three studies, but I'd have to  
20 qualify that by saying they don't tell you one way or  
21 the other. They don't tell you whether there is a  
22 risk, they don't tell you that there isn't a risk.  
23 There isn't enough, the studies just don't have the  
24 ability to be able to evaluate it very well.

25 When you compare it to the risks that you are

1 seeing in chromate production, you can't compare it  
2 because you don't know what their exposures were. We  
3 don't have any hexavalent chromium measurements. I  
4 can't use those studies to say there is not a risk.

5 DR. MARR: Well, could you ever say there is  
6 not a risk?

7 DR. GIBB: I think determining whether there  
8 is a risk depends on -- you have to look over the range  
9 of studies, the range of information that you have.  
10 You can't focus on one or two studies and say well,  
11 this study says there is not a risk. You have to look  
12 over the range of information you've got and take it  
13 given the information that you know on other exposures.  
14 You have to make that determination.

15 DR. MARR: That is sort of a weight of  
16 evidence thing?

17 DR. GIBB: I think the weight of evidence is  
18 a risk assessor. The weight of evidence doesn't  
19 pertain just to -- you are looking at hexavalent  
20 chromium. Is hexavalent chromium carcinogenic? That's  
21 the question here, okay?

22 For that, you use the weight of evidence. You  
23 look at all of the studies, and then you have to make a  
24 determination.

25 DR. MARR: Well, you say the question here

1 is --

2 ADMINISTRATIVE LAW JUDGE VITTONI: Mr. Marr,  
3 we could carry this on for a long time.

4 DR. MARR: Thank you.

5 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you.  
6 Mr. Clewell?

7 MS. SHERMAN: Your Honor, I would like to  
8 introduce Dr. Gibb's statement as Exhibit 44-4.

9 ADMINISTRATIVE LAW JUDGE VITTONI: It will be  
10 received into evidence.

11 **(Whereupon, Exhibit Number 44-4 was marked for**  
12 **identification and admitted into evidence.)**

13 ADMINISTRATIVE LAW JUDGE VITTONI: All right.  
14 Dr. Clewell, would you state your complete name and who  
15 you represent?

16 DR. CLEWELL: Harvey Joseph Clewell. I am a  
17 principal with Environ Health Sciences Institute.

18 ADMINISTRATIVE LAW JUDGE VITTONI: Okay. Do  
19 you have a statement that you want to read before we go  
20 to the questioning?

21 DR. CLEWELL: Yes, I do.

22 ADMINISTRATIVE LAW JUDGE VITTONI: Okay.  
23  
24  
25



1 compounds perhaps being more potent than the highly  
2 soluble or highly insoluble.

3           The animal evidence is not adequate to  
4 quantitatively estimate comparative potencies. It is  
5 not adequate to demonstrate that a particular  
6 hexavalent chromium compound is not carcinogenic under  
7 any conditions.

8           The mechanistic studies that have been  
9 performed on hexavalent chromium compounds suggest a  
10 mode of action that involves genotoxicity, primarily  
11 the production of DNA reactive species from the  
12 reduction of hexavalent chromium in the cells. The  
13 dose response for the carcinogenicity of hexavalent  
14 chromium may be non-linear.

15           For example, there is extra cellular reduction  
16 of hexavalent chromium that produces species, chromium  
17 (III) in particular, that can't enter the cells. So  
18 saturation of those processes would result in a  
19 relative increase in the cellular uptake of the  
20 hexavalent chromium. There is also intercellular  
21 reduction that could affect the delivery of the  
22 chromium species to the nucleus, but the available data  
23 is not adequate to support a departure from the default  
24 linear dose response assumption.

25           It is important to understand that extra

1 cellular reduction of chrome (VI) doesn't result in a  
2 threshold in the way people usually use the term for  
3 effects. Saturation would produce a dose-dependent  
4 transition from one dose response slope to another. In  
5 other words, a non-linearity. In order to actually try  
6 to describe anything quantitatively, one would need  
7 extensive data and the development of a biologically  
8 based model to describe the cellular kinetics of the  
9 various chromium species.

10 With regard to the animal evidence of  
11 carcinogenicity, there has only been a small number of  
12 animal studies of chromium that have been conducted by  
13 inhalation. The only full lifetime inhalation bioassay  
14 was positive. It demonstrated a statistically  
15 significant increase in lung tumors for calcium  
16 chromate.

17 There are also increases, although not  
18 statistically significant, in lung tumors for chromic  
19 acid and sodium dichromate in partial lifetime  
20 bioassays. But the carcinogenicity of chrome (VI) is  
21 also supported by studies in which chrome (VI)  
22 compounds were administered by installation or  
23 injection, and compounds that were found positive on  
24 these protocols were sodium dichromate, calcium  
25 chromate, strontium chromate, zinc chromate, and lead

1 chromate.

2           While the tumor increases observed in  
3 individual studies sometimes failed to achieve  
4 statistical significance, taken together, the evidence  
5 from the animal carcinogenicity studies supports the  
6 conclusion that inhalation of chrome (VI) compounds is  
7 associated with an increase in lung tumors.

8           The evidence from animal studies also tends to  
9 support the generalization that slightly soluble  
10 chromate compounds, such as calcium, strontium, or zinc  
11 chromate, are the more potent respiratory carcinogens  
12 with highly soluble compounds such as sodium,  
13 potassium, and ammonium chromate, or highly insoluble  
14 compounds such as lead and barium chromate being  
15 somewhat less active.

16           The presumption is that the slightly soluble  
17 salts can serve as a persistent source of locally  
18 available chromium, whereas highly soluble compounds  
19 tend to be rapidly cleared, and the highly insoluble  
20 compounds will be very slowly solubilized.

21           This is a bit simple-minded though. It is a  
22 fairly simple minded generalization, that is. There  
23 is, for example, evidence specifically supporting the  
24 carcinogenic activity of a highly soluble chemical,  
25 sodium dichromate, and a highly insoluble chemical,

1 lead chromate.

2           The solubility argument tends to overlook the  
3 role of phagocytation, direct uptake of particulate  
4 into the cell, and solubilization in a vacuole with  
5 delivery in the perinuclear area, which has been  
6 demonstrated in the case of nickel for nickel  
7 subsulfide, for example, and there is some evidence for  
8 lead chromate of the direct uptake into the cell of the  
9 particulate form.

10           The mode of action studies have demonstrated  
11 that the hexavalent chromates can damage DNA, producing  
12 both mutagenic and clastogenic lesions in a variety of  
13 systems, including both soluble chromates, such as  
14 potassium dichromate, and insoluble chromate, such as  
15 lead chromate.

16           Importantly, chrome (VI), the hexavalent form,  
17 is positive in cellular intact systems, whereas the  
18 chrome (III) compounds are inactive, unless they are  
19 allowed a direct interaction with DNA. This appears to  
20 result from the fact that trivalent chromium can't  
21 readily cross the cell membrane, whereas hexavalent  
22 can.

23           Once hexavalent chromate reaches the interior  
24 of the cell, it can be reduced to the trivalent form,  
25 which is then trapped inside the cell to some extent,

1 and so that increases the potential for exposure of the  
2 nucleus. Trivalent chromium has been shown to interact  
3 with DNA.

4 The alternative theories for the genotoxic  
5 effects of hexavalent chromium are based either on the  
6 intracellular production of trivalent chromium as the  
7 ultimate form, this table form, and its reaction or  
8 interaction with DNA to inhibit DNA repair, or to form  
9 DNA cross links or adducts. But the other alternative  
10 is the formation of the reactive intermediates, chrome  
11 (V) and chrome (IV), the reactive oxygen species that  
12 are in turn generated by those produced from the  
13 intracellular reduction of hexavalent chromium.

14 With regard to this reduction, the effect of  
15 extracellular and intracellular reduction, it has been  
16 shown that there are several processes that exist that  
17 reduce chrome (VI) to chrome (III). They are saturable  
18 processes, they are basically a reaction with things  
19 like ascorbic acid and glutathione. If they are  
20 saturated, then a greater proportion of chrome (VI)  
21 could become available to cross the cell membrane and  
22 enter the cell.

23 It is important to understand, though, that  
24 even though there have been studies that have described  
25 capacities for extracellular reduction of chrome (VI),

1 the extracellular reduction and the cellular uptake of  
2 chrome (VI) are parallel competing kinetic processes.  
3 It is not a matter of stirring them together in a pot  
4 to see how much is reduced, and then giving that to the  
5 second pot that can be taken up by the cell. Both  
6 processes are going on in parallel, so even at low  
7 concentrations where the reductive capacity is  
8 undiminished, some fraction of the chrome (VI) will be  
9 taken up into the cells as determined by the relative  
10 rates, the kinetics of the reduction in transport.

11 For this reason, reductive capacity shouldn't  
12 be construed to imply thresholds below which chrome  
13 (VI) will be completely reduced prior to uptake.  
14 Rather, they indicate there is likely to be a dose-  
15 dependent transition, that is a non-linearity in the  
16 concentration dependence of the cellular exposure to  
17 chrome (VI).

18 Evaluation of this concentration dependence  
19 would require more data than is currently available on  
20 the relative kinetics of dissolution, extracellular  
21 reduction, and cellular uptake, as well as on the  
22 homeostatic response to depletion of reductive  
23 resources, such as induction of glutathione reductase.

24 Once crossing into the cell, there is a  
25 continued opportunity for reduction by the same kinds

1 of species, reducing it to chrome (V) and chrome (IV),  
2 which are relatively unstable, and then to chrome  
3 (III), which is stable. The effect of those reductive  
4 processes depends on the mode of action, what is  
5 actually the important species for the carcinogenicity  
6 of chrome (VI).

7 If it is chrome (III), then intercellular  
8 reduction actually produces the toxic form. If it is  
9 the intermediate species, then the production of chrome  
10 (III) would be protective. Unfortunately, there is not  
11 adequate data to rule out, or to determine the level of  
12 contribution from the nuclear activity of chrome (III).  
13 So there is really no way to suggest that there is  
14 evidence for a threshold below which chrome (VI) would  
15 be considered to possess no carcinogenic activity at  
16 all.

17 This is a theme which occurred a number of  
18 times in the comments to OSHA of someone suggesting  
19 that some study demonstrated a threshold for the  
20 carcinogenicity of chrome (VI). For example, it has  
21 been suggested that some of the animal carcinogenicity  
22 studies provide evidence of a threshold.

23 There appear to be two basic premises that  
24 these suggestions rest on. One is that a non-linearity  
25 in dose response implies a threshold below which there

1 is no activity, and the other which is failure to  
2 detect an increased incidence of tumors from a given  
3 exposure indicates that there is no carcinogenic  
4 activity at that exposure. Each of these premises is  
5 faulty.

6 First of all, non-linearities only involve a  
7 change in slope of the dose response for an effect.  
8 They don't necessarily entail a threshold. A threshold  
9 is primarily a mechanistic question. The saturation of  
10 extracellular reductive processes provides a non-  
11 linearity, but does not imply a threshold.

12 So as I said before, if you don't have enough  
13 data, which there currently isn't to be able to model  
14 the kinetic processes, you can't determine the level or  
15 the extent of departure from the linear default due to  
16 the depletion of these kinds of reductive resources.

17 It has been suggested, for example, that the  
18 results of the Steinhoff study suggest that dose rate  
19 is an important factor in the carcinogenic potency of  
20 chrome (VI), and therefore, there must be a threshold.  
21 But these data, while they do provide an indication of  
22 a dose rate effect, they don't provide any basis for  
23 creating an alternative to the default assumption of  
24 linear. They don't provide information about where and  
25 whether a threshold, or even a non-linearity occur, and

1 to what extent it does occur at lower concentrations.

2 The second problem in looking at empirical  
3 data and trying to determine whether there is a  
4 threshold is that a statistically based No Observed  
5 Adverse Effect Level, or NOAEL, in a toxicity study,  
6 does not necessarily mean that there is no risk of an  
7 adverse effect.

8 It has been estimated by a colleague of mine  
9 that a NOAEL in a typical animal study can actually be  
10 associated with the presence of an effect in as many as  
11 10 to 30 percent of the animals. OSHA considers lung  
12 cancer risks at or above 1 in 1,000 to be clearly  
13 significant. So if a study with no observed effect  
14 dose that could entail risks higher than 10 percent,  
15 that doesn't provide adequate assurance that there is  
16 no significant risk.

17 One comment suggested that, for example, that  
18 the fact that there was no increase in the low dose in  
19 the study of Snyder, that that demonstrated the lack of  
20 a carcinogenic effect. But in fact if you look at the  
21 higher dose, which is 20 fold higher, there is a small  
22 increase in lung tumors, 4 per 100 and 1 per 100, and  
23 if you then calculate what one would expect at the  
24 lower dose, it would be a fraction of an animal.  
25 Unfortunately it doesn't work that way in an animal

1 study, so you have to use statistical dose response  
2 modeling to be able to actually determine what the  
3 response rate would be at the lower dose.

4 In order to actually show a significant,  
5 statistically significant effect, one would need to use  
6 a much larger number of animals. So as Dr. Gibb  
7 mentioned, the power of the study is critical.

8 The same can be said about the failure of Levy  
9 to detect an increase in tumors for the lead chromate  
10 study that they did. It has been suggested that that  
11 demonstrates a lack of carcinogenic activity for lead.  
12 But it really only demonstrates a lower activity  
13 perhaps under those experimental conditions for that  
14 compared to other compounds, whereas there are other  
15 studies that demonstrate that lead chromate is  
16 solubilized, that there is cellular uptake, and that  
17 there is effects on DNA from exposure in vitro. There  
18 is also studies demonstrating some in vivo activity  
19 from injection studies.

20 The bioassay of Glaser provides an example of  
21 this same question of whether an outcome of zero is  
22 meaningful. The tumor outcomes appear to be non-  
23 linear, zero out of 18, zero out of 18, and three out  
24 of 19 at .025, .05, and .1 milligrams chromium per  
25 cubic meter. But if you do dose response modeling on

1 that data, you find that the maximum likelihood  
2 estimate of the risk at the middle dose is greater than  
3 zero. So the assumption that the zero is zero is  
4 wrong.

5 In conclusion, the evidence from animal  
6 studies does provide some support for the conclusion  
7 that inhalation of chrome (VI) compounds is associated  
8 with increased risk of lung tumors. Some animal  
9 studies suggest that the solubility of hexavalent  
10 Chromium compounds influences their carcinogenic  
11 potency with the slightly soluble compounds having the  
12 higher potencies. Mechanistic studies provide evidence  
13 that both soluble and insoluble chromates are taken up  
14 by the cell and reduced to form the damage to DNA.

15 Although studies have attempted to estimate  
16 capacities for extracellular reduction of chrome (VI),  
17 the extracellular reduction and cellular uptake of  
18 chrome (VI) are parallel competing processes. So even  
19 at low concentrations, some fraction of chromium will  
20 be taken up into the cells.

21 Evaluation of the concentration dependence of  
22 the cellular uptake of chrome (VI) would require more  
23 data than is currently available on the relative  
24 kinetics of all the processes involved in its cellular  
25 delivery. The same is true of intracellular reduction,

1 that at this point there is not enough data to be able  
2 to develop a model of the cellular dosimetry and  
3 predict the impact on the target tissue, the nucleus.

4 The saturation and reductive processes, while  
5 providing a possible source of non-linearity, does not  
6 provide adequate data for departure from linear dose  
7 response which still appears to be reasonable and  
8 prudent. That's the end of my comments.

9 ADMINISTRATIVE LAW JUDGE VITTON: Thank you,  
10 sir. May I have a showing of hands, please? You, sir.

11 MR. ROBINSON: Hi, I'm Larry Robinson with  
12 the Color Pigments Manufacturers Association. Thank  
13 you.

14 On page two of your written testimony that I  
15 believe is the same testimony that was on the table  
16 this morning, the second paragraph describes the Levy  
17 et al. study in the third and fourth sentences. Just  
18 to let everybody know what we're talking about here,  
19 I'll quote from that.

20 "In another set of studies, increased  
21 bronchial carcinoma was reported following a single  
22 intrabronchial administration, in a steel pellet, using  
23 slightly soluble compounds, calcium chromate or  
24 strontium chromate, as well as using a mixture of  
25 poorly soluble zinc chromates. On the other hand, no

1 statistically significant increases were reported for  
2 similar doses of the soluble compounds chromic acid or  
3 sodium dichromate, or the insoluble compounds zinc  
4 tetroxy chromate, lead chromate, or barium chromate."  
5 That's from the Levy study.

6 I'm interested in the distinction you made,  
7 and you touched on it this afternoon, the distinction  
8 you made about the solubility of the chromate compounds  
9 and the results found in the study. It would appear  
10 that you agree that the solubility of these compounds  
11 has an important influence on the response in this  
12 assay. The evidence from the Levy et al. study shows  
13 that the slightly soluble compounds produced an  
14 increase in bronchial carcinomas, whereas similar doses  
15 of insoluble compounds did not.

16 Are you aware of the Davies et al. 1992 and  
17 others that show a patterned result similar to the  
18 animal studies that slightly soluble compounds produce  
19 a higher incidence of cancer in workers, but insoluble  
20 lead chromate does not? I don't know if you're  
21 familiar with that study or not.

22 DR. CLEWELL: I haven't really focused on the  
23 epidemiological studies, no.

24 MR. ROBINSON: Because we would think that in  
25 this respect whether you would agree then that

1 carcinogenicity in lab animals and humans shows a  
2 similar pattern related to the slightly soluble or  
3 insoluble nature of the compound? I guess if you're  
4 not familiar with that study, you can't really answer  
5 that question.

6 DR. CLEWELL: No, I really can't comment on  
7 the epi studies. I have seen that conclusion reached,  
8 but I have never tried to evaluate it.

9 The conclusion from the animal studies needs  
10 to be couched in the nature of the data that is  
11 available. The comparative studies are uniformly  
12 studies of installation. There are studies where there  
13 is repeated installation, and there is studies where  
14 there is single installation in a pellet which then the  
15 duration of delivery and the level of delivery is to  
16 some extent unknown, depending on the affinity of the  
17 chemical for the cholesterol that the pellet, the  
18 vehicle that was used to hold the chemical in the  
19 pellet.

20 So it is very difficult to extrapolate that  
21 inhalation. The basic problem in the case of the  
22 animal studies is that there have not been good  
23 comparative inhalation studies such as the NTP did for  
24 nickel where they looked at the oxide, the subsulfide  
25 in some soluble form under similar experimental

1 conditions for whole lifetime inhalation.

2 If you really want to know the relative  
3 potency of compounds for lifetime inhalation, you need  
4 to do lifetime inhalation.

5 MR. ROBINSON: Thank you. You also stated in  
6 that same paragraph that lead chromium had been found  
7 to cause injection site sarcomas following  
8 intramuscular, subcutaneous injection.

9 Would you agree that this route of  
10 administration isn't routinely done these days, can be  
11 caused by any inert material, and has little or no  
12 relevance to the routes of exposure for workers in an  
13 occupational environment?

14 DR. CLEWELL: I guess I'd say yes, maybe no.  
15 I'm familiar with the fact that that is frowned upon as  
16 a technique nowadays, and that it is more because of  
17 its difficulty of interpretation, and that it is prone  
18 to, I mean, there are a large number of materials,  
19 including cutting off 1/3 of the liver, that can  
20 produce similar effects because of the cytokines that  
21 can be generated.

22 So it is a fairly low level in terms of its  
23 weight of evidence, I would agree with that. But it is  
24 not true to say that any inert material can cause those  
25 kinds of reactions. Actually there are many things one

1 can put under the skin that don't cause a neoplastic  
2 change, that might cause fibrosis or something.

3 So I would say it is not without value, but it  
4 is certainly in the lower part of the weight of  
5 evidence.

6 MR. ROBINSON: Thank you. Turning to the  
7 section that begins at the bottom of page seven of your  
8 written statement on genotoxicity and mutagenicity.  
9 Would you agree that most, if not all of the studies  
10 that you described were done in systems that can be  
11 characterized as in vitro tests?

12 DR. CLEWELL: Yes. The ones that I described  
13 for the effects of lead chromate. I guess I spoke too  
14 soon. All of the things that I described with regard  
15 to what? I'm not looking at page seven, so I don't  
16 know.

17 MR. ROBINSON: I know, lead chromate. Geno  
18 and mutagenicity tests described were done in systems  
19 that can be characterized as in vitro.

20 DR. CLEWELL: There are some in vivo tests,  
21 but not for lead.

22 ADMINISTRATIVE LAW JUDGE VITTONI: One at a  
23 time.

24 DR. CLEWELL: In general on chromates, there  
25 are some in vivo tests. But in the specific case of

1 lead chromate, all I remember are in vitro.

2 MR. ROBINSON: Aside from possible usefulness  
3 in determining genotoxic potential or mechanistic  
4 considerations, I think we'd probably agree then that  
5 the in vitro data have less relevance in assessing the  
6 effects on whole animals than actual tests using whole  
7 animals. Is that correct?

8 DR. CLEWELL: I wouldn't put it that way, no.

9 MR. ROBINSON: Okay.

10 DR. CLEWELL: I think that actually neither  
11 one of them stands very well on its own. Certainly the  
12 gold standard is a positive in vivo bioassay. But when  
13 you have a situation such as the case for many metals,  
14 arsenic, nickel, in addition to chromium where the  
15 animal evidence is often equivocal and sometimes fails  
16 to achieve statistical significance, even though there  
17 is an awful lot of cases where increases are seen, the  
18 mechanistic data can actually become extremely  
19 important.

20 It provides a mode of action hypothesis that  
21 underlies the belief that there could indeed be an  
22 effect, which is even while unobserved, is nevertheless  
23 quite real. In the case of the chromates, the issue,  
24 since there have not been a lifetime inhalation  
25 bioassay performed on each and every chromate, it is

1 necessary to try to put the evidence together in that  
2 way.

3           So if you actually do see phagocytation of a  
4 particular particulate, that increases the likelihood  
5 that there would be a carcinogenic effect. If you  
6 actually see that when the particles are put in the  
7 same media with the cells that there are effects on the  
8 DNA and there is the presence of chromium in the  
9 nucleus, then that increases the likelihood that that  
10 chromate, as well as other chromates, can also cause  
11 carcinogenic effects. So that allows you to weave a  
12 web by which you can infer that there is a potential  
13 carcinogenic activity, even without having a positive  
14 bioassay.

15           MR. ROBINSON: Fine. Thank you very much. I  
16 appreciate it.

17           ADMINISTRATIVE LAW JUDGE VITTON: Thank you,  
18 sir. Any other hands? Ms. McMahon?

19           MS. MCMAHON: Mr. Clewell, I just have one  
20 question. I don't pretend to think that I understood  
21 quite everything you said a little while ago, but I  
22 want to clear up one thing.

23           Are you saying that there is mechanistic or  
24 kinetic or animal study data that shows that there is  
25 no risk threshold? Or are you saying that there is no

1 mechanistic analysis or animal studies or kinetic  
2 studies that allow for the possibility of a risk  
3 threshold?

4 DR. CLEWELL: No. Any other questions? No.  
5 It is essentially, well, I'll just say it is extremely  
6 difficult to demonstrate a threshold.

7 MS. MCMAHON: It is difficult to demonstrate  
8 a negative.

9 DR. CLEWELL: Well, that's exactly the case.  
10 In the case of chromium, there is mechanistic evidence  
11 that is consistent with a carcinogenic process that  
12 could occur at any level of exposure, which suggests  
13 that it is unlikely that there is an inherent  
14 threshold.

15 Let me explain that by differentiating  
16 chromium from, well, no. Let me just explain that.  
17 The things that chromium does, there is a variety of  
18 things, just like many of the metals. They involve  
19 generation of reactive oxygen species, and the  
20 inhibition of DNA repair.

21 Now, the inhibition of DNA repair is something  
22 that is likely to have a threshold, because you will  
23 get to a concentration below which there is just not  
24 enough of whatever chemical you're delivering to reduce  
25 the activity of the critical protein.

1                   But the generation of reactive oxygen species,  
2 particularly in the case of chromium where there is  
3 kind of a self-continuing process, a cycling process  
4 that one can get in the multiple valences. There is  
5 really no inherent reason why that process can't take  
6 place at any concentrations of chromium.

7                   So that provides for a plausible mechanism for  
8 the carcinogenicity of chromium where there would be no  
9 expectation of a threshold. There could be a number of  
10 kinds of non-linearities that would cause the dose  
11 response to change, but there is no reason to say well,  
12 if you get down to here, there won't be any activity.

13                   In particular, the fact that you end up  
14 producing trivalent which then is known to interact  
15 with DNA in a number of ways means that you end up even  
16 if all of the reductive processes in the cell do their  
17 thing, you still have a potential for interaction.

18                   So I would say that theoretically, I don't see  
19 any evidence that would suggest to me the likelihood of  
20 an inherent threshold. That doesn't say that there  
21 couldn't be an effective threshold that would have to  
22 be demonstrated by some significant dose response  
23 studies.

24                   MS. MCMAHON:    Which currently don't exist.

25                   DR. CLEWELL:    Which don't exist.

1 MS. MCMAHON: That you're aware of.

2 DR. CLEWELL: That I'm not aware of, right.

3 MS. MCMAHON: Okay. All right. And then

4 just one question on trivalent chromium. Am I

5 understanding you to say that there is evidence of

6 carcinogenic effect of trivalent chromium?

7 DR. CLEWELL: No. There is evidence of in

8 vitro activity of trivalent chromium with DNA. It is

9 one of the keys for trivalent chromium is it tends not

10 to cross cell membranes, unless that is actively

11 mediated. There are places that -- it is an essential

12 nutrient, there are places where it is needed.

13 So when you test intact systems, the chromium

14 is excluded from the cells, so you don't see any

15 effects. When you test in vivo, you don't see that

16 there haven't been effects. But if you generate, as

17 chrome (VI) does, the chrome (III) in the cell, then

18 there is evidence of DNA adducts of chrome (III), and

19 of inhibition of DNA repair by chrome (III).

20 So you are unlikely to see a carcinogenic

21 effect from chrome (III). You need sort of a pro

22 carcinogen, which in this case is the hexavalent

23 chromium to deliver the active species to the inside of

24 the cell.

25 MS. MCMAHON: And then you are saying the

1 trivalent chromium prohibits the remedying of that  
2 situation, right?

3 DR. CLEWELL: Right. It tends to be trapped  
4 in the cell, just as it was trapped out before. It  
5 kind of accentuates the problem in that by inhibiting  
6 DNA repair, it makes the effects of the reactive oxygen  
7 species more pronounced in terms of mutagenicity.

8 MS. MCMAHON: And is there a particular study  
9 that you are relying on?

10 DR. CLEWELL: Well, there is a series of  
11 studies that were done with lead chromate. There are  
12 two by Wise, I believe it is. Anyway, there is a  
13 series of studies of lead chromate that looked at the  
14 facts of, or the generation of reactive oxygen species,  
15 the inhibition of DNA repair. There is quite a large  
16 body of evidence on the mutagenetic and clastogenetic  
17 effects of the various chromate species, (VI) versus  
18 (III), which are I believe in the testimony. But at  
19 any rate, it is a pretty large body of work on both  
20 species.

21 MS. MCMAHON: Right. Okay. Thank you.

22 DR. CLEWELL: Thank you.

23 ADMINISTRATIVE LAW JUDGE VITTON: Thank you.

24 Let me take this lady back here first.

25 MS. PROCTOR: Deborah Proctor with Exponent.

1 Dr. Clewell, I have a couple of questions. In the two  
2 epidemiological studies that are the focus studies or  
3 featured studies the Gibb cohort and the Luippold et  
4 al. cohort, in both cases the cohort had pretty high  
5 rates of respiratory irritation associated with their  
6 exposures.

7 How do you think irritation could influence  
8 the carcinogenic risk observed in those cohorts?

9 DR. CLEWELL: In general, one expects in any  
10 kind of irritation if it produces a mytogenic stimulus  
11 of pressure for cells to divide it is going to  
12 exacerbate the effects of a carcinogenic, any  
13 carcinogenic process. But that is completely  
14 speculative. I haven't actually looked at those  
15 studies obviously.

16 It is just one more of the non-linearities  
17 that could occur in the dose response, just as the  
18 reductive processes, any kind of proliferative process  
19 could also affect the dose response.

20 MS. PROCTOR: Okay. And then you talked  
21 about the Steinhoff et al. study. That's the study  
22 where they instilled calcium chromate and sodium  
23 dichromate in rats. You said that it is not evidence  
24 of a threshold per se, but it is more of evidence of a  
25 dose effect.

1                   Can I characterize your opinion that the dose  
2 effect observed in Steinhoff is that high doses which  
3 were irritating caused a greater, higher rate of tumors  
4 than lower doses given like throughout the course of a  
5 week, even though the cumulative dose was equal. Is  
6 that correct?

7                   DR. CLEWELL: Well, that was the  
8 interpretation of the authors, and I don't see any  
9 reason to disagree with it.

10                  MS. PROCTOR: So if it is an important  
11 consideration when we're doing quantitative risk  
12 assessment for hexavalent chromium that we are making  
13 the interpretation that cumulative dose is the most  
14 appropriate dose metric, and certainly it is the one  
15 that is most typically used.

16                  But in that case, we aren't making the  
17 assumption that one year of exposure to 45 micrograms  
18 per cubic meter is equal to 45 years of exposure to one  
19 microgram, that they are in fact equal, have equal  
20 toxicological consequence.

21                  Do you think that based on the Steinhoff et  
22 al. evidence that perhaps there is some uncertainty  
23 there?

24                  DR. CLEWELL: I agree there is uncertainty.  
25 It has been one of the frustrations I have had over the

1 years is that it is not possible to do anything  
2 quantitative with such information, and generally  
3 people don't seem to be motivated to actually collect  
4 whatever data would be necessary in order to try to  
5 become quantitative.

6 So one can only say that that is a factor  
7 which suggests that the risk estimate might be to some  
8 degree, some unknown degree, conservative. But as far  
9 as trying to provide an alternative to the standard  
10 risk assessment paradigm, it doesn't actually provide  
11 you an alternative.

12 MS. PROCTOR: What kind of data do you think  
13 would be the kind of data that would allow you to  
14 quantify any sublinearity in the low dose range?

15 DR. CLEWELL: Well, there has been much  
16 better data collected in the case of nickel, for  
17 example, in looking at the actual cell dosimetry of the  
18 nickel, several different forms of nickel, and the dose  
19 response.

20 Even that doesn't reach to the level of being  
21 usable yet, but there is work in progress going in that  
22 direction. So it is a matter of doing a dose response  
23 on the kinetic processes, as I mentioned. If you are  
24 wanting to consider the effect of irritation, then that  
25 requires also looking at the dose response on cell

1 proliferation, similar to what CIIT has done in the  
2 past with formaldehyde and chloroform.

3 So you can imagine the scope of the studies  
4 that we're talking about here. There are very few  
5 chemicals that have been studied to the extent of  
6 formaldehyde and chloroform.

7 MS. PROCTOR: You need to do whole animal  
8 studies in a sense to get the full immuno --

9 DR. CLEWELL: Well, you need something to tie  
10 the in vitro studies to. So yes, there always have to  
11 be some sort of whole animal studies. I would say for  
12 chromium, the lynchpin would be a whole animal  
13 inhalation bioassay for a couple of key forms like they  
14 did with nickel, supported by in vitro studies of the  
15 cellular kinetics.

16 MS. PROCTOR: Okay. Thank you.

17 ADMINISTRATIVE LAW JUDGE VITTONI: Anyone  
18 else? This gentleman up here first.

19 MR. BURDGE: Gavin Burdge with BMT Designers  
20 and Planners. I have two quick questions.

21 In light of the toxicological action of the  
22 different chromium (VI) compounds, do you feel that all  
23 forms of hexavalent chromium should be occupationally  
24 equally regulated?

25 DR. CLEWELL: Well, that's a bit much for me

1 to opine on. I would say that I don't see an  
2 alternative at the moment, because I don't believe that  
3 there is adequate data to perform a quantitative  
4 potency evaluation across different forms of chromium.

5 So as much as there may be evidence that there  
6 are different potencies for different compounds in  
7 different experimental paradigms, I don't see at this  
8 time any way of trying to use that information in a  
9 quantitative form. So it seems to me the most prudent  
10 thing to do is the approach of using the same value for  
11 all compounds.

12 MR. BURDGE: Did you look at any  
13 toxicological significance from different physical  
14 forms of hexavalent chromium? Dust? Fumes?

15 DR. CLEWELL: No, I didn't look at the  
16 question of dust versus fumes, no.

17 MR. BURDGE: That's all.

18 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you,  
19 sir. One question. Go ahead. I'm sorry.

20 DR. NESTMANN: Earle Nestmann with Cantox on  
21 behalf of Dominion Color Corporation. I just wanted to  
22 follow up with the competing processes of uptake that  
23 you mentioned, the uptake versus the saturation of the  
24 chromium (VI) and so forth. How do those competing  
25 processes relate to insoluble compounds?

1 DR. CLEWELL: Well, there is a third process  
2 then for insoluble compounds, which is the rate of  
3 solubilization. So as the compound is being  
4 solubilized in the biological matrix, then it becomes  
5 available for either reaction with the reducing  
6 species, or being taken up in the ionic channels into  
7 the cell.

8 So in a way it doesn't actually change the  
9 competition between reduction and uptake, it just  
10 changes the rate at which the chemical is being  
11 provided, which of course you have competing factors,  
12 if it is insoluble, its residence time may be longer,  
13 depending on how well it is cleared, and whether it is  
14 chemotactic.

15 With particulates, you also have to consider  
16 the possibility of phagocytosis and the direct uptake  
17 of the particle intact into the cell, at which point  
18 then that other competition really doesn't count.

19 DR. NESTMANN: But in your third alternative,  
20 you talk about localized solubilization. But if the  
21 compound is insoluble, that's not likely to happen.

22 DR. CLEWELL: Oh, not at all true. Insoluble  
23 compounds of relatively insoluble -- I don't know what  
24 you mean by insoluble as in absolutely insoluble, like  
25 the Grand Canyon insoluble. But everything is soluble

1 to some extent, it is just some more slowly than  
2 others.

3 So it is all a matter, as I say, of kinetic  
4 processes. It is not black and white. There are  
5 studies that have demonstrated, for example, with lead  
6 chromate, the internalization of the lead chromate  
7 particles, and also the presence of lead in the nucleus  
8 which have a hand of chromium in the nucleus,  
9 presumably due to the dissolution of the particle.

10 It depends on what the cell does to the  
11 phagocytized particle, and what is in the vacuole. It  
12 has been seen with nickel subsulfide, for example, that  
13 dissolution can be surprisingly quick once it is in the  
14 cell. The local environment is critical. Also the  
15 particle size is critical. If you take large  
16 particles, the surface to volume ratio is very small.  
17 But if you get very fine particles, then the surface to  
18 volume is very large. Depending on the matrix that's  
19 in the solubility, that can actually be much higher.

20 DR. NESTMANN: The first two processes you  
21 considered I think in great detail with respect to the  
22 possibility of a threshold. Now, phagocytosis, what is  
23 your view of phagocytosis with respect to a possible  
24 threshold?

25 DR. CLEWELL: I don't really see any obvious

1 relationship of phagocytosis to concentration. I would  
2 guess -- no, I really can't think of any reason why  
3 that would be, unless you're talking about by  
4 macrophages and macrophage recruitment. I'm talking  
5 about phagocytosis by the epithelial cells. I think  
6 that's just a contact phenomenon. It seems to be more  
7 pronounced for some compounds than others. For  
8 example, for nickel sulfide, different forms tend to be  
9 highly phagocytized, other forms are not. As far as I  
10 can tell, no one has ever really looked at that  
11 question carefully for any of the chromates, so I  
12 really don't know. But whether there is a difference  
13 in the chemotactic properties of the various forms of  
14 the chromates. But I wouldn't expect a threshold  
15 process in that, no.

16 DR. NESTMANN: You made the point about  
17 particle size being incredibly important, and of course  
18 you characterized the Wise studies in which the  
19 chromium seemed to be taken up into the nucleus, and  
20 you've talked about that at some length.

21 Are you aware that the lead chromate in those  
22 studies was ground to a fine, fine powder with mortar  
23 and pestle?

24 DR. CLEWELL: As I recall, it was suspended  
25 in acetone and ultrasonically shaken to reduce it to

1 submicron size particles, which seems like a reasonably  
2 good thing to do.

3           There are actually a couple of other studies  
4 besides the Wise studies that have looked at the  
5 question of the uptake of lead chromate. I have looked  
6 at those studies, and I don't really see any basic  
7 flaws in what they did. It is obviously a challenge to  
8 try to reproduce inhalation exposure in vitro.

9           Because of the fact that you would like to  
10 reproduce realistic particle sizes, it is necessary to  
11 take some method of breaking the particle up. I think  
12 the methods that they used were reasonable.

13           DR. NESTMANN: Well, you make the point that  
14 reasonable particle size is important. The particle  
15 size to which people in the workplace would be exposed  
16 in terms of lead chromate particles, those particles  
17 are huge compared to the fine powder that we're talking  
18 about in these in vitro studies.

19           DR. CLEWELL: I really have no knowledge of  
20 the occupational exposure conditions. I'm surprised to  
21 know that you have characterized the particle size  
22 distribution for the exposures. That's pretty rare to  
23 find that kind of information. But I agree it is  
24 critical.

25           DR. NESTMANN: And in one final question, and

1 | you have pointed out that these studies on intake by  
2 | cells are in vitro studies, right?

3 | DR. CLEWELL: Right.

4 | ADMINISTRATIVE LAW JUDGE VITTONI: Thank you,  
5 | sir. Mr. Lurie?

6 | DR. LURIE: Good afternoon. My first  
7 | question to you is do you have any evidence to conclude  
8 | that any particular hexavalent chromium compound is not  
9 | carcinogenic?

10 | DR. CLEWELL: No.

11 | DR. LURIE: You don't. But you have some  
12 | evidence that suggests that some might be more  
13 | carcinogenic than others?

14 | DR. CLEWELL: Perhaps, yes.

15 | DR. LURIE: Perhaps. And if anything, the  
16 | more carcinogenic ones would include calcium,  
17 | strontium, and zinc, right?

18 | DR. CLEWELL: Well, that's using the Levy  
19 | protocol, yes.

20 | DR. LURIE: And an example of a less  
21 | carcinogenic one might be sodium chromates, is that  
22 | right?

23 | DR. CLEWELL: Right.

24 | DR. LURIE: Which are the ones that were used  
25 | in the critical Gibb study, right?

1 DR. CLEWELL: I don't know.

2 DR. LURIE: Okay. Well, let's stipulate that  
3 for a moment.

4 DR. CLEWELL: Okay.

5 DR. LURIE: Because it is so. Then if it  
6 were true that the sodium chromate was if anything less  
7 carcinogenic than some others, and one in an  
8 epidemiological study found an association of a  
9 particular magnitude, is it not true that you might be  
10 in fact underestimating the size of the risk if you  
11 depended upon say sodium?

12 DR. CLEWELL: It's possible. There's a great  
13 deal of uncertainty in that characterization of these  
14 compounds being more potent than others. It is one of  
15 those things that gets a life of its own.

16 It is clearly the conclusion from the Levy  
17 study, but if you look at the inhalation bioassays, if  
18 anything, you would conclude that the carcinogenicity  
19 of sodium dichromate is similar to that of calcium  
20 chromate. So it is a highly uncertain comparison.

21 I think that it is a useful generalization  
22 only as long as it is not taken to extremes. By  
23 extremes, I mean trying to actually use that  
24 information in some sort of quantitative fashion.  
25 There is simply not a good quantitative comparison.

1 DR. LURIE: Right. So your testimony would  
2 be that even if the sodium chromate in general was less  
3 carcinogenic than some other forms, the differences are  
4 too uncertain and too difficult to quantify to be the  
5 basis for distinguishing between the various chromium  
6 compounds?

7 DR. CLEWELL: That's what I would think, yes.

8 DR. LURIE: Okay. Fine. Fair enough. So  
9 let me just try and make it a little bit more concrete,  
10 some of this discussion about thresholds and non-  
11 linearity, which might be confusing to some people,  
12 perhaps including me.

13 Your argument seems to be that it is possible  
14 that they might not be an absolute straight line,  
15 right? So, for example, if you looked at this  
16 microphone, you might say that this is not actually a  
17 straight line. But you might say that for all intents  
18 and purposes, it is a straight line, that it is close  
19 enough to a straight line, right? Is that in effect  
20 what you're saying?

21 DR. CLEWELL: Well, that's part of it. I  
22 work with one of the premier dose response modelers in  
23 the world, Kenny Crump, and he drives me crazy with  
24 continually saying not statistically different from  
25 linear. So I have been kind of ingrained with the idea

1 that the fact that I look at something and say oh,  
2 that's a non-linear dose response doesn't mean that it  
3 is inherently non-linear, or that it is indeed even  
4 factually non-linear. It just means that it may appear  
5 to be on first glance, but statistical variation may be  
6 tricking me.

7 So that is the problem, is that we can  
8 speculate that processes go on, but without hard data  
9 on their dose response with uncertainty bounds, we  
10 can't really be sure that our conclusions are  
11 quantitatively correct.

12 DR. LURIE: Right. So even if we really knew  
13 with certainty that something was non-linear, I mean,  
14 if we could really describe the line of this microphone  
15 with absolute certainty, that would be one thing. Of  
16 course we can't, we have only certain points, right?

17 So you are looking for a best approximation,  
18 right? The approximation that you're saying, if I  
19 understand you correctly, is that the linear is the  
20 best approximation?

21 DR. CLEWELL: Well, it is the most prudent,  
22 conservative approximation. Actually I can't think of  
23 another one. If you ask me, well, what would you  
24 suggest as an alternative, that's the problem. I  
25 really don't have a method of providing some reliable

1 basis for doing a dose response apart from the linear  
2 on the basis of the level of information that's  
3 available.

4 DR. LURIE: Right. So even if we know that  
5 there are some kinks in this microphone, you don't have  
6 an equation that you could write that would reasonably  
7 describe the kinks in this microphone. You can draw a  
8 line and you can tell me with some degree of certainty  
9 that actually is very close to that. Nothing departs  
10 much from the line. That's the essence of what you're  
11 saying, isn't it?

12 DR. CLEWELL: Yes.

13 DR. LURIE: Okay. And for some reason you  
14 say in your testimony that the linearity is the  
15 default, your word, I think you used it twice in your  
16 testimony, as well as --

17 DR. CLEWELL: I'm sorry. I come out of an  
18 environmental, so they use the word default a lot.  
19 Regulatory agencies have traditionally used a linear  
20 dose response as a default, meaning the approach one  
21 takes when data is too limited to attempt something  
22 more sophisticated for that chemical.

23 DR. LURIE: And why is it that they do that?

24 DR. CLEWELL: Because it is felt in general  
25 to be a conservative approach, although people have

1 shown that there are cases where it is not  
2 conservative. It is a science policy, public  
3 protective health position that agencies have generally  
4 taken.

5 DR. LURIE: So conservative in the sense  
6 means more health protective, is that fair?

7 DR. CLEWELL: That's right.

8 DR. LURIE: Usually.

9 DR. CLEWELL: Usually.

10 DR. LURIE: Sometimes there are exceptions.

11 DR. CLEWELL: Right.

12 DR. LURIE: As a final question then, let's  
13 assume for a moment that there is a non-linearity of  
14 some kind that exists based on mechanisms and in vitro  
15 studies. By the way, do you see an alternative to  
16 investigating these questions that have been asked of  
17 you to any in vitro system?

18 DR. CLEWELL: Well, I mentioned that it does  
19 need anchoring. In vitro measurements need anchoring,  
20 which is the reason that I am suggesting in vivo  
21 studies would also be necessary. But the principle  
22 data would need to be obtained in in vitro systems, the  
23 kinetics of uptake, distribution, those kinds of  
24 things.

25 DR. LURIE: Right. There is nothing

1 particularly unusual about the fact that much of the  
2 data upon which you rely is in vitro. There is nothing  
3 very unusual about that?

4 DR. CLEWELL: No.

5 DR. LURIE: No. Okay. So back to my  
6 question. Assuming that there is indeed some form of  
7 non-linearity that could be demonstrated, or at least  
8 theorized in these in vitro mechanistic type studies,  
9 how would you go about relating that to the  
10 epidemiological study?

11 Is there any way to say if the non-linearity,  
12 you know, at such and such a concentration of  
13 hexavalent chromium extracellularly, and the  
14 stoichiometry of hexavalent chromium going in and out  
15 of the cells could be shown to be somehow non-linear at  
16 such and such a concentration in an in vitro system,  
17 how do you go about relating that to the epidemiology?

18 DR. CLEWELL: Funny you should ask. That is  
19 actually what is one of my major research interests  
20 that unfortunately I am pursuing mostly in terms of  
21 nickel and arsenic, not chromium. But the issues are  
22 very, very similar. Same systems that are affected.

23 What one needs are in vitro studies in both  
24 the animal and human cell lines, which one can do, and  
25 a biologically based model that describes both the

1 pharmacokinetics of the chemical. For example, there  
2 is a chromium model Ellen O'Flaherty developed in the  
3 rat, and there is an oral version of it in the human,  
4 but there is not, as far as I know, an inhalation  
5 version of it that could do the dosimetry of chromium  
6 on the broad perspective of the whole body dosimetry.

7 But what is also needed is what I call a  
8 cellular dosimetry model. In other words, a model that  
9 looks at the uptake of the chemical in say magnesium  
10 channels or however it is taken up, and the kinetics of  
11 the delivery to the perinuclear area crossing the  
12 nuclear membrane. But there is a lot of model  
13 parameters that would be based on the in vitro studies  
14 in both the rat and the human. There would also be the  
15 blood flow and partitioning effects that would have to  
16 be part of it.

17 Anyway, that model is what would allow one to  
18 extrapolate from the evidence that the animal studies  
19 give you to the exposures in the epidemiological  
20 studies. It is not a small matter to collect all that  
21 information and do all of that modeling.

22 DR. LURIE: Right. And it doesn't exist for  
23 chromium, correct?

24 DR. CLEWELL: That's correct.

25 DR. LURIE: Okay. So at present, given the

1 data that we have, there is no way to say that even if  
2 one accepted the notion that there was non-linearity in  
3 some particular chemical reaction, or some particular  
4 movement of atoms or ions between cells, you would have  
5 no way to convert that into an equivalent place in  
6 terms of the dose response relationship in the  
7 epidemiological study. You could not convert those  
8 things, is that true?

9 DR. CLEWELL: Not in any reliable,  
10 quantitative fashion. You can make suggestions, if one  
11 has an idea of the concentrations that are produced,  
12 which is the key uncertainly, then one could look at  
13 whether there is irritation that gives you an idea that  
14 you are in a range where irritation occurs, those kinds  
15 of things. But broad uncertainty and probably really  
16 only a qualitative comparison, yes.

17 DR. LURIE: Okay. Thank you.

18 ADMINISTRATIVE LAW JUDGE VITTON: Going  
19 once, twice. I hope you have a high bid. Follow up  
20 question?

21 DR. NESTMANN: Yes, Earle Nestmann. Just a  
22 follow up on the solid state foreign body  
23 carcinogenesis arising from implants and subcutaneous  
24 injection and so forth.

25 I just wanted to follow on your

1 characterization of not every material will cause such  
2 a reaction, but certainly a lot of inert materials have  
3 all kinds of cellophane, silk, and Teflon even. You  
4 are aware of that?

5 DR. CLEWELL: Right. Of course we have a  
6 strange notion of what inert is. We have found over  
7 time that electrostatic properties are important, too.  
8 So a lot of the things whether they are insulators  
9 makes a big difference.

10 So we just don't know enough about the nature  
11 of materials, but you can almost say by definition if  
12 something causes a response, it wasn't inert.

13 DR. NESTMANN: And so that wouldn't explain  
14 why glucose causes the same kind of --

15 DR. CLEWELL: Well, the fact that something  
16 is natural doesn't mean it is good for you in high  
17 concentrations. So no, I wouldn't inject glucose under  
18 my skin, no.

19 DR. NESTMANN: That's it. Thank you.

20 ADMINISTRATIVE LAW JUDGE VITTON: Thank you,  
21 sir. Do you have any questions?

22 DR. SCHAEFFER: I have a few questions, Dr.  
23 Clewell.

24 I know you have testified that respiratory, or  
25 at least chronic lung inflammation can provide a

1 mytogenic stimulus and accelerate the rate, you might  
2 get tumors. But in your review of the animal studies  
3 and the mode of action, can you address the question of  
4 whether you found any plausible evidence that this lung  
5 damage or chronic inflammation has necessary and  
6 essential condition for chromate carcinogenesis?

7 DR. CLEWELL: No. I didn't find any evidence  
8 that it was necessary and essential. In particular, I  
9 think the Glaser study was pretty good in demonstrating  
10 that there were effects where they saw no evidence of  
11 irritation, or any clinical signs of those kinds of  
12 processes. I think that was sodium dichromate.

13 The study that was mentioned, I think it is  
14 Steinhoff that did the two different protocols. There,  
15 there was some sign of irritation. I would not say  
16 that it is necessary and sufficient, but rather that it  
17 exacerbates an underlying process. If there is a  
18 carcinogenic process, then increased self-  
19 proliferations secondary to irritation is going to put  
20 mytogenic pressure on the cells, and this will cause  
21 more likelihood of a transformation.

22 DR. SCHAEFFER: Then you certainly wouldn't  
23 consider the chronic lung inflammation or the lung  
24 damage as some kind of a threshold that's required?

25 DR. CLEWELL: No, I wouldn't call it a

1 threshold. Again, because it increases the likelihood,  
2 you can end up with kind of observable or apparent  
3 thresholds just because you are more likely to see the  
4 tumors under those conditions.

5 DR. SCHAEFFER: In the Steinhoff study, I  
6 believe they showed some, or at the 1.2 milligram per  
7 KG does, the showed considerable inflammation in the  
8 rats.

9 In your mind, can that dose in any way be in  
10 form on what levels that workers breathing chromate  
11 might cause the same equivalent to that particular  
12 administrative --

13 DR. CLEWELL: I certainly wouldn't want to  
14 have to try to do that. Well, in the first place, the  
15 rat and human lung responses are quite different,  
16 particularly to responses to irritation and to  
17 irritating chemicals.

18 The nature of the response in the rodents is  
19 inflammatory response, it is quite different. There  
20 are differences in deposition and clearance, there are  
21 still orders of magnitude difference in the predictions  
22 of various models of the lung when trying to do animal  
23 to human extrapolation. The uncertainties are huge.

24 DR. SCHAEFFER: Thank you.

25 ADMINISTRATIVE LAW JUDGE VITTON: Do you

1 have anything else?

2 MS. SHERMAN: I don't believe we have any  
3 others.

4 ADMINISTRATIVE LAW JUDGE VITTONI: Okay.

5 MS. SHERMAN: Your Honor, I would like to ask  
6 to admit Dr. Clewell's testimony as Exhibit 44-5.

7 ADMINISTRATIVE LAW JUDGE VITTONI: It will be  
8 received into evidence.

9 **(Whereupon, Exhibit Number 44-5 was marked for**  
10 **identification and admitted into evidence.)**

11 ADMINISTRATIVE LAW JUDGE VITTONI: Thank you,  
12 Dr. Clewell.

13 That completes our list of witnesses for  
14 today. We will resume again tomorrow morning at 9:30  
15 in this room. We will begin with the OSHA expert  
16 witnesses from Shaw Environmental. Thank you very  
17 much. Have a good day.

18 (Whereupon, at 3:24 p.m., the meeting was  
19 recessed subject to reconvening.)

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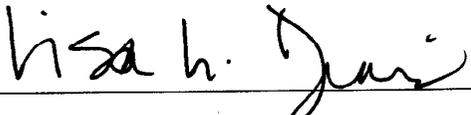
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C E R T I F I C A T E

This is to certify that the foregoing of a an informal Public Hearing for the Proposed Rule on Hexavalent Chromium before Administrative Law Judge John M. Vittone, held on Tuesday, February 1, 2005, were transcribed as herein appears, and this is the original of transcript thereof.

  
\_\_\_\_\_  
Lisa Dennis, CVR