

# ORIGINAL

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1 THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND  
2 HEALTH/NATIONAL PERSONAL PROTECTIVE TECHNOLOGY  
3 LABORATORY (NIOSH/NPPTL) PUBLIC MEETING

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Wednesday, August 25, 2004

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BEFORE THE NIOSH/NPPTL PANEL:

11

ROLAND BERRY ANN

12

LES BOORD

13

DON CAMPBELL

14

RICH METZLER

15

BILL NEWCOMB

16

ZIQING ZHUANG

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Commencing at 9:02 a.m. at the Marriott

22

Key Bridge Hotel, Arlington, Virginia.

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## PROCEEDINGS

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MR. BOORD: Good morning, and welcome to NIOSH public meeting on Total Inward Leakage, so everybody can check to make sure you are in the right room.

What I would like to do is, first of all, introduce the NIOSH presenters today. And they are basically seated at the front table there, and we will begin from the far right, Don Campbell.

MR. CAMPBELL: I'm working with the NPPTL. I'm recently retired from the commission.

I'm a contractor working with NIOSH assigned to NPPTL.

MR. BOORD: Mr. Zhuang.

MR. ZHUANG: Ziqing Zhuang, and I'm working for the technology branch in NPPTL.

MR. BERRY ANN: Roland Berry Ann.

I'm the branch chief of the respirator branch.

MR. METZLER: Rich Metzler, director of the National Personal Protective Technology lab.

MR. NEWCOMB: Bill Newcomb, project

1 manager of the TIL program.

2 MR. BOORD: And my name is Les Boord. I  
3 am the Deputy Director of NPPTL.

4 What we would like to do is start off  
5 with some of the ground rules or protocol for the  
6 meeting that we are going to have today.

7 As far as the presentations are  
8 concerned, we do have NIOSH presentations from --  
9 primarily from the people at the panel. And we  
10 will have other presenters from the audience that  
11 will deliver presentations.

12 After a presentation is given, we would  
13 welcome questions. In fact, we encourage  
14 questions.

15 The question and answer portion of the  
16 discussions and presentations are very important to  
17 developing the concepts that we are presenting.  
18 Over the long haul, they help to provide clarity to  
19 the issues and an understanding of what actions are  
20 required. So we would encourage comments and  
21 questions.

22 And when we do that, we would ask that

1 the person with the comment or question go to the  
2 microphone in the middle of the room, identify your  
3 name and the organization that you represent, and  
4 then -- then the comment or question.

5           Following the presentations of the NIOSH  
6 presenters and the guest presenters, we will set up  
7 a panel discussion to further discuss any of the  
8 open issues or to provide additional comment and  
9 discussion around any of the topics that were  
10 raised during the presentations.

11           And then as a final note, the meeting  
12 today is being transcribed and recorded, so speak  
13 clearly and deliberately.

14           And then finally, we do have a meeting  
15 survey form that has been provided in the  
16 information packets that everybody has. We would  
17 like for everyone to fill out the survey because  
18 that does provide us constructive input on  
19 delivering and presenting these types of meetings.

20           I would like to go over the agenda, the  
21 planned agenda for today, and I think everybody  
22 does have an official agenda in their information

1 packet.

2           Basically, we have the opening and the --  
3 the opening remarks and the welcome. Then we will  
4 go into a presentation on our Total Inward Leakage  
5 program, and we will have Mr. Bill Newcomb  
6 delivering that presentation.

7           Then the third item on the agenda is a  
8 discussion of the respirator fit test panel and a  
9 concept for developing and implementing a new test  
10 panel, and Dr. Zhuang will deliver that  
11 presentation.

12           Then we will have guest speakers. And I  
13 understand that we have at least three speakers who  
14 signed up to deliver presentations, followed by the  
15 NIOSH panel discussion and then closing remarks.

16           A very important piece of information is  
17 the slide that's on the screen now, and I believe  
18 this is also provided in your information packets.

19           And this is the docket information for  
20 interested parties to provide information, comment,  
21 question, clarifications to us on any of the topics  
22 that are discussed and presented today.

1           We have the NIOSH docket with the mail  
2 address identified, the email address, and then  
3 also the fax phone numbers and the website for  
4 NPPTL where you can find the concepts surrounding  
5 the TIL program and other programs that we are  
6 currently working on.

7           In the field of personal protective  
8 equipment, Total Inward Leakage is an important  
9 topic.

10           And basically, Total Inward Leakage is a  
11 parameter, a performance parameter of PPE, Person  
12 Protective Equipment, that provides a barrier  
13 between the hazards in the environment and the user  
14 of the equipment.

15           The two most obvious examples and those  
16 in the forefront are protective garments, personal  
17 protective garments, encapsulating suits and other  
18 types of protective garments that protect against  
19 skin exposure, percutaneous exposures to  
20 environmental hazards, and then respirators and  
21 respiratory protection where the respirator  
22 provides a barrier to the inhalation and the

1 breathing zone of the wearer of the respirator.

2           Since the PPE is intended to protect the  
3 user from those environments, Total Inward Leakage  
4 is an important consideration in determining and  
5 establishing the performance of a personal  
6 protective equipment.

7           For the NIOSH TIL program, the goal of  
8 our program is really structured to identify and to  
9 focus on that type of parameter.

10           The goal is as illustrated in the  
11 overhead, which is the NIOSH -- or the NPPTL Total  
12 Inward Leakage program will establish TIL  
13 performance requirements and laboratory test  
14 capability for testing of personal protective  
15 equipment, including all classes of respirators and  
16 protective garments.

17           The initial part or initial segment of  
18 our TIL program will address half-mask respirators.

19           We envision the TIL program having  
20 multiple aspects and the multiple faces to it,  
21 half-masks being the first, other classes of  
22 protective equipment to be addressed in the future. as

1 well as work and research into the areas of the  
2 test methods and protocols required to evaluate  
3 different types of personal protective garments.

4 As just a brief overview of the  
5 half-mask, the NPPTL half-mask program, we have  
6 five primary components to the program.

7 The first -- and these are identified in  
8 the program concept that's I think in the packet  
9 and also posted on the website.

10 And the first is to develop the TIL  
11 requirement and the test protocol for evaluating  
12 that requirement. That effort is being led from a  
13 program management point of view by Mr. Bill  
14 Newcomb.

15 The second component of our half-mask TIL  
16 program is to establish the Total Inward Leakage  
17 test capability.

18 And this really does extend beyond just a  
19 half-mask program, as you will learn as the  
20 presentations are delivered today, but Mr. Tim  
21 Rehak is currently leading the program to establish  
22 and -- identify and establish the Total Inward



1 Leakage facilities for the laboratory.

2           The third element of the program -- and  
3 those of you who have attended some of our other  
4 concept development meetings will recognize that  
5 the benchmark testing is a crucial part of pretty  
6 much anything that we do. It is the benchmark  
7 testing that is used to really gauge where the  
8 technology is and to help us identify and define  
9 requirements.

10           In the presentations today, we will  
11 discuss the benchmark testing components for the  
12 half-mask TIL program.

13           The final two elements in the program are  
14 peer review and our public meetings, and we will  
15 talk a little more about those in just a minute.

16           Concerning the technical aspects for the  
17 half-mask TIL program, certainly we have the  
18 performance requirement that -- to develop the  
19 performance requirement for the half-mask  
20 respirators.

21           And when we think about the performance,  
22 it is really two aspects that we need to be

1 concerned about:

2           One is respirator performance, what is  
3 the capable -- capabilities of the respirator to  
4 perform; and then, secondly, the ability to test  
5 and the test equipment capabilities.

6           So from a performance point of view, our  
7 aim is to establish and determine state-of-the-art  
8 technology in both of these areas as they apply to  
9 half-mask respirator.

10           Secondly, the anthropometrically correct  
11 test panel concept, which will be discussed here  
12 today, is a key component to the half-mask TIL  
13 program.

14           Then finally we have established the OSHA  
15 exercises as a baseline for determining some of the  
16 performance requirements and for some of the  
17 evaluations and discussions that will take place  
18 today and then also the importance of the  
19 manufacture user's instructions as we look to -- to  
20 a half-mask Total Inward Leakage performance  
21 requirement.

22           So these are the four, I think, key

1 primary technical aspects to the half-mask program.  
2 Indeed, there are a lot of other technical  
3 concerns; but when we look at the overall program,  
4 these are the four primary areas.

5 In terms of the peer review, we  
6 anticipate in the -- this program that we will have  
7 both programmatic and scientific reviews. I think  
8 as the discussions today unfold, that will become  
9 more clear that both of these types of reviews are  
10 important to the program and important to the  
11 success of the overall program.

12 Concerning the program concept reviews,  
13 we have identified reviewers that are  
14 representative of the manufacturing industry, of  
15 government, academia, labor, and subject matter  
16 experts. That pool of reviewers is currently  
17 looking at the content of the half-mask TIL  
18 program.

19 Secondly, for the scientific review, our  
20 intention is to use scientific experts as reviewers  
21 to review and critique some of the science that is  
22 being developed.

1           Public meetings, obviously we are at the  
2 first of the two planned public meetings for the  
3 half-mask TIL program. We do anticipate that a  
4 second meeting will be held early next year. And  
5 as the program develops and becomes more mature,  
6 the exact date for that will be identified.

7           So in summary, for today's discussions  
8 and presentations, we are here today to share with  
9 you our concepts and ideas relative to a TIL  
10 program.

11           And the overall program goal is to  
12 establish personal protective equipment,  
13 performance requirements, and test capabilities for  
14 Total Inward Leakage as it applies to personal  
15 protective equipment.

16           The first PPE that we are looking at and  
17 addressing the TIL for is the half-mask respirator.  
18 Other respirator classes will be considered. And  
19 we do anticipate research into other areas of PPE,  
20 such as protective garments for the -- this  
21 important characteristic of Total Inward Leakage.

22           And with that I would like to introduce

1 the Director of NPPTL, Rich Metzler, who will share  
2 with you a few thoughts about TIL and why we are  
3 here.

4 MR. METZLER: Good morning, ladies and  
5 gentlemen, friends and partners for improving  
6 worker safety and health.

7 We think of this as a very important  
8 public meeting. This is not part of a formal  
9 rulemaking process. It is an informal public  
10 meeting. Please feel free to participate in the  
11 discussions today.

12 Send your comments to the docket, contact  
13 the project manager, arrange for individual  
14 stakeholder meetings.

15 This is a forum giving the public and  
16 interested parties an opportunity to exchange  
17 information so that the measurement of Total Inward  
18 Leakage for PPE of any type -- specifically today  
19 we are talking about half-mask respirators -- has  
20 your input into the program and the science.

21 I would like to underscore a few main  
22 points that will be made by today's speakers.

1           For me, when I answer the question why  
2 TIL, I think it's extremely important to start by  
3 saying that there is a public health benefit.

4           This will improve the fitting  
5 characteristics of respirators and improve the  
6 protection that -- offer an opportunity to improve  
7 the protection that workers will receive when  
8 wearing a NIOSH certified product. It will also  
9 have, in my judgment, an economic benefit.

10           In increasing the likelihood of having  
11 individuals pass an initial fit test, there is an  
12 economic benefit where fewer tests, fewer trials to  
13 get a good fitting respirator will be benefitted  
14 from, and thus have a corresponding economic  
15 benefit.

16           I also think it will increase the  
17 confidence of the wearers of these devices in the  
18 protection that they are receiving.

19           I also think that there is a benefit by  
20 having a standardized evaluation of the complete  
21 PPE or today, respiratory system, in providing a  
22 laboratory based performance test, a standard

1 applied to all respirators in the various class  
2 that is being studied.

3 And the test will provide a more uniform  
4 fitting characteristic for all respirators in the  
5 specific class. And we know based upon research by  
6 NIOSH and others, that there is model to model  
7 variation because of the lack of having a  
8 standardized test in the past.

9 What is the TIL test?

10 The TIL is a laboratory based performance  
11 test judging the performance capability of  
12 respirators which will have an impact on the design  
13 so that these respirators will have improved  
14 fitting characteristics.

15 It is going to be based, as Les has  
16 indicated, on the state-of-the-art technology for  
17 each respirator class.

18 Benchmark testing will be described where  
19 we will be collecting data. That data will be used  
20 in establishing pass/fail standards, but will also  
21 identify the capabilities of each respirator class  
22 for providing a fit factor.

1           And it is best -- it is also developed  
2 based upon the best available instrumentation for  
3 making measurements of the respirator fitting  
4 capabilities.

5           What it is not, throughout the day, I  
6 would like you to listen closely to the  
7 presentations on the program in that a TIL is not  
8 an APF.

9           APFs are factors which are being  
10 established by OSHA in its current rulemaking  
11 procedure, used as a selection tool based upon  
12 statistical studies of simulated workplace  
13 protection factor studies and workplace studies.

14           TIL is a performance measurement of each  
15 respirator in a class as part of the certification  
16 program, as NIOSH sees it. And TIL will not, and I  
17 underscore will not, eliminate the need for  
18 individual fit testing to ensure that each  
19 individual has a properly fitting respirator.

20           Again, I want to thank you for coming  
21 today. If we need more than two public meetings,  
22 we certainly will be glad to have them, and we are



1 receptive to your comments and exchange of  
2 information throughout this entire process.

3 Please feel free to participate actively.

4 Thank you.

5 Our next speaker is Bill Newcomb, and  
6 Bill Newcomb has already got things upside down.  
7 Typically someone finishes a federal career and  
8 then moves on to the private sector looking for a  
9 consulting job.

10 Bill has spent 40 some years plus in the  
11 respiratory protection PPE business and after  
12 retirement has joined the government, which is a  
13 little bit different than is customary.

14 But without further ado, I would like to  
15 introduce Bill Newcomb to present the program.

16 MR. NEWCOMB: Thank you, for your kind  
17 words.

18 Welcome. Okay. Do I have to go in and  
19 find my slides here?

20 Good morning. My name is Bill Newcomb.  
21 I am sure that my face is familiar to a few of you.  
22 As Rich said, I have been around the industry for

1 over 40 years. I am now a federal employee and  
2 working with NIOSH and the project manager for the  
3 Total Inward Leakage program.

4 Total Inward Leakage as a component of a  
5 certification program is nothing new. Back when  
6 the Bureau of Mines approved respirators -- sorry  
7 about that -- under Schedule 21, published August  
8 30, 1934, fit tests using coal dust were mandatory.  
9 That is even before I started with respirators.

10 Three individuals donned respirators and  
11 did a regimen of moderate work and rest periods for  
12 30 minutes in a room full of coal dust, after which  
13 their forced nasal discharge, sputum, nasal  
14 cavities, and face were examined for black  
15 particulates.

16 Sounds like a lot of fun.

17 Requirements were similar under 21A in  
18 1959. And by 1965, when 21B was approved, coal  
19 dust was blown gently into the subject's face and  
20 exercises were omitted.

21 The isomyl acetate test was also  
22 introduced since the Bureau of Mines was now

1 approving organic paper respirators in addition to  
2 dust mesh respirators.

3 It wasn't until NIOSH came along in 1972  
4 that the requirement for atomizing coal dust into a  
5 subject's face was abolished.

6 NIOSH, being a public health organization  
7 had concerns about subjecting humans to known  
8 toxins. So for 21C, NIOSH decided to use isoamyl  
9 acetate instead of coal dust to qualify the ability  
10 of a tight fitting and some loose fitting  
11 respirators to fit wearers.

12 There's only one problem with this.  
13 Isoamyl acetate is a vapor which is removed by an  
14 organic vapor filtering element, but not by dust,  
15 mist, fume, or high efficiency particulate filters.

16 Therefore, any respirator that did not  
17 come equipped with organic vapor filtering elements  
18 had to be altered in order to be tested. The  
19 resulting surrogate respirator oftentimes was  
20 heavier, bulkier, and didn't fit as well as the  
21 respirator that was trying to be evaluated and, in  
22 the case of filtering face pieces, virtually

1 impossible to construct.

2 So when Part 84 was promulgated in 1995,  
3 this non-validated test of questionable  
4 effectiveness was too eliminated.

5 Many tests were looked at in the process  
6 of writing 84, but none were found capable of  
7 quantifying the fit, and no one could agree on a  
8 simulated workplace.

9 Furthermore, since OSHA by this time  
10 required individual fit testing as a qualification  
11 for wearing tight fitting respirators, it was felt  
12 by some that poor fitting respirators would be  
13 eliminated from the marketplace because of the  
14 inability to achieve the required fit factor.

15 In the preamble of Part 84, it is stated,  
16 The purpose of fit testing and certification  
17 program has been to assure that respirators have  
18 generally good face fitting characteristics.

19 However at this time, NIOSH has not had  
20 studies that define the effectiveness of either  
21 isoamyl acetate or ANSI/OSHA accepted fit tests in  
22 predicting actual workplace protection provided to

1 the worker.

2 NIOSH is presently conducting research  
3 for this purpose. In the interim, lacking  
4 validation and correlation of testing protocols,  
5 workers' health concerns are best served through  
6 the application of fit testing and fit checking  
7 procedures on individual workers in a quality  
8 respirator program.

9 NIOSH will address issues associated with  
10 face fit efficacy in a separate module on the  
11 completion of the necessary research.

12 Unfortunately, in a study entitled  
13 "Respirator Usage in the Private Sector Firms,  
14 2001," that was published by NIOSH in 2003, it  
15 shows that only 53 percent of respondents indicated  
16 they were actually conducting fit tests, hardly  
17 enough effort to make the marketplace affect the  
18 poor fitting respirators.

19 It is now almost a decade since the  
20 promulgation of Part 84. The issue of lack of fit  
21 testing as a component of respirator certification  
22 was again raised when OSHA held its public hearing

1 on the proposed revisions to 29CFR 1910 134, to add  
2 assigned protection factor table and maximum use  
3 concentration based thereon.

4 At this meeting, Rich Metzler, Director  
5 of NIOSH's National Protective Technologies  
6 Laboratory, pledged to add a method of qualifying  
7 fit to the requirements for certification of the  
8 respirators.

9 Then he hired me. I guess he isn't  
10 perfect either.

11 NIOSH has embarked in a program to assess  
12 the Total Inward Leakage of respirators and other  
13 PPE, such as total encapsulation suits. With tight  
14 fitting respirators, tight face fit is a major  
15 contributor to Total Inward Leakage.

16 In the rewrite of ANSI Z88.2, American  
17 Standard of Respiratory Protection, and in the OSHA  
18 proposed APF schedules, there are two areas where  
19 there is most debate by the experts as to the  
20 actual protection afforded by respirator devices  
21 and, therefore, their assigned protection factors.

22 They are half-mask respirators and, in

1 particular, filtering face pieces. And hood/helmet  
2 devices, both air supplied and powered air.

3           The latter was a subject of a study at  
4 Lawrence Livermore National Laboratory, which  
5 showed extremes in overall leakage, Total Inward  
6 Leakage of products, which all passed the NIOSH  
7 present certification criteria.

8           In a continuation of NIOSH's modular  
9 approach to standards writing, it was decided to  
10 begin the Total Inward Leakage program by  
11 developing requirements for half-mask respirators.

12           The next project will probably be for  
13 respirator types that were the subject of the  
14 Livermore study.

15           The project is organized into three  
16 phases over a 12-month period. The phases,  
17 although independent, may run concurrently. The  
18 three project phases and the objectives of each are  
19 the -- Phase 1, the investigative and concept  
20 draft, which is gathering and revising existing --  
21 reviewing existing TIL respirator information,  
22 reviewing existing TIL test equipment, capabilities

1 and technical specifications, identifying a peer  
2 review team composed of manufacturers, users,  
3 academia, and government, developing an initial TIL  
4 concept, addressing the performance requirements  
5 and test protocol, and establishing the technical  
6 specification for the TIL test facility.

7 Phase 2 was the test facility and  
8 benchmark testing establishing the NPPTL TIL test  
9 facility.

10 If I'm going to work there, I'm going to  
11 have to learn how to say that.

12 Perform benchmark testing to establish  
13 state-of-the-art respirator performance, continue  
14 developing the TIL concept, requirements and  
15 protocols, and identification of a draft  
16 implementation plan.

17 Phase 3 was consistency testing and  
18 implementation, which consists of conducting  
19 validation testing for the TIL facility, final  
20 implementation plan, and final TIL concept  
21 requirements and protocol.

22 Where do we stand?



1           The first thing that NIOSH did was define  
2 the project. It was agreed that Total Inward  
3 Leakage project would not be based on OSHA assigned  
4 protection factors. APFs are an OSHA user issue  
5 for respirator selection.

6           TIL is a NIOSH manufacturer issue, a  
7 laboratory evaluation of the capabilities of a  
8 respirator. The acceptable TIL will most likely be  
9 greater than the APF value, at least for the  
10 half-mask respirators.

11           TIL will be a method of determining  
12 whether a respirator is capable of fitting the  
13 majority of people for whom it was designed to fit.

14           For example, if a respirator is designed  
15 as a small size, then it should fit a majority of  
16 small faces. But before we can decide what a small  
17 face is, we had -- whether it fits small faces, we  
18 have to decide what a small face is.

19           Dr. Zhuang has conducted a research in  
20 this field and will be presenting some data later  
21 on in this program.

22           It was agreed that the Total Inward

1 Leakage program would not be a substitute for OSHA  
2 mandated individual fit testing of wearers. The  
3 only method for assessing the capabilities of a  
4 respirator to fit an individual is and will remain  
5 the administration of initial and periodic fit  
6 tests on the wearer.

7 No respirator can ever be certified to  
8 fit, nor will any respirator be able to fit  
9 everyone in a class, no matter what the TIL  
10 requirements eventually imposed, but I welcome any  
11 manufacturer to prove me wrong.

12 The next thing we had to decide was about  
13 how to establish the performance criteria.

14 As stated earlier, the requirement will  
15 be based -- will not be based on OSHA assigned  
16 protection factors, but on a higher value based on  
17 actual respirator fit.

18 Fit testing is, by nature, imperfect, and  
19 we realize this. There are debates about  
20 methodology, test agents, probes, probe placement,  
21 exercises, redonning, et cetera.

22 But despite these, three decades of

1 research have led us to believe that current  
2 technology now allows TIL testing to be used in a  
3 certification process.

4           Because the message that we are proposing  
5 may not be the same and the fit test panel may be  
6 different, it was deemed inappropriate to use any  
7 previously obtained fit test data, whether from  
8 NIOSH or from somewhere else.

9           Thus, it was determined that the best  
10 method to obtain results would be to conduct  
11 benchmark testing on state-of-the-art respirators  
12 within the class under consideration.

13           As part of the determination of the  
14 portion of the fit of the panel which a specific  
15 respirator is design to fit, NIOSH will rely on  
16 user's instructions.

17           Lacking any guidance, the entire panel  
18 will be used for Total Inward Leakage testing. It  
19 is anticipated that some user's instructions for  
20 respirators may change as a result of this process.

21           The methods for measuring fit were  
22 compared and the conclusions reached that the

1 methods appropriate for testing different  
2 respirators, different classes of respirators would  
3 be different.

4 For half-mask, the project -- for the  
5 half-mask project, the following test method  
6 characteristics were compared:

7 Ability to be used to measure TIL on all  
8 styles of half-masks, quarter-masks, and filtering  
9 facepieces, regardless of air purifying elements;

10 Required sensitivity for the desired  
11 results;

12 Ability to give accurate, repeatable  
13 results;

14 The ability to do the required test  
15 exercises without disturbing the fit due to test  
16 equipment, probes, et cetera;

17 Ease of duplication and hopefully  
18 intralab reproducibility;

19 Cost of equipment;

20 Need for a test chamber;

21 And ease of preparation, use, clean up,  
22 et cetera.

1           The conclusion reached is that the  
2   PortaCount Plus in a direct reading mode would be  
3   the best choice of measuring Total Inward Leakage  
4   of half-mask respirators.

5           Because the PortaCount does not require a  
6   specialized facility, construction of a test  
7   facility is not an issue.

8           Given the method, what exercises should  
9   be conducted? The most reproducible methods were  
10  thought to be the ones in the OSHA fit test  
11  protocol.

12           Obviously, this does not simulate actual  
13  workplace, but then what does? There is no such  
14  thing as a standardized workplace.

15           Comments concerning exercises are  
16  welcome.

17           Given the Health and Human Services  
18  mandate, the project will be peer reviewed both  
19  programmatically and scientifically, with input  
20  from stakeholders as much as possible.

21           Peer reviewers have been identified, and  
22  the programmatic review is being conducted.

1           This is the first of two planned public  
2 meetings on the half-mask project. NIOSH has just  
3 begun the process of benchmark testing and plans to  
4 have the testing completed this year. It is our  
5 hope to have a certification plan by next spring.  
6 The method of implementation has not been  
7 finalized, and recommendations are sought.

8           Reviewing the half-mask project  
9 milestones and objectives, Phase 1, the  
10 investigative/concept draft, the dates are March  
11 '04 through August '04. The milestones are the TIL  
12 concept, facility specifications, peer review, and  
13 public meetings. We consider ourselves to be at  
14 the end of Phase 1.

15           Phase 2, the test facility and benchmark  
16 testing, was to run from May of '04 through  
17 February of '05.

18           And the milestones would be to draft the  
19 implementation plan, to have peer reviews, another  
20 public meeting, and to complete the test facility.

21           Obviously with this program, the latter  
22 point is moot.

1           Phase 3, the validation testing and  
2           implementation plan, milestones are the peer  
3           review, completed implementation plan, and the  
4           final concept.

5           We are here to solicit your invaluable  
6           input as manufacturers, users, and regulators of  
7           these types of products.

8           Let us know your feelings, good, bad,  
9           about this project, either at this meeting, to the  
10          docket, or directly to me at a later date.

11          Thank you.

12          Are there any questions before Dr. Z's  
13          presentation?

14          MR. DENNY: What is NIOSH's involvement  
15          with OHSA's fit factor?

16          MR. BOORD: Excuse me.

17          Frank, could you identify who and --

18          MR. DENNY: Frank Denny. I'm the Program  
19          Manager for Occupational Safety and Health  
20          Department, Veterans Affairs.

21          And I'm interested in finding out how  
22          NIOSH is dealing with OHSA's fit factor

1 progression, what their -- how this relationship is  
2 all involved.

3 MR. METZLER: NIOSH has provided comments  
4 on the APF rulemaking, if that's what you were  
5 referring to, and our comments are a matter of  
6 public record.

7 But specifically we are here today to  
8 address the one omission we felt existed in the --  
9 in the rulemaking, and that was a standardized test  
10 by an appropriate certification authority.

11 And as I indicated in my remarks and Les  
12 did in his, NIOSH has said we will implement  
13 standardized test procedures for each respirator  
14 class and add that as a portion of the  
15 certification program.

16 MS. WOODHALL: Hi, I'm Jean Woodhall with  
17 ORC, and I commend you on this. This is a  
18 wonderful project. We will support your efforts in  
19 this area.

20 I have one question. To what extent --  
21 or what form do you expect to provide this  
22 information to users?



1 I mean, how do you -- how do you envision  
2 a user making use of this information, and do you  
3 anticipate that it will influence their purchasing  
4 decisions in half-mask respirators and other  
5 equipment?

6 MR. NEWCOMB: As I said in the  
7 presentation, the -- this TIL concept is really a  
8 manufacturer/NIOSH issue where NIOSH will be  
9 assessing the capabilities of fit as a portion of  
10 Total Inward Leakage in a certification process.

11 The users will still be required by the  
12 OHSA requirements to use a -- the APFs that are  
13 assigned by OHSA to select the respirators.

14 And their benefit will be hopefully that  
15 the users will have more confidence in the products  
16 and also the fact that we assume that this will  
17 result in better fitting respirators overall as a  
18 result of our process.

19 As Rich mentioned in his presentation,  
20 that would presumably be an economic benefit to the  
21 users because hopefully fit testing will go a  
22 little easier in the field.

1           The actual data from eventual  
2 certification has not generally been given to the  
3 public either by NIOSH or the manufacturers. So  
4 the fit test data itself, when this eventually  
5 becomes the -- a certification process, probably  
6 will not be public.

7           But there will be, as in any other NIOSH  
8 certification criteria, a minimal -- minimum level  
9 of fit that will have to be obtained in a panel, so  
10 it's assumed that generally the capability of that  
11 respirator will be that good in the field when  
12 initially fit testing -- fit tested.

13           MR. METZLER: I would add that NIOSH has  
14 already begun developing a respirator selection  
15 logic and a new edition of the Industrial Guide to  
16 Respiratory Protection. Both of those projects are  
17 underway.

18           The respirator selection logic is already  
19 being peer reviewed. And the intent on that  
20 particular document is to have it placed on a  
21 website and frequently updated as changes, like for  
22 example, OSHA's final APFs, or the implementation

1 of a new TIL test.

2 Changes will be made to the selection  
3 logic in small steps whenever there is a change to  
4 impact it.

5 MR. SAWICKI: Jack Sawicki, Global Secure  
6 Safety. I have two questions.

7 You don't have to use the PortaCount  
8 methodology for clothing TILs as well as  
9 respirators?

10 MR. NEWCOMB: We haven't begun the  
11 program for testing clothing yet.

12 I presume that methods will be  
13 different -- well, I know methods will be different  
14 for different types of respirators and probably  
15 different PPE.

16 So I don't anticipate that the PortaCount  
17 will be the standard instrument for all TIL  
18 testing.

19 MR. SAWICKI: Okay. And the second  
20 question related to the last question.

21 Would that preclude manufacturers from  
22 publishing its TIL and publish the NIOSH core

1 tests, or just not published by NIOSH?

2 MR. NEWCOMB: Manufacturers can publish  
3 any results that they want to on their product.

4 I don't know whether they could say that  
5 they were NIOSH results.

6 MR. METZLER: Actually, I don't think  
7 there is a problem.

8 The manufacturer is publishing the data  
9 on the equipment from NIOSH tests and using it as  
10 indicated, that it's on data that NIOSH has  
11 collected.

12 MR. SAWICKI: Thank you.

13 MR. METZLER: I would also add that with  
14 regard to PPE TIL, on fully encapsulated garments,  
15 we have already started literature searches and  
16 have a number of people looking into the facility  
17 requirements to support that program.

18 I agree with Bill that I doubt that  
19 PortaCount technology would be appropriate for that  
20 sort of PPE, but we have initiated the early  
21 studies of collecting information from various  
22 sources on what technology would be needed for

1 doing manned and simulated sort of testing.

2 MR. BIEN: Ching-tsen Bien, LAO  
3 Consulting. Just one comment on your PortaCount  
4 for the TIL testing.

5 Based on the experience at the OSHA, when  
6 I worked for OSHA, OSHA is the biggest customer for  
7 PortaCount.

8 We purchased PortaCount for every area  
9 office to fit in our office. We receive a lot of  
10 complaints on the -- in our office, the problem on  
11 the test results because it rely on the  
12 concentration, the fine particle in the ending, the  
13 particle concentration is not stable.

14 If you run the test alone, your result  
15 changes.

16 So if you run PortaCounts, okay, you must  
17 have stable environment, have stable  
18 concentrations. Otherwise, your result, you cannot  
19 get a reasonable data for results, then you going  
20 to have a problem for the certification.

21 MR. ZHUANG: Yeah, let me add a comment  
22 to that.

1           Originally we looked at the effect of  
2 ambient concentration on fit factor, and we did not  
3 see significant effect there.

4           It looks like -- yeah, early on when we  
5 collected some data from the field, from a  
6 consultant -- he collected a lot of data while  
7 doing field testing for various companies -- and he  
8 just gave us the data, so we looked at that. And  
9 we thought there may be an effect from that data.

10           But when we looked at our own laboratory  
11 data that we collected, we did not see the effect.  
12 Basically, we look at ambient concentration of less  
13 than 2,000 -- or maybe 2 or 3,000 particle per cc,  
14 up to 16, 15,000 particle per cc. But then the fit  
15 factor did not vary according to the concentration.

16           MR. BIEN: You tried to turn the fan on,  
17 fan off, off and on so many times to see what kind  
18 of results you going to get.

19           You should try that.

20           MR. ZHUANG: Yeah, I know. Right.

21           Yeah, I looked at that. I know the  
22 concentration can go up and down.

1           But when you look at the fit factor, it  
2 is the ratio of the ambient concentration and also  
3 the facial leakage. So when you look at the ratio,  
4 the fit factor is not a function of ambient  
5 concentration.

6           MR. BIRKNER: Jeff Birkner, Moldex.

7           Actually, my question or comment is  
8 somewhat in line with Ching's comment.

9           MR. ZHUANG: By the way, I think we would  
10 like that comment. I think we can conceive of  
11 that, like try to have a stable environment, but I  
12 just -- yeah. The information that we looked at  
13 the data, and that's what we found.

14           Go ahead.

15           MR. BIRKNER: But in any case, I'm a  
16 little bit confused and concerned that you are  
17 using the term TIL instead of fit factor.

18           If you are using this as -- this  
19 procedure as a benchmark, you are -- you have  
20 presumably already certified the filters  
21 themselves.

22           And what you probably should be looking

1 at, if your -- if your main intent is to ensure  
2 that respirators fit better in the field, those  
3 that are certified fit better in the field, what  
4 you really want to be doing is looking at the fit  
5 factors.

6 In addition to that, there -- like -- I  
7 would be a little bit concerned with the variation  
8 that you are going to see based on the type of  
9 filter that is used with the facepiece.

10 So if we are talking about an elastomer  
11 facepiece, you could use a 95 or a 100 filter.

12 The penetration through the filter itself  
13 is going to change based on the ambient -- based on  
14 whatever the ambient aerosol is. And that's going  
15 to, you know, depend on which way the wind is  
16 blowing, you know, what is upstream from the --  
17 from your point zero of where you are doing the  
18 testing.

19 So I would encourage you, number one, to  
20 change the concept from TIL to fit factor, and I  
21 think you will achieve your goals just as well.

22 MR. NEWCOMB: Jeff, one of the things



1 that we are trying to look at is total respirator  
2 efficacy, which could include seals and exhalation  
3 valve and other types of things as well as the fit.

4 And that is one of the reasons we are  
5 looking at Total Inward Leakage because that's  
6 actually what we want to see is how well the  
7 respirator performs and not necessarily just how  
8 well it fits.

9 MR. BIRKNER: It's true. But you guys  
10 will have already certified the filters themselves.

11 MR. NEWCOMB: The filters, yes.

12 MR. BIRKNER: And you are going to have  
13 very high variations which ultimately is going to  
14 result in larger standard deviations in your data,  
15 and you are going to have to ultimately lower  
16 whatever benchmarks you set.

17 So --

18 MR. NEWCOMB: We will most likely find  
19 that out in our benchmark testing. And consider it  
20 done.

21 Thank you.

22 MR. BERNDTSSON: Goran Berndtsson from

1 the SEA Group.

2 I think it is really, really important  
3 that you manage to hold the concentration.

4 If you are going to use the PortaCount,  
5 you are going to have to control the concentration  
6 of particulates. Otherwise -- and you -- I mean, I  
7 thought you said in your slides that you want to  
8 develop a method here who can be used by different  
9 laboratories and try to correlate some of the  
10 results.

11 And of course, if the challenge  
12 concentration is variable, you will never be able  
13 to correlate any results.

14 I think that is absolutely necessary.

15 The other thing I have to ask is can I  
16 read this -- when you start talking about the Total  
17 Inward Leakage on suits that NIOSH is having done  
18 in total system testing including suits and  
19 respirators.

20 Is that what I'm hearing?

21 MR. METZLER: Yes.

22 MR. BERNDTSSON: Very good.

1 MR. NEWCOMB: Any other question?

2 Well, we are running a little ahead of  
3 schedule. Why don't we take our 15-minute break  
4 now and come back at quarter past 10.

5 Thank you.

6 (A recess was taken.)

7 MR. BOORD: Okay. Before we begin, there  
8 are a few items that I would like to provide some  
9 clarification and further information regarding.

10 And the first one is the question that  
11 was raised relative to a manufacturer publishing or  
12 listing or advertising their information relative  
13 to TIL performance.

14 And I think the clarification is that  
15 concerning NIOSH information, data, research, any  
16 of the information that NIOSH has is obviously  
17 available to the general public through freedom of  
18 information. So any information that is obtained  
19 and is in our files, that is available to the  
20 public.

21 And a manufacturer can use information as  
22 they determine that they feel appropriate,

1 particularly for their product.

2           However, it is important to note that if  
3 a NIOSH data or piece of information is used, it  
4 cannot be construed as an endorsement by NIOSH for  
5 whatever product or item it's being presented  
6 relative to.

7           So in general -- not in general. NIOSH  
8 information is available to the public through  
9 freedom of information.

10           The second thing I would like to clarify  
11 and re-emphasize is that the program that we are  
12 talking about today is very much conceptual.

13           The discussions relative to the test  
14 methods that we are discussing, those are concepts.  
15 The information that Dr. Zhuang is going to talk  
16 about here in a few minutes is conceptual at this  
17 point in time.

18           And the public meeting in the forum that  
19 we are in now is certainly a source of information  
20 that we use and we welcome to help us develop and  
21 mature the concepts that we are talking about.

22           So please keep that in mind, though, that

1 the information, the aspects of the program, they  
2 are at this time conceptual items.

3 Now, to move on with our program, I think  
4 everybody in the audience who is familiar with fit  
5 testing and inward leakage type studies and  
6 applications down through the years is familiar  
7 with the LANL, Los Alamos National Laboratory,  
8 panel. It has really become the industry accepted  
9 tool in the respirator industry.

10 The work that Dr. Zhuang is about to  
11 present to you is directly related to that panel,  
12 which for the past thirty years has been the  
13 benchmark that the industry has used.

14 So at this point, I would like to  
15 introduce Dr. Zhuang, who is in our technology  
16 branch at the laboratory, and has spent  
17 considerable amount of time researching the  
18 anthropometrics as they apply to personal  
19 protective equipment and especially respirators.

20 MR. ZHUANG: Okay. Thank you, Les, for  
21 your introduction.

22 Yeah, the title of my presentation is New

1 Respirator Fit Test Panels Representing the Current  
2 U.S. Civilian Workforce. And here is the outline  
3 of what I'm going to talk today.

4 I will talk about the importance of test  
5 panels that we use in the industry and then the  
6 appropriateness of the Los Alamos National  
7 Laboratory panels.

8 I will talk about that in detail later  
9 on, and then I will talk about what we did at NIOSH  
10 in this area. And then we will show you guys the  
11 proposed NIOSH panel and then give you some  
12 timeline about the development of the panel.

13 Yeah, anthropometric panels of facial  
14 dimensions are often relied upon to provide sizing  
15 references for respirators in many applications.

16 Initially, after Los Alamos finished the  
17 develop of the current panels, they used their  
18 panels to test many half-mask respirator and  
19 full-facepiece respirator. And they publish those  
20 data, and the data were the basics for the size  
21 protection factor that we set for the common APF  
22 value.

1           And also manufacturer rely on the panels  
2 to -- yeah, to test their prototype respirator  
3 before they put the respirator in production. So  
4 respirator design and development also need the  
5 panels.

6           And then we are going to include the  
7 panel as part of the Total Inward Leakage test  
8 certification here that we are talking about today.

9           And then also, many researchers have  
10 used -- have used the panels to recruit subjects to  
11 get various face size. And then so it is very  
12 common tools among the researchers. And then,  
13 yeah -- in order to get good subject and then  
14 uniform subject.

15           So, yeah, the current panels, as I  
16 mentioned earlier, were developed by Los Alamos  
17 National Laboratory based on the 1967, 1968, U.S.  
18 Air Force survey of the serviceman and woman in the  
19 Air Force.

20           And so the panel would develop based on  
21 those data, and the data was the best available at  
22 that time.

1           And Los Alamos also measure 200 male  
2 employee and compared the mean of their subject  
3 with the Air Force mean and variation. And they  
4 found that -- they assumed that the facial  
5 anthropometry of the Air Force subject was assumed  
6 to be representative of U.S. adults.

7           Basically, the mean was not quite  
8 different. I guess they did not look at the -- by  
9 variable distribution at that time, just simply  
10 looked at the mean and standard deviation, and did  
11 not find major differences there.

12           And so, but the fact is the military  
13 personnel is a subset of the civilian population --  
14 or the U.S. population. But, again, I will point  
15 out some concern later on.

16           But -- and the then panel, at that point,  
17 when it develop the panel, they expect the panel to  
18 accommodate 90 to 95 percent of the U.S.  
19 population.

20           Here is the 25-member panel for the --  
21 for testing full-facepiece respirator. So it is  
22 based on two dimensions, face width and face



1 length. And the limit for face width is from 117.5  
2 millimeter to 153.

3 And the upper limit was determined by  
4 using the mean of the male population and add two  
5 standard deviation to get that. And the lower is  
6 the mean of the female, subtracting two standard  
7 deviations. And similarly, that's how they  
8 constructed the lower and upper limits for face  
9 length.

10 And so face size can be divided or  
11 classified into ten categories, size one to ten.  
12 And the total number of subjects is 25. And these  
13 are the subjects that we are going to sample from  
14 each cell, like two person from here, two person  
15 from here, and two person from Cell No. 3.

16 And this is the panel for testing  
17 half-mask respirator. And so here, they use lip  
18 length instead of face width, and the limits were  
19 constructed similarly. And also the number of  
20 subject is 25, and these are the subject from each  
21 of the cell.

22 And lip length was selected simply based

1 on what they used to design the oxygen masks, the  
2 oxygen masks for the Air Force.

3 The company, the contractor that  
4 developed the panel was -- the people with Allen.  
5 Allen Hagg (phonetic) is not here today, but I talk  
6 to him from time to time.

7 And so when they -- before they  
8 established this panel, they already decided to use  
9 lip length as a parameter to design the oxygen  
10 masks for the Air Force. So they simply use that  
11 dimension here also.

12 So basically, there was no scientific  
13 data available at that time for them to consider  
14 whether they should use lip length or any other  
15 dimension.

16 So, yes, concerns was raised about the  
17 applicability of the LANL panel to the general  
18 civilian workforce. Here are two of them.

19 Like the first one is the demographics of  
20 the U.S. population has changed over the last 30  
21 years. And then, military personnel is just a  
22 subset of the population. So the military data may

1 not fairly represent the diversity of face size  
2 seen in the civilian population.

3 And this figure shows the race  
4 distribution of the 1967-1968 Air Force survey  
5 subjects and the 2000 census data. And this is  
6 white, African-American, Hispanic, and others.

7 And as you can see, the U.S. Air Force  
8 male, they are mainly white, 98 percent, 99  
9 percent, and just one percent African-American.  
10 And therefore U.S. Air Force female, it's about 90  
11 percent white females, and then 10 percent  
12 African-American female.

13 And -- but as you can see from these two  
14 bars, from the census 2000 data, it is a more  
15 diverse population. Roughly 70 percent white or --  
16 white female or male, and then 11 percent  
17 African-American male or female, and then Hispanic  
18 also of about 12 percent. And then the others  
19 group, it's about like 4 or 5 percent for the  
20 others, male or females.

21 So just from the ratio composition of the  
22 base workforce, it is quite different from what

1 they collected in the database back in the '60s,  
2 yeah, in '67 or '68.

3 And here is the picture showing the  
4 rate -- age distribution of the '67, '68 survey  
5 subject and the 2000 census data also. And, yeah,  
6 this is the age group from 18 to 29, and this is 30  
7 to 44, and 45 to 66.

8 So as you can see from the census data,  
9 they are quite uniform, roughly one-third for each  
10 of the group. And then -- but if you look at the  
11 Air Force data, they only have young like, yeah,  
12 male and female.

13 For the male, that we have some older  
14 like subject like maybe between 30 to 44, but you  
15 can hardly see any subject in the 45 to 66 age  
16 group.

17 And then, we also did some literature  
18 search and have some scientific evidence to show  
19 that the current panel may also have problem.

20 As early as 1975, they measured 1,467  
21 employee of a company. The name of the company is  
22 called Dow Chemicals, U.S.A. And they measured

1 these people in their -- they call it Rocky Flat  
2 Division in Colorado.

3 And this is part of their respiratory  
4 protection program. They do fit tests annually.  
5 And so while doing this kind of fit test and  
6 training, they just measure them.

7 And they only measure the three facial  
8 dimensions that are used to define the current  
9 panel, yeah, face length, face width, and lip  
10 length.

11 What they found was more than 10 percent  
12 like, to be exact, it is like 10.3 percent of their  
13 measurements were outside the selection area of the  
14 LANL panel for half-mask respirator.

15 But for the full facepiece, it is even  
16 higher. It is 12.6 percent of their subject  
17 falling outside the selection area. So they  
18 concluded that a change in the LANL panel selection  
19 area will be advantageous in their report.

20 And then we find a second study, Bureau  
21 of Mines survey 48 male mine rescue workers. So  
22 this is white and male.

1           So they compared their data with the Air  
2 Force. They looked at by varied distribution,  
3 which is face width and face length. So they found  
4 the distribution to be quite different from the  
5 military data.

6           So -- and they feel they have a good  
7 understanding of the variation for white male at  
8 that time, but they concluded that a more extensive  
9 survey of the actual population who use personal  
10 protective equipment is needed or is required.  
11 So -- for other racial group and female population.

12           And then before we did our own survey or  
13 research, we also looked at this problem. We used  
14 the data from -- from a project, I think, organized  
15 by the Air Force. And the project name is Civilian  
16 American and European Surface Anthropometry  
17 Resources.

18           They collected data for -- from the U.S.  
19 and also in Europe. We only used the data  
20 collected in U.S. And they measure 44 dimension,  
21 but it's whole body, not just the face. They only  
22 measure face length and face width. But they

1 measure like standing height or sitting height or  
2 arm length or leg.

3           So they measure those traditionally, and  
4 their main contribution is the 3-D scanner. They  
5 use a 3-D scanner, using four camera, and so they  
6 scan the subject while the subject is standing or  
7 sitting.

8           And so that will be there -- like their  
9 own data set, but they have some traditional  
10 measurements.

11           So I used the face length and face width  
12 data. And we look at that data set and then  
13 compare that to the panel for full-facepiece  
14 respirator. And what we found was 16 percent of  
15 the CAESAR subject were outside the limits of the  
16 LANL panel.

17           And a NIOSH recent survey indicated that  
18 we have about 3.3 million required users today.  
19 And so if you look at 3.3 million, and 16 percent  
20 of that number, it will be more than 500,000  
21 workers that are outside the limits.

22           The result, yeah, I'm presenting to you

1 are draft and subject to change since the study is  
2 still undergoing peer review. And my presentation  
3 represents my personal view and does not  
4 necessarily represent the views of NIOSH.

5 So the purpose of presenting this draft  
6 information today is to support a full discussion  
7 about the Total Inward Leakage program.

8 Here are the four areas that we did at  
9 NIOSH.

10 We developed an anthropometric database  
11 detailing the face size distribution of respirator  
12 users. And after we collected the data, we went on  
13 to evaluate the applicability of the LANL  
14 respirator fit test panel to the civilian  
15 population. And then we also did a parallel study  
16 to look at correlation between facial dimension and  
17 respirator fit, and then we also developed a new  
18 panel using various approach.

19 Our database, we use a stratified  
20 sampling approach, three -- yeah, factors we  
21 considered here. We look at gender, male and  
22 female. And then we look at four race ethnics



1 groups, white, African-American, Hispanic, and  
2 others. And then also three age groups, 18 to 29,  
3 30 to 44, and 45 to 66. Our final count, the good,  
4 yeah, data point is 3,997.

5 So basically we considered these three  
6 factor. And once these three factor are taken into  
7 account, we think that no matter where you get your  
8 sample, it will be very representative of the  
9 population.

10 But then, we also -- in order to make  
11 sure that we get a national -- yeah, it is a  
12 nationwide survey, we went to eight different  
13 states: California, Texas, Pennsylvania, Ohio, and  
14 Illinois, and Virginia, and New York.

15 So -- and then we also recruited our  
16 subject from various industry: Manufacturing,  
17 construction, and health care, and firefighter, and  
18 also police -- law enforcement officer.

19 So we get a very good database.

20 And these are the tools that we use.

21 This is a sliding caliper, and this is a spreading  
22 caliper, and this is the anthropometer that we use

1 to measure the height.

2 And this is a picture showing our  
3 measurer making landmark on the face before we do  
4 the measurement, and this is just to show how they  
5 use the tool to measure face width.

6 And this is the, yeah, the summary table  
7 for the subject that we measure in our database.

8 As you can see, we have male and female,  
9 and age group, three age group. And then we have  
10 the four racial groups here.

11 Our total male subject is 2,543, and we  
12 have a little bit less female, yeah, 14 -- 1,454.  
13 And as you can see from this table, we get varied  
14 representative from each of the stratum that we  
15 design -- yeah, in our survey design.

16 So once we collected the data, the first  
17 thing we did was to scientifically prove that  
18 whether the LANL panel is applicable to civilian  
19 workers.

20 So what we did was to look at our subject  
21 and see where they are distributed in -- yeah,  
22 against the panel, and only 24 percent of our

1 subject in this cell, and .5 here. And you can see  
2 it go up like -- yeah, this is the cell that we  
3 have like more and -- yeah, here. So it is like  
4 18.3 percent.

5 And so -- but when you sum them up, the  
6 total is only 84.7. So we have the other like are  
7 outside -- and this is a scatter part of face  
8 length and face width of the subject. So this  
9 represents one data point, like one subject, his or  
10 her face width and face length, and this is how the  
11 data show.

12 And this cell represent the LANL panel.  
13 So as you can see, you do have like many subjects  
14 here, and then we do have some to the top and to  
15 the right.

16 And this trend is very similar to the  
17 trend that I mentioned earlier, the study back in  
18 the '75. They find similar trend.

19 So this is just a pie chart to show we  
20 have 15.3 percent not being included in the panel,  
21 and then the panel only include 84.7 percent. So  
22 here are the preliminary findings.

1           The 1967, '68 Air Force survey data was  
2 not reflective of the anthropometric distribution  
3 of the current U.S. workers, and new respirator fit  
4 test panel needed to be developed.

5           Yeah, in our other study that when we  
6 look at the facial correlation, yeah, correlation  
7 between facial dimension and respirator feed, we  
8 found our preliminary finding is like facial  
9 dimensions were found to be significantly  
10 correlated with fit factor in 28 of the 33  
11 respirator model size combination.

12           So we have several other -- seven other  
13 studies. They look at one or two models. But here  
14 in our study, we look at 20 -- we look at 18 of  
15 them. And some model has one size, and some model  
16 have two size, and some have three sizes.

17           So we have about -- we have exactly 33  
18 combination. And we were able to find one way or  
19 another like one dimension or two dimension, and  
20 they were significant. They were significantly  
21 correlated with fit factors.

22           And so -- and then when you look at the

1 facial dimension, face width, bigonial breadth,  
2 nose protrusion, and face length were most  
3 frequently found to have significant correlation  
4 with fit factors.

5 And then we also did a systematic review  
6 of the literature. And I found -- basically I can  
7 find seven other studies that have looked at this  
8 subject matter.

9 And so the conclusion here will be lip  
10 length is not appropriate, and face length and face  
11 width are recommended for defining the panel for  
12 testing half-mask respirators.

13 So, yeah, here is the proposed panel.

14 So we also would like to keep the ten  
15 cell, ten category, and then 25 subject. And we  
16 would like to have at least two subjects for each  
17 cell.

18 We would like to match the distribution  
19 of the subject like -- or the subject for the panel  
20 to be similar to what the population --  
21 distribution of the population. So we would like  
22 to match that also. But then we would like to have

1 at least two subjects first, and then we will try  
2 to match as close as possible.

3 And another key point here is face length  
4 and face width were selected to define the panel  
5 for both half-mask and full-facepiece respirator.

6 So this is the new under the proposed  
7 NIOSH panel.

8 So you can see this is face width and  
9 face length, and the limits now becomes from 99 and  
10 a half to 139 and a half millimeters. And then for  
11 face width, it is 120 and a half to 160 and a half.

12 And as you can see, in order to have more  
13 percentage in this cell, we shifted the upper like  
14 five cells to the left. So the shape is different  
15 from what the LANL panel -- yeah. So -- and so --  
16 and these other subjects that we are going to  
17 select from each of the cells.

18 So you know the minimum is two, and so  
19 this -- yeah, these are the two cells that we have  
20 4 and 5, and -- because like we have more subjects  
21 in these two cells.

22 And this is the percentage.

1           It is like 6.2 percent, 6.8, and this  
2 is -- here we have 25 and here we have 19. So the  
3 total subject -- yeah, the percentage is 96 and a  
4 half percent of our subjects are in the selection  
5 area.

6           And here is a scatter part of the face  
7 length and face width data for our subject. And  
8 then we superimposed the new proposed panel on top  
9 of that, so you can see it cover the population  
10 very well.

11           The initial use of the panel will be for  
12 the benchmark testing. And so for  
13 one-size-fits-all model, we will use the subject  
14 from Cells 1 to 10. And the total number of  
15 subject will be 25.

16           And then two donnings. Each subject will  
17 don the respirator twice.

18           And for two size model. Yeah, they may  
19 call small-medium, medium-large, and only two size  
20 for that particular model.

21           Then we will test cells 1 through 6 or 4  
22 to 10 for each of those size. And then the total

1 number of subjects will still be 50.

2 And for three-size respirator models, we  
3 will test 1 to 5 for small, 4 to 7 for medium, and  
4 6 to 10 for large size. And the total number of  
5 subject is 75. But this is the initial proposal.  
6 We may change it like -- yeah, when we do more  
7 tests, we may change the number just to get a very  
8 good understanding of the performance -- of the  
9 state of our technology.

10 So, yeah, here is the timeline for this  
11 piece of work.

12 We developed the protocol, and then we  
13 have a peer review panel of five reviewers to  
14 review our protocol. And we incorporate their  
15 comments and then submitted the protocol to NIOSH,  
16 Human Subject Review Board for their review. And  
17 the NIOSH Human Subject Review Board has about 16  
18 members.

19 Then after that, we published our  
20 protocol in Federal Register to ask for public  
21 comments, and then we submitted the package to OMB  
22 for their review. And the final approval was back



1 in November of 2002.

2 So -- and we started collecting data  
3 earlier 2003, and we finished the data collection  
4 in September of 2003. And we went on to do more,  
5 do the data analysis and prepare a report, and we  
6 finished that by May.

7 And data analysis still continue as we  
8 developed various manage group, and then we will go  
9 through the peer review. We expect to finish the  
10 peer review process in the Second Quarter of next  
11 year.

12 Okay. So I would like -- this is our  
13 proposal, and I would welcome any comments that you  
14 may have.

15 Thank you.

16 MR. PLATNER: Just a quick one. This is  
17 Jim Platner from the Center to Protect Worker's  
18 Rights.

19 One of your slides is pointing out that  
20 other parameters, like nose protrusion and other  
21 factors, significantly correlated with the fit  
22 factor.

1           Why did you choose just face width and  
2 face length as your parameters for stratifying your  
3 population?

4           MR. ZHUANG: Okay. I guess like after  
5 reviewing their study results -- and we have eight  
6 study.

7           So face width and face length were found  
8 to have significant correlation in four of the  
9 eight studies, and this is the highest frequency.

10          Like nose protrusion may be one or two of  
11 them, and bigonial breadth is, yeah, one or two of  
12 them also.

13          So -- and then, the fact is face width  
14 and face length was used in the LANL panel for full  
15 facepiece. And so at this point, we feel like it  
16 will be better to go with that.

17          But as I say earlier, to develop this  
18 panel, we also look into several other approach.

19          One of them is called Principal Component  
20 Analysis approach, and this is the type of analysis  
21 that you could not do back in the '70s. There is  
22 no computer software available. The calculation is

1 just impossible at that point to do the  
2 calculation.

3 But nowadays, you can have statistical  
4 package out there like SAS, which is Statistical  
5 Analysis System, that I use. And they also have  
6 some other -- several like other package.

7 And they have -- these cover algorithm in  
8 the software that you can compute real quick, just  
9 in a few seconds.

10 And basically what it is is like if you  
11 have ten dimensions, you will get ten principal  
12 components, but you don't need all ten of them to  
13 explain a hundred percent of your variation in the  
14 ten dimension. So basically you only need two or  
15 three.

16 And you will -- like this two or three  
17 component will explain maybe 80 or 90 percent of  
18 your variation already. But each component is a  
19 function of each dimension, so it is a linear  
20 combination.

21 So basically you will calculate the  
22 coefficient for each -- dimension for each

1 component, and then you will only need the first  
2 two or three principal component to represent your  
3 variation.

4 So that is something we also considered,  
5 but it is not mature yet. And so we feel more  
6 confident with the bivariated (phonetic)  
7 distribution.

8 And it is still much better than single  
9 dimension. Nowadays, if you want to design for one  
10 dimension, you use 95 percentile, then you only  
11 include 95 percent. But if you bring in two  
12 dimension, then once you exclude the other five  
13 dimension, you bring in another 1 and 5 percent.  
14 That come down to real quick to 90 percent or so.

15 But the way we design our panel, we try  
16 to include 95 percent.

17 MS. FEINER: Lynn Feiner, North Safety  
18 Products.

19 Do you have the plus or minus error rate  
20 with your sampling versus the general U.S.  
21 population?

22 MR. ZHUANG: The error rate -- I'm not

1 quite sure what error rate you are looking for  
2 here.

3 MS. FEINER: Well, I'm looking at your  
4 sampling size here and --

5 MR. ZHUANG: Okay.

6 MS. FEINER: -- I'm not sure -- I'm  
7 questioning -- and I don't know what the population  
8 is, but the Hispanic versus the white and  
9 African-American, I'm wondering why that number is  
10 so low.

11 So if you compare to the general  
12 population, black, Hispanic, white and other male  
13 and female, what is the general population to get a  
14 plus or minus error rate placed on your own  
15 sampling size?

16 MR. ZHUANG: Oh, okay. Our sampling  
17 size -- I think I do not have the table here, but  
18 it's very close.

19 If you look at proportional sample, like  
20 70 percent white and 11 percent African-American,  
21 12 percent Hispanic, and 6 -- I think our database  
22 are very similar to that percentage.

1           We did not estimate the error rate,  
2   and -- but and then also we also look at -- I mean,  
3   when you look at the face length or face width, in  
4   fact, we use face length as the parameter to  
5   determine our sample sizes, and you also have a  
6   variation.

7           So our calculations show that if you look  
8   at each of the group, and you want to be 95 percent  
9   confident that your estimate, the 50 percentile of  
10   the 5 -- of the estimate for that particular group,  
11   the accuracy to be within 1.2 millimeter of the  
12   true 93 percentile.

13           But then -- so that number is 166. But  
14   then if you consider sometimes you may have  
15   differences when you have two measure the same  
16   subject, so one or two millimeter.

17           So we only need about a 40 something or  
18   so to have a very good confidence in that  
19   particular like sampling strata.

20           So we have more than that. Like, you  
21   know, each of our category, maybe one or two we  
22   have about like 40, but most of them we need that

1 kind of samplings goal.

2 MR. BERNDTSSON: Goran Berndtsson from  
3 the SEA Group.

4 I just want to share with you a little  
5 bit of experience. I'm sure that some of you maybe  
6 know that the ISO work was going on, and we had --  
7 just a couple of weeks ago, we had a meeting in  
8 London in the human factors group.

9 And one of the issues we are talking  
10 about is face sizes, and we are looking very much  
11 forward to your final report here because that  
12 would be taken into consideration.

13 However, what we are doing there is we  
14 are looking at this point of time on 18  
15 (unintelligible) commission, and this include all  
16 type of respiratory protection. So we are talking  
17 certain sizes of head, the heights and -- for  
18 hoods, et cetera, et cetera.

19 What was shared with us in the last  
20 meeting was that some years ago, Sweden went  
21 through a defense program to put national  
22 respirators into the entire population.

1           They started off in the same way as we  
2 did, looked at a very large number of measurement.

3           But the final result come down to three.  
4 And this was, of course, full facemasks. The idea  
5 was to cover the entire population of the Swedish  
6 population. At the time it was about 7 million  
7 people, I think, at the time when they did this.

8           And they come down that the length,  
9 width, and the mouth was the three critical when  
10 they start correlating it back to protection  
11 factors on on full facemasks.

12           When we are looking at half-masks, you  
13 possibly have another very important measurement  
14 which is not considered, and that is the width and  
15 the height of the bridge of your nose. Because  
16 this is the critical areas where it is not  
17 considered in any standard at this point of time,  
18 and maybe you should have a look into that for this  
19 particular study.

20           MR. ZHUANG: Yeah. It is a smaller  
21 dimension, the nose. And I think -- I don't know.  
22 You guys may know Dr. Ken Ostenstead (phonetic) at



1 the University of Alabama. He did find nasal root  
2 breadth to be a significant dimension in his study.

3 But in our study, we did not see that.

4 So when you look at the eight study that  
5 I put together, like when I chose the literature,  
6 these are the seven study plus our own study.

7 So again, I would like to consider your  
8 comment, and let's continue to work together.

9 And so by that time, when we develop the  
10 ISO standard -- and then we will get this through  
11 the peer review process also, and then we will see  
12 everyone.

13 I did talk to Allen Hagg. He was the one  
14 in charge of the LANL panel development. And he  
15 agreed with me that like face length and face width  
16 is the right choice.

17 But I will get his comments officially in  
18 the future and then other people as well.

19 MR. PFRIEM: Dale Pfriem, ICS Labs.

20 First, I applaud your work.

21 We have been struggling with the  
22 applicability of the LANL panel since 1996 and even

1 more so since the tripling and quadrupling of  
2 subjects needed for LRPL testing. There is no  
3 applicability there whatsoever, so the sooner it  
4 comes out the better.

5 Three questions I have.

6 You had mentioned that you had -- did  
7 your fit measurement studies on the population,  
8 then you went back and corrected the data.

9 What did you mean by corrected the data?

10 MR. ZHUANG: Corrected what data?

11 MR. PFRIEM: You had said, We took the  
12 measurements. Then we went back and corrected the  
13 data.

14 What did you mean by that?

15 It was collected?

16 MR. ZHUANG: Oh, collected. I'm sorry.

17 MR. PFRIEM: Okay. I thought there was  
18 some data correction going on, and I wanted to ...

19 MR. ZHUANG: No.

20 MR. PFRIEM: Pardon me.

21 I have another question.

22 MR. ZHUANG: Okay.

1 MR. PFRIEM: When you did your  
2 measurement --

3 MR. ZHUANG: By the way, let me respond  
4 to your first question.

5 We do have a software like -- I mean,  
6 like when you go out and measure a hundred people a  
7 day, it is also -- it's a very tough job. But we  
8 have a software that we developed.

9 And so when you enter the information, it  
10 will give you some type of measure, say, Hey, this  
11 number is too small, too large, and then we will go  
12 back and remeasure it.

13 So we do have that kind of editing, like  
14 routine measurement process.

15 But once we collected the data, we do not  
16 have any type of correction.

17 MR. PFRIEM: That's interesting.

18 So how did it say it was too small, too  
19 large? How did it make that distinction?

20 MR. ZHUANG: It is based on the -- like  
21 we have some -- like I said, the CAESAR.

22 But Army also did a survey like back in

1 '88, and I looked at their data set also. And so  
2 based on that kind of data, we developed some kind  
3 of correlation equation.

4 Like when you have -- you have like one  
5 dimension can be predicted by the other.

6 MR. PFRIEM: Exactly.

7 MR. ZHUANG: Based on that variable, if  
8 you know your prediction is not close, we just  
9 trigger a remeasurement to make sure that it's not  
10 a human error or something.

11 MR. PFRIEM: That question goes to my  
12 next question.

13 MR. ZHUANG: Okay.

14 MR. PFRIEM: We have discovered that  
15 there is a large amount of variance in tissue  
16 density, especially in heavier set individuals,  
17 especially when we are measuring bizygomatic  
18 breadth.

19 MR. ZHUANG: Right.

20 MR. PFRIEM: We can jump one cell,  
21 sometimes two cells, and give rise to a category  
22 change just by differing amounts in issue density.

1           Did your study take into account an  
2 inter-correlation study between people doing  
3 measurements to see how well these measurements  
4 correlated by people taking the measurements and  
5 how they would treat varying tissue densities?

6           MR. ZHUANG: Yeah. What we did is we  
7 just have a training, like maybe one week of  
8 training of the measurer.

9           So the principal -- there is another  
10 principal investigator. He is the president of  
11 that company helping me collect the data.

12           So we did look at that.

13           Like we have some subject coming in.  
14 Everyone did the measurement, and we look at the  
15 consistency.

16           And we used the observer error defined in  
17 the Army survey in '88. And as long as we feel  
18 like our subject -- I would think that kind of  
19 error limit, we stopped the training.

20           So it -- we tried to solve that problem  
21 through training to make sure that like if I  
22 measure the same person, you do the same person, we

1 have similar results, at least to a certain  
2 tolerance limits.

3 MR. PFRIEM: Is that correlation data  
4 available?

5 I would like to see it.

6 MR. ZHUANG: We did not look at the  
7 correlation, but we look at their observation  
8 differences.

9 But this is something that I guess we --  
10 I will consider whether I can release that or not.

11 MR. PFRIEM: And then I guess a step  
12 forward into that, something that we have toyed  
13 with is the typical wide-mouth calipers, since they  
14 actually -- they are really the cause and effect of  
15 this variance, especially, in breadth  
16 measurement --

17 MR. ZHUANG: Yeah.

18 MR. PFRIEM: -- and a face mask doesn't  
19 fit like that.

20 If you take a -- say a one-by-two-inch  
21 flat, okay, and pivot it on a ball joint on the tip  
22 of those calipers, you are going to get a broader

1 face so you are not affected as much by tissue  
2 density, and it is much easier to scale the face  
3 and get the breadth without trying to scan it with  
4 a probe.

5 So you may want to look at toying with  
6 that yourself.

7 MR. ZHUANG: Okay.

8 MR. PFRIEM: Thanks a lot.

9 MR. SAWICKI: Jack Sawicki, Global  
10 Secure.

11 You are talking about correlation between  
12 the facial dimensions and the respirator fit.

13 Did you just test one respirator size  
14 based on the predicted range, or did you test, say,  
15 three sizes with each subject to determine if they  
16 were correctly allocated to the size?

17 MR. ZHUANG: In our study, we did not --  
18 not every subject of the panel. We used 25 subject  
19 panels.

20 But like if it is one size fits all, we  
21 have data for all 25 subjects, but for two or three  
22 size, we don't have that.

1           So we only have like maybe ten subjects  
2           for small and five for medium. So we have limited  
3           number of subjects for some of the size.

4           MR. SAWICKI: Do you have any plans to  
5           look at multiple size respirators to determine if  
6           you are accurately predicting the size with the  
7           data you have?

8           MR. ZHUANG: I guess like it would be  
9           hard to go back and improve that study.

10           So that data has been collected and  
11           analysis has been done. But in a future study, we  
12           can consider that.

13           MR. SAWICKI: Okay. Because I think it's  
14           important.

15           In a previous experience where we were  
16           actually fit testing workers, we would often find  
17           that they wouldn't fit a model in the predicted  
18           range -- and this is looking at the military mask,  
19           the M-40s and MC2Ps.

20           MR. ZHUANG: Okay.

21           MR. SAWICKI: For example, some of you  
22           predicted you go into a size medium. You couldn't



1 pass a fit test with a size medium, but you could  
2 pass a fit test on a size small, even though it was  
3 not within the predicted size range.

4 MR. ZHUANG: Oh, okay. For our benchmark  
5 testing, we may consider that. And just to see  
6 different size, how they vary, like using the  
7 panel -- yeah, according to the panel, how  
8 different size may vary, and so on.

9 MR. PFRIEM: One other question. This  
10 kind of goes back to you, Bill.

11 You had mentioned that if you are going  
12 to follow manufacturer's guidelines or user  
13 instructions -- and I'm trying to recall -- and  
14 then in the absence of that, you would fit the full  
15 panel.

16 And I guess this ties into what Jack was  
17 saying. And a lot of times, we will see  
18 respirators that for some reason or another,  
19 because of their design, don't fit in the box.

20 They don't fit in the small box. They  
21 don't fit in the medium box. They don't fit in the  
22 large box. But if you follow the manufacturer's

1 fitting instructions and the guidance they give,  
2 you will end up with a proper fitting respirator  
3 for that guy's category.

4 So how are these two things going to work  
5 together as far as following user manufacturer  
6 instructions as provided with the respirator for  
7 fitting instruction, and then the mandate that a  
8 respirator of a size small has to fit this lower  
9 five-matrix cells, and a medium has to fit the  
10 medium, and then the large has to fit the upper  
11 matrix cells.

12 How will those co-exist?

13 MR. NEWCOMB: There is really, yeah, two  
14 issues.

15 One is, What do you do with the benchmark  
16 testing? And the other is, What do you do with the  
17 final requirement that will come into the  
18 certification process?

19 The benchmark testing, we are going to  
20 test to define where these respirators fit people.  
21 What we are looking at, though, for the final  
22 regulation is testing them according to the

1 manufacturer's instructions.

2 In other words, if the manufacturer just  
3 says these are a small, we would test it on what we  
4 consider the small panel.

5 If the manufacturer actually had, for  
6 instance, a diagram like that that indicated where  
7 this respirator was designed to fit, we would test  
8 it in that area.

9 MR. PFRIEM: So then the matrix panel and  
10 those size structures would fall by the wayside?

11 MR. NEWCOMB: Yes.

12 MR. PFRIEM: Excellent.

13 MR. SAWICKI: Jack Sawicki from Global  
14 Secure. Let me understand maybe a little better  
15 what you are saying.

16 So if I, as a manufacturer, had three  
17 sizes of respirators, and I, for example, put a  
18 line across the middle of a box and saying, In this  
19 range you might fit into a small or medium; you  
20 would test both small and medium and allow a pass  
21 based on one of them fitting or --

22 MR. NEWCOMB: Well, I can't say we would

1 definitely do that at this point, but that is the  
2 thinking, that we are going to rely on the  
3 manufacturer to say where this product is designed  
4 to fit.

5 MR. SAWICKI: Okay. But back to my  
6 question, I guess. Would you do two tests?

7 If you failed one test on size small,  
8 would you say, Okay, well, that guy is in the  
9 middle range there. We are also going to test the  
10 medium. If you pass the medium, you get a pass for  
11 that subject?

12 MR. NEWCOMB: If the -- the way it is  
13 done now, if there is a -- an overlap, what we are  
14 trying to do is make sure that the -- if a  
15 respirator comes in more than one size, that it  
16 actually is capable of fitting either one size or  
17 the other of that individual.

18 I can't speak for what we are going to do  
19 with the final regulation. That's up for grabs at  
20 this point. But, you know, we don't want to be  
21 design restrictive of the respirator.

22 MR. BERNDTSSON: Goran Berndtsson from

1 the SEA Group again.

2 Just to clarify here, if one manufacturer  
3 come in with just one size, and it is a small size,  
4 and write that in the instructions only fitting the  
5 small size, is that going to be possible to prove  
6 that, or do you intend to have the whole range?

7 MR. NEWCOMB: No. If a respirator comes  
8 in, and it says size small, then as far as we are  
9 concerned, it's a size small, and we will test it  
10 as a size small.

11 MR. BERNDTSSON: So they are saying the  
12 type of respirator doesn't have to cover the  
13 whole -- the different sizes. Okay.

14 MR. VINCENT: John Vincent of North  
15 Safety Products.

16 Just so I understand this correctly, when  
17 a manufacturer brings a respirator to get NIOSH  
18 approved, are they going to be -- let's assume  
19 three sizes -- will there be 75 people or 75  
20 subjects would have to test into the three sizes?

21 MR. NEWCOMB: No. The chart with the  
22 number of subjects that Dr. Z put up was the -- for

1 the benchmark testing plan that we have at the  
2 present time, which is undergoing peer review isn't  
3 that we are trying to get 25 data points on every  
4 respirator to do the benchmark testing.

5 In the final regulation, I don't  
6 anticipate that there will be that many tests. But  
7 again, it's -- that's going to be part of the final  
8 plan and peer review as well.

9 MR. VINCENT: You expect this would cost  
10 to the submittals and delay the timing of the  
11 submittals?

12 MR. NEWCOMB: Well, obviously the --  
13 there is going to be a cost associated with the fit  
14 testing and/or the TIL testing, I should say.

15 Whether it will be different for a one  
16 size fits all or a multi size, I can't even  
17 conceive at this point.

18 MR. METZLER: By the next public meeting  
19 we should have more information about the costs  
20 that are going to be associated with that in this  
21 test.

22 MR. VINCENT: It's also, we have had

1 experience, our company, with trying to get a  
2 subject panel together has been the longest time  
3 factor in getting submittal approval.

4 MR. PFRIEM: I'm glad I sat there.

5 Just brought up the issue of cost, and I  
6 guess I have to ask this question.

7 Has there been any thought as when this  
8 regulation goes into promulgation that it would be  
9 opened up to the private sector for NIOSH  
10 acceptance based on accreditation, or will this be  
11 solely a NIOSH structured test done at NPPTL?

12 MR. METZLER: Well, we are open minded  
13 about using contractors to support our  
14 certification process.

15 We currently, as you know, are using  
16 military labs to contract for live warfare agent  
17 tests for us. So we would invite comments on both  
18 sides of that argument from the public.

19 And we are open minded in approaching the  
20 program.

21 MR. BOORD: Thank you, Dr. Zhuang.

22 Since we are moving right along on the

1 schedule, what I would like to do now is we will  
2 take a ten-minute break, then we will come back and  
3 resume with the guest speakers. And we may be able  
4 to get in several of those before we break for  
5 lunch.

6 So let's take a ten-minute break, and  
7 then we will be back and begin with the speaker,  
8 and Mr. Bien will be first.

9 We will follow the sequence as listed in  
10 the agenda.

11 (A recess was taken.)

12 MR. METZLER: Let's try to go on with the  
13 next speaker, Mr. Kojola. And I hope that any  
14 information that you require to be on the screen  
15 has been loaded.

16 But let's try to do that if we can.

17 MR. KOJOLA: I just might as well do it  
18 from here since I don't have anything.

19 I'm a low tech guy, so we have nothing  
20 that --

21 MR. BOORD: Maybe that's good.

22 MR. KOJOLA: Yeah, well, in this case, it



1 might be.

2           Yeah, my name is Bill Kojola. I am with  
3 the Safety and Health Department of the AFL-CIO.  
4 And I do want to, you know, congratulate NIOSH for  
5 moving forward on this initiative.

6           I think it's an important piece in the --  
7 that has been missing in the respirator  
8 certification process that NIOSH has established.

9           But there is a backdrop to our interest  
10 in this whole area, and that backdrop has to do  
11 with OSHA's promulgation of proposed APFs for  
12 respirator protection, particularly the issue that  
13 was discussed earlier, the controversial issue  
14 about what should an APF be for a filtering  
15 facepiece.

16           The agency and NIOSH both believe that an  
17 APF of 10 is appropriate for both a filtering  
18 facepiece and an elastomeric half-mask, so we have,  
19 I would say, a very vigorous dispute with both OSHA  
20 and NIOSH on that issue, at least as it applies to  
21 the proposed APF for a filtering facepiece.

22           Now, I went up on the NIOSH website

1 yesterday afternoon to look at how many filtering  
2 facepiece respirators are certified by the agency.  
3 And at least my by my count, yesterday afternoon,  
4 there were 196 filtering facepieces that were  
5 certified under Part 84 certification requirements.

6 That's quite a few respirators.

7 But our concern has to do with the  
8 certification process. The agency really has no  
9 way of judging whether those respirators actually  
10 fit appropriately on a wearer's face. So this  
11 initiative, I think, by NIOSH will help to address  
12 that issue.

13 We have some very serious concerns  
14 primarily with the ability of filtering facepieces  
15 to fit on wearers, so -- but we need -- we think we  
16 need -- that NIOSH needs to develop this  
17 certification process here to test the fit of  
18 filtering facepiece respirators and indeed all  
19 half-masks so that it weeds out those filtering  
20 facepieces and other half-masks that don't fit on a  
21 wearers faces.

22 Now, I just have couple of preliminary

1 issues or points that I want to make, and then  
2 essentially I'm done.

3 We think the certification test  
4 procedures and protocol, you know, has to be  
5 evaluated and validated before, you know, before  
6 they are implemented in a certification program by  
7 NIOSH.

8 And I think we have already discussed  
9 that NIOSH is moving forward on that. We think  
10 that's an important step.

11 We think the protocol must assure that  
12 test subjects follow exactly all of the  
13 instructions provided by the manufacturer for a  
14 given respirator they are wearing, and I think this  
15 was also talked about in Bill Newcomb's discussion.

16 We think that's a very critical element  
17 in improving any of the half-mask respirators,  
18 particularly filtering facepieces. We think  
19 respirators should be failed if the manufacturer's  
20 instructions are flawed or deficient, thus the  
21 necessity that the instructions be followed to the  
22 letter to determine the adequacy of the

1 manufacturer's instructions.

2 As part of this process, we need to  
3 establish some criteria for certification approval  
4 and disapproval, and then we have to kind of  
5 grapple with that idea. What are the criteria that  
6 NIOSH is going to use?

7 We think that the fit factors that are  
8 established for a NIOSH certification must be more  
9 stringent than those contained in the OSHA  
10 respirator standard. We think this builds in an  
11 additional degree of worker protection for those  
12 respirators that ultimately achieve that NIOSH  
13 certification.

14 We think the exercise incorporated into  
15 the certification protocol at this point, at least  
16 as you are proposing, only mirror those required by  
17 OSHA's respirator standard.

18 We think some serious consideration needs  
19 to be given to building in some additional,  
20 possibly more rigorous exercises that ought to be  
21 included because this is really sort of the first  
22 cut at making sure that respirators that don't fit

1 on wearers' faces are not certified.

2 So I think this is an important first  
3 step in terms of building a margin of safety for  
4 employers when they select certified respirators  
5 for use by the workforce.

6 We also have some serious concerns  
7 particularly with filtering facepieces about the  
8 ability of a wearer to do a user's seal check. And  
9 of course, this issue was discussed at considerable  
10 length in the OSHA public hearing earlier this  
11 year. There is very serious concern with filtering  
12 facepieces.

13 It's very difficult to do an effective  
14 user seal check. And, as the record showed, very  
15 few workers actually perform a user seal check on  
16 filtering facepiece respirators.

17 So we think that that needs to be built  
18 into the process of certification. And maybe  
19 multiple donnings where you begin to examine  
20 whether a wearer can do an effective user seal  
21 check ought to be part of the protocol.

22 So we are pleased to be here today. We

1 are pleased to be able to, you know, engage in  
2 dialogue and discussion and expression of our  
3 perspectives on this issue, and we look forward to,  
4 you know, to NIOSH moving forward on this.

5 Thank you very much.

6 MR. BOORD: Thank you, Bill. We  
7 appreciate the comments. And I'm sure you saw  
8 everyone at the front panel frantically writing as  
9 you were speaking.

10 So thank you for your insights and your  
11 input into the concepts we are developing.

12 With that, I would like to move on to Jim  
13 Platner from the Center to Protect Worker's Rights.

14 MR. PLATNER: Good morning, and thank you  
15 for the opportunity to speak.

16 I think this is a much-needed effort on  
17 the part of NIOSH, and I think it's a big effort  
18 that we will probably be working on for some time,  
19 but well worth the time.

20 Now, for those of you that aren't  
21 familiar with it, The Center to Protect Worker's  
22 Rights is a nonprofit research arm for the Building

1 and Construction Trades Department of the AFL-CIO.

2 Our 15 affiliated unions have about 3 and  
3 a half million workers, about 80,000 signatory  
4 contractors. And we have been working with NIOSH  
5 for almost 15 years now as a construction research  
6 partner.

7 And just recently, actually, we were  
8 awarded a competitive award with NIOSH to continue  
9 that effort for another five years. So I look  
10 forward to working with you as part of that effort  
11 as well.

12 Now, I wanted to encourage you to, as we  
13 develop test methods, to look broadly at Total  
14 Inward Leakage.

15 I think there is a lot of factors that  
16 are going to turn out to be important, and I don't  
17 think we yet know which ones are most important,  
18 necessarily.

19 Focusing only on face seal I think would  
20 be a mistake. I think that's clearly -- it's  
21 likely to be an important or even the most  
22 important factor, but there is a whole range of

1 other factors that may also be important. And I  
2 want to talk -- mention a couple of those as I go  
3 down.

4 I think some of the issues that come to  
5 mind and that we have heard at different times from  
6 our members include distortion of the face seal  
7 when storage is improper or with extended use or at  
8 very high or low temperatures.

9 The effect of filter or cartridge  
10 loading, which increases the differential pressure  
11 and very likely increases Total Inward Leakage,  
12 which really isn't evaluated now.

13 Not only the shape of the face seal,  
14 which Dr. Zhuang has described in quite a bit of  
15 detail, but also the ability of the face seal to  
16 conform to the face, I think very significant with  
17 the product and the design. And there may be other  
18 factors related to that.

19 I also think that we have to step back a  
20 bit from the general population data that  
21 Dr. Zhuang presented, and consider whether there  
22 might be subpopulations that are largely excluded



1 from work that requires respirator fit.

2 And based on no data, but just personal  
3 observation, some of those might be, for example,  
4 individuals that weigh over 350 pounds, many of the  
5 Native Americans and Pacific islanders.

6 I would guess that we might have as high  
7 as 50 percent failure in fit tests in some of those  
8 subpopulations.

9 So even though they are not large in the  
10 general population, for those groups, it can be  
11 very important. So we have to consider how we can  
12 develop a sampling method to identify those very  
13 high risk groups.

14 I think we need to consider a more  
15 realistic and possibly even field test to look at  
16 face and body motion. I think the rainbow passage  
17 is probably inadequate, certainly for construction  
18 workers.

19 And for some of the respirators that are  
20 available, for example, PAPRs where the blower is  
21 mounted on the nose facepiece, I think general body  
22 motion actually affects seal.

1           If you have to jump or you have to move  
2 significantly with a lot of momentum on a heavy  
3 mask, I think you can -- any seal that is there  
4 when you are standing still may well be gone.

5           So I think we need to think more broadly  
6 of the -- about the -- this leakage area and  
7 consider the motion of the face and the body during  
8 the expected work tasks.

9           I would like to think that indicators,  
10 cartridge indicators that are now allowed and are  
11 used in a limited number of cases might also be a  
12 part of this evaluation because I think cartridge  
13 break-through and conceivable failure of the  
14 indicators may well result in increased Total  
15 Inward Leakage.

16           And I think we still have limited  
17 knowledge about those, and that's an area where I  
18 think there will be quite a bit of development in  
19 the next ten years.

20           We have to think about mechanical  
21 failures in field use, the blowers on the PAPR, the  
22 valves that can freeze up, valves that can split.

1 And these kind of mechanical failures or even just  
2 batteries that are dead may well contribute a  
3 significant amount of exposure.

4 In construction, we often find that  
5 exposures are very clearly task related in that  
6 most of the exposure may occur in very short time  
7 intervals associated with very high exposure tasks.

8 So when that's the case, it doesn't take  
9 long to receive the equivalent of a 40-hour day at  
10 the pel (phonetic). So we have to consider when  
11 these failures are likely to occur under field  
12 conditions.

13 And I think, like the seal check, we need  
14 to come up with simple, quick, and dependable field  
15 checks so that workers can self-identify when their  
16 respirator has failed or is likely to fail soon.

17 You know, if workers can't recognize that  
18 the seal is broken, that the valve is split, that  
19 the cartridge has already absorbed all it can  
20 absorb, then they are likely to receive significant  
21 exposure before somebody else spots that problem.

22 So I think some sort of -- as we define

1 failure modes, which I don't think we have really  
2 defined adequately yet, we need to think of  
3 mechanisms for evaluating -- for the worker to  
4 evaluate on the job site. Has it failed in the way  
5 we have identified as a significant failure mode?

6           And I think when new respirators are  
7 developed that require new kinds of field checks,  
8 we have to realize that there is a significant  
9 training burden or retraining burden that is  
10 introduced when you change the way that we expect  
11 workers to evaluate the fit.

12           So positive and negative seal check is  
13 something everybody knows. If we start to  
14 introduce anything different than that as a field  
15 check to evaluate whether your respirator is still  
16 working, we have to think about the huge burden of  
17 retraining workers to use this new field check  
18 method.

19           I think as we go through this whole  
20 process, we need to think about the whole range of  
21 failures, not just is it sealed to the face.

22           And I think that's a challenge. We don't

1 really, in my mind, don't know what will turn out  
2 to be the important variables until we start to  
3 look at this more closely. But certainly we at the  
4 Building Trades and at the Center to Protect  
5 Worker's Rights look forward to working with you.

6 I think we consume, in the construction  
7 sector, about a third of all of the respirators  
8 sold in the U.S., so it's close to our heart.

9 Thank you.

10 MR. BOORD: Thank you, Jim.

11 At this time, let's back up a little bit.

12 Are there any questions that the audience would  
13 like to direct to either of the previous two  
14 presenters?

15 Okay. If not, then we will move on to  
16 Mr. Shine from the International Association of  
17 Heat and Frost Insulators and Asbestos Workers.

18 MR. SHINE: Good morning. My name is J.  
19 F. Shine. I worked with the Insulators Union in  
20 Chicago as a trainer for the last 18 years.

21 Before that, I worked in the field as a  
22 helper and apprentice, journeyman, foreman. I have

1 had a lot of experience with the training of the  
2 respirators, with the standards, and been through a  
3 lot of the classes.

4 That being said, I have listened to many  
5 people and have experience with many types of  
6 respirators, such as half-face dust masks, which  
7 someone decided to change the name, naming it a  
8 filtering facepiece.

9 I can't figure out why they changed the  
10 names. I always thought it was just to confuse  
11 people, but who knows.

12 When I speak with people who have never  
13 worked in construction, they never think that there  
14 are places that can harm you. They look at these  
15 big strong looking people and they think they are  
16 invincible, but in reality a lot of these people  
17 get into construction when they are young because  
18 they were thought of as poor students.

19 They were antsy. They did not like to  
20 sit in a chair. They had to move.

21 Construction when you are young can be  
22 fun, but a little dangerous. Then you get a little

1 older, a little wiser and you hear these same  
2 people telling the young ones coming up, Stay in  
3 school; get an education.

4           They know there is a trap, and that's  
5 money. You have a family. How are you going to  
6 feed them, house them and educate them? You have  
7 stick at it.

8           The winters get colder; the summers get  
9 hotter; the job sites get smellier. The dose that  
10 you taking gets larger, but what can you do? This  
11 is all you know.

12           These people may be at risk.

13           Who here today has worn a respirator at a  
14 construction site or anywhere else, for that  
15 matter? How does it affect you? How long have you  
16 warn them?

17           Can you take them off without being hurt  
18 or overcome with a gas or a vapor?

19           How will the winter of cold affect the  
20 face shield? How does the heat from a boiler  
21 affect the seal when someone is sweating profusely?  
22 These people have to put up with that.

1           These are the questions that these -- the  
2 people doing the inward face sealing testing should  
3 be able to answer.

4           How do you know what you -- how do you  
5 know what we should be doing these tests for these  
6 masks? What process do we follow?

7           Are we the ones here who are starting the  
8 process?

9           What we do here today is the start of  
10 protecting workers' health in the future and  
11 actually saving medical costs in the future. If  
12 people do not get exposed at work by wearing a mask  
13 that has a good face seal, they will not,  
14 hopefully, need medical health help later in their  
15 lives.

16           What was done in the past should be  
17 improved. It did not work. Let us start to fix  
18 the problem.

19           My father, an immigrant construction  
20 worker, always said to me, Leave it better than you  
21 found it. I hope it can apply to many things in  
22 live, and I hope it applies here.



1           The big question today that I see will be  
2 what and where are the inward leakage areas on the  
3 worker's face, and why does it leak?

4           There have been many days that I have  
5 worn respirators for my protection at work. I did  
6 not receive a lot of instruction when I started.  
7 There were no rules we knew of. The thing that has  
8 always bothered me the most, though, was when I  
9 started as a helper, it was on the mask box. The  
10 box's label told me that the dust mask had been  
11 tested for asbestos and lead.

12           I was beginning to hear it was bad for my  
13 health. The label said that it was approved by  
14 NIOSH. Those labels made me feel good that a  
15 government agency was looking out for my health.

16           I had been raised in a family that said  
17 the government was there to help the workers. I  
18 was confused when all of a sudden, after I had been  
19 around asbestos for a few years, that assurance  
20 went away. It was no longer on the box. My  
21 question was why?

22           I did not know. I couldn't get an

1 answer. I still wonder today why the assurance  
2 went away. Did somebody not do his job?

3 I think it was -- I think that I have a  
4 bit of work experience with respirators, though. I  
5 have worn respirators at oil refineries, steel  
6 mills, chemical plants, manufacturing facilities,  
7 nuclear power houses, and commercial buildings. I  
8 have even worn one when I had to go into my attic  
9 once.

10 Fiberglass is pretty dusty. Okay.

11 I wear them at training classes also to  
12 show the students how to do it. Wearing a  
13 respirator is not what I consider fun.

14 When you wear a respirator, think about  
15 this. You are cutting down the amount of air that  
16 you are bringing into your lungs. You are putting  
17 a filter medium that blocks or holds the dust, and  
18 dust can be a very vague description.

19 Where did it come from? What is it? How  
20 big are the particles?

21 This determines how fast the filter gets  
22 clogged, as you know. Where will the air come in I

1 need to breath from? Will it sneak in from the  
2 sides? That's my concern.

3 Is the mask elastomeric? Does it have a  
4 solid form, or is it soft and flexible?

5 If it's a filtering facepiece, how long  
6 does it take for the filter medium or cartridge  
7 sorbent to absorb the moisture my lungs are kicking  
8 out?

9 Think about the vapor you see in the  
10 winter. I never thought about that before I got  
11 the job, so I think I'm flipping out. But I got  
12 this job. We breath out moisture. That moisture,  
13 when I wore the masks would eventually clog it up.  
14 And the dust and the dirt -- the filtering  
15 facepieces didn't work. I had to get air from  
16 somewhere, and that was usually from the side.

17 People believe when the trainer or the  
18 safety director tell them the masks are tested, not  
19 everybody understands what NIOSH tests. They put  
20 their faith in the fact that educated people  
21 understand what they are doing and would not let  
22 them use a piece of equipment that would get them

1 hurt.

2 We have at our Union Hall a plaque about  
3 25 feet long. It has a listing of all the people  
4 on it that have been members and passed on to a  
5 better place. These people could have been helped  
6 a long time ago if there were regulations in place  
7 to protect their health from the asbestos problem.  
8 They could have been helped if the equipment was  
9 available for them that was tested correctly and  
10 effectively.

11 I remember Bob Martinotti (phonetic) of  
12 the OSHA Training Institute showing me a three-inch  
13 wide, seven-inch long piece of foam rubber that  
14 looked like an air filter for a lawnmower. It had  
15 a one-inch hole at each end. He told me he found  
16 it when he was given the job of starting to train  
17 for the asbestos standard.

18 He told me that this piece of foam was  
19 sold as a dust mask for asbestos years ago. He  
20 also told me about a small bag of charcoal that was  
21 sold, and it was shown to be put in your nasal  
22 cavity or pushed up into your nose.

1           He said this was an organic vapor  
2 cartridge. Okay.

3           I don't think they were approved by  
4 NIOSH. As a matter of fact, we laughed about it,  
5 thank God. God bless America, though, you can buy  
6 anything here.

7           I also remember a high school teacher  
8 told me about caveat emptor, buyer beware. This is  
9 what we must not let happen. NIOSH testing should  
10 mean something.

11           We were told the government tested the  
12 masks, and it's okay at work. I have found since  
13 that it doesn't always hold true. NIOSH has made  
14 sure all of the problems -- NIOSH has to make sure  
15 that all of the problems are considered, such as  
16 inward leakage.

17           The respirators come in many sizes. The  
18 tests -- this test, I would believe, will lead into  
19 testing other face coverage or mask sizes. This is  
20 a good start. You have different coverages, the  
21 quarter, the half, the full, the PAPRs, and all the  
22 rest.

1 I would also like to suggest that there  
2 are different face types for male and female. More  
3 women are entering the construction arena. They  
4 have to be considered as well as the smaller  
5 people.

6 The respirator face-to-mask seal I feel  
7 is extremely important in the testing issue, as is  
8 the medium.

9 I am distressed by the fact -- and  
10 correct me if I'm wrong -- by the way the  
11 face-to-respirator seal has not been included in  
12 the past tests, just the medium.

13 People that wear the respirators come in  
14 all sizes and shapes, as we have talked about. One  
15 size does not fit all.

16 The next thing I would make sure was  
17 included in the testing is inhalation and  
18 exhalation valve problems. The exhalation valve  
19 freezes in the winter, and it is very difficult to  
20 breathe when nothing goes out or in.

21 The inhalation valve sticks from excess  
22 water in the summer. The environment these people

1 work in is not also a nice place to be generally.

2 If it were, they wouldn't be wearing a mask.

3 We need to make sure that all types of  
4 environments, hot, cold, wet, and dry, are included  
5 in this testing.

6 We need to include workload of breathing  
7 is included. Light work, walking around, heavy  
8 work, climbing ladders, scaffolds, all of these  
9 things have to be taken into consideration because  
10 these people have to do this or they won't be  
11 around long.

12 When working in hazardous work areas,  
13 there is also a psychological factor of the  
14 breathing that should be considered. Because I  
15 remember wearing the mask, and for whatever reason,  
16 the areas I were in were bad.

17 My face always itched. My nose always  
18 itched. I was anxious. I was scared. I'm not  
19 supposed to be in this place, but it's the only  
20 place that they have right now.

21 Some other examples taken into  
22 consideration, the one size for the filtering

1 facepiece. We have already worked that over pretty  
2 good. Is the mask too big or too small?

3           These size differences must be taken into  
4 consideration. What would happen if they were worn  
5 in the wrong size?

6           I have an apprentice school where the  
7 students have to wear dust masks because we work  
8 with fiberglass. I put them -- some of them take  
9 the masks, after I tell them how to put them on,  
10 the strap on the top of the head, the strap on the  
11 neck, and they have to take the bottom strap and  
12 put it on the top of their head. They have to take  
13 the top strap and put it on the bottom. They  
14 reverse it.

15           That's not how it was designed, but it is  
16 the only way that they can get it even close to  
17 fitting their face.

18           Next is heat. It has a dramatic effect  
19 on these people, on the rubber, on the silicone.  
20 They don't come back to their original shape when  
21 they have been heated. Our people work around  
22 boilers. They work around steam pipes. We have



1 even had instances where the masks have melted.

2 What effect does the cold have on the  
3 efficiency of the respirator?

4 We all know about the mask freezing. You  
5 exhale. Water sits down in the bottom. Difficult  
6 to breath. Some people have even thought of is  
7 there an expiration on the mask because of those  
8 problems.

9 How long will the people be able to wear  
10 these masks, ten, 15 years? Believe me, there's  
11 masks around that have been there that long.

12 What happen to the mask straps when the  
13 straps are not new anymore and they loosen up?

14 Most people that I deal with tell me that  
15 after 45 minutes, an hour, the mask is loose; they  
16 have to readjust it. That affects the fit.

17 There is many others, and I have worn  
18 these respirators in the winter, and the exhalation  
19 valve does not take long to freeze. Okay.

20 Another consideration is the work  
21 situation when people have to lay on their back,  
22 climb in, climb under, slide around. The mask

1 moves on their face. The valves don't operate  
2 correctly.

3           These work practices put a damper on  
4 their breathing. In asbestos abatement, we use a  
5 lot of water. Look at the rules. It lessens their  
6 exposure, but the water affects the filter. It  
7 also gets on their face, the mask slides around on  
8 their face. That affects their fit.

9           I have worked in areas that when I left  
10 and took off the filtering facepiece and blew my  
11 nose in the handkerchief, it was black with dirt.  
12 The fit doesn't work on the filtering facepieces  
13 all the time when you are working in a steel mill.

14           What happens to these people when they  
15 are working, and the filter starts to do its job?  
16 It starts to clog up. The air intake is  
17 diminished, and the person has to suck in air  
18 through a restricted -- that is going to put a  
19 bigger impact upon their seals. If they are not  
20 good, it's going to leak.

21           What will this practical seal test be?

22           I believe this is the question we are

1 here to answer today, and at least -- or at least  
2 start to answer.

3 I have found a difficult problem,  
4 solutions come after trial and error.

5 You can only test the media now. We have  
6 to put the two together, the media and the seal.

7 And then I hope I have helped in your  
8 effort. And if you have any questions, I would be  
9 more than happy to answer them.

10 Thank you for your time.

11 MR. BOORD: Yes. Thank you, Jack, for  
12 identifying and sharing with us the realities of  
13 the construction site, the realities of wearing  
14 respirators, and some of the realities of what  
15 really happens out there in the real world.

16 I think all of the points that you have  
17 mentioned are certainly points that a lot of us  
18 can't identify with, but I think you really drove  
19 it home.

20 Thank you.

21 Any questions from the audience?

22 MR. BERNDTSSON: Goran Berndtsson from

1 the SEA Group.

2 Not a question. I would like to -- I'm  
3 really pleased I'm here today. And I'm hearing  
4 something which is really, really positive on the  
5 manufacturers. I want to see better respirators  
6 for people who wear them, my customers out there.

7 But I think what really grabbed me was  
8 the two last speakers, Jim and Jack, who point out  
9 the difficulties in wearing respirators. I would  
10 encourage them to write a -- to the docket about  
11 their concerns.

12 What I heard here is that -- it's a  
13 little bit different to what we have -- what NIOSH  
14 has said they are going to do.

15 We started off, we are talking about the  
16 Total Inward Leakage in regards to the OSHA  
17 protocol. What I'm hearing from the users is that  
18 that's not going to be good enough. They want to  
19 have some information on respirators more similar  
20 to how they are going to be used out in the  
21 workplace.

22 They want to see how -- what is happening

1 when they get hot, when people are stressed at  
2 different work rates, and how the Total Inward  
3 Leakage.

4           There have been some discussions here  
5 today, are we looking at Total Inward Leakage or  
6 are we looking at fit testing? Of course, from the  
7 end user's point of view, it is only one thing that  
8 matter, Total Inward Leakage.

9           They want to know is this respirator  
10 going to protect me when I'm doing what I have to  
11 do. All the others is academic from the end user's  
12 point of view.

13           Again, I really applaud this forum. As I  
14 used to say to my colleagues, it's a new NIOSH.  
15 It's a NIOSH that is listening, a NIOSH that want  
16 to do better, better standard for the end users,  
17 and that is why we are here. We are doing --  
18 rewriting standards for end users who have to wear  
19 respirators.

20           Well done.

21           MR. BOORD: I almost said thank you.

22           MR. BERNDTSSON: One thing we should not

1 forget, it was said in the opening that this is  
2 going to save money for the users.

3 It is going to save money to every  
4 American at the end of the day because the growing  
5 health bill is something who is going to be paid  
6 out of taxes.

7 But more importantly, the people who have  
8 to wear respirators, if the respirators are  
9 working, are going to have a better quality of  
10 life. And I think that is really the important  
11 part.

12 MR. BOORD: Thank you.

13 I think at this point, what we will do is  
14 we will break for lunch.

15 Following lunch, we will have Mr. Bien's  
16 presentation loaded into the computer, so we will  
17 start with his presentation.

18 And then we will go into the -- following  
19 his presentation, we will have a brief break, and  
20 then go into our panel discussion.

21 So let's resume at 1:30.

22 (A recess was taken.)

1 MR. BOORD: Okay. If we can, we will  
2 resume with the presentation from with Mr. Bien.

3 MR. BIEN: Thank you. I did not realize  
4 the strange properties about this morning, being  
5 obsolete, become just like me. Finally, I fix it.

6 At OSHA's APF hearing earlier this year,  
7 Mr. Metzler mentioned that NIOSH propose to render  
8 Total Inward Leakage Tests, TILIS, and he mentions  
9 simulated workplace testing.

10 I just want to share with you the OSHA  
11 NRC sponsored a simulated workplace testing, just  
12 to show you the details. And I think NIOSH should  
13 adopt this testing protocol to certify respirators.

14 First, let's talk to some background  
15 information. We all know that there is three types  
16 of testing respirator performance.

17 In '87, NIOSH revised regulations,  
18 proposed, workplace testing.

19 And I think NIOSH received many comments  
20 on this issue in 1991. NIOSH called a technical  
21 conference on workplace testing.

22 And this year, NIOSH proposed using Total

1 Inward Leakage tests for half-mask respirator  
2 certifications.

3 I just want to just summarize some  
4 consultant's report from the 1991 conference. This  
5 is another consultant talking about a simulated  
6 workplace testing.

7 Mr. Barry Palley, he conduct several  
8 workplace studies for NIOSH, and I just want to  
9 summarize what he mentioned at the meeting on those  
10 variables. And I think those variables can be  
11 controlled or minimized during a simulated  
12 workplace testing.

13 This was jointly sponsored by OSHA and  
14 NRC, Nuclear Regulatory Commission in the mid '80s,  
15 the time when NIOSH started to run the workplace  
16 testing almost the same time.

17 Los Alamos National Lab was selected to  
18 run the test. We test seven respirators, except  
19 the SEBA, as it would test all the available  
20 categories.

21 Each respirator was tested on ten  
22 subjects. The testing subject wear the PPE during



1 the testing. It was a large chamber with submicron  
2 particles measured with photometer.

3 And we select three temperatures, zero,  
4 21 and 32 Celcius, and the two humidity levels 15  
5 and 85, a total six different environments. The  
6 exercise was one hour.

7 I'm going to show the test results.

8 You can see at the high temperature and  
9 humidity, the respirator really deteriorated  
10 performance, especially for the half-mask. At the  
11 21 degrees Celsius, the fit factor is 2900. You go  
12 to 32 to 85, you reduce to 80. It is a quite a  
13 change.

14 We did achieve a temperature on the  
15 half-mask safety pressure respirators. The other  
16 device also have some.

17 One thing is, seem the temperature has a  
18 little effect on the half-mask PAPRs, which OSHA  
19 has assigned a very low protection factor of 50,  
20 which on this test, it very high protection factor.

21 This is overall based on all the  
22 different testing conditions overall, mean,

1 geometric mean, and the standard deviation. We can  
2 see the half-mask has a very high variation in the  
3 test results.

4 This is a conclusion found at Los Alamos.  
5 As indicated, the exercises is not good enough for  
6 those fit testing.

7 Also the temperature has a very serious  
8 effect on the respirators. Also mention the  
9 temperature had no effect on the hood.

10 However, the loose fitting Powered Air  
11 Purifying Respirator doesn't have an effect during  
12 the high temperature and humidity.

13 And the test results generally agree with  
14 the workplace studies. Those two loose fitting  
15 PAPRs have very low protection factors during the  
16 simulated workplace test, which was confirmed  
17 during the actual workplace testing.

18 This is what I propose for testing the  
19 Total Inward Leakage.

20 We now in -- when NIOSH proposed the  
21 filter testing, NIOSH proposed a worst case  
22 scenario using the highest flow rate, lowest --

1 very small aerosols.

2           So if we want to select the worst case  
3 scenario, we should test the device at the high  
4 temperature humidity to determine what is the  
5 effect on respirator performance.

6           And this method should be screening the  
7 poor performing respirators.

8           And the test should be representative of  
9 work environments.

10           All the respirator tests in the same  
11 conditions.

12           The tests exercise should be rigorous  
13 enough to challenge the face seal.

14           The chamber composition is stable and  
15 reproducible.

16           The particle size should be a respirable  
17 size.

18           So if you have those stable  
19 concentrations, you should have a better  
20 correlation for the test result.

21           The workload should be moderate to heavy  
22 exercise.

1           And we should know how to correct the --  
2           the probe or bias when you are testing respirators.

3           This is what is proposed. Ten subjects  
4           with facial features fit the LANL/NIOSH test panel.

5           I just know this morning NIOSH has  
6           adopted a new anthropometric test panel.

7           The PPE should wear this -- each test  
8           shall wear the PPE equipment than most -- most  
9           worker use in the field. They should wear hardhat,  
10          safety boots, coveralls, safety glasses, and  
11          gloves.

12          You need a pretest to measure the worker.  
13          They have to pass the test. And to test aerosol, I  
14          would propose a non-toxic aerosol, the  
15          concentration of 15 milligram per cubic meter, the  
16          particle size .4 to .6 micrometer Mass Median  
17          Aerodynamic Diameter size, and Geometric Standard  
18          Deviation less than 2.

19          Was can also use the Lawrence Livermore  
20          impactor to reduce lung deposition effect, which  
21          Mrs. Baltarosa (phonetic) made a presentation  
22          during the OSHA hearing on revision of the OSHA

1 respirator standard.

2 The test chamber variation should not be  
3 more than plus or minus 20 percent. Also the  
4 chamber concentration and the particle size should  
5 be verified as accurate.

6 The instrument should be as FSphotometer.  
7 That's what Los Alamos and Lawrence Livermore use.  
8 And a real time measurement with data logger. The  
9 detection limit should be around 50,000.

10 Now, just the same test conditions Los  
11 Alamos is using.

12 The exercise. The first one is step and  
13 then down, a two-step platform for five minutes,  
14 and then you rest for five minutes.

15 The next phase is move oiled gravel  
16 between two bins at about six feet distance, which  
17 is shoveled gravel, one being dumped to another,  
18 this continuously for ten minutes.

19 You rest five minutes. And then you  
20 pounding nails in the overhead board for ten  
21 minutes.

22 Then you move the cinder block from one

1 side the test chamber to another side chamber for  
2 ten minutes. Then you rest five minutes.

3 Now you are pounding a board with sledge  
4 hammer for five minutes, and then you rest five  
5 minutes.

6 The total time is 65 minutes, just a  
7 little over one hour.

8 The passing criterion, what I propose,  
9 under normal temperature and humidity is 500, which  
10 is Los Alamos has it. I'm just using that little  
11 bit -- little bit lower than 500.

12 If we pass in the high temperature and  
13 humidity, passing Simulated Workplace Protection  
14 Factor 100.

15 Also, allow one or two trials, retrieals  
16 in case in some tests it failed the tests.

17 The conclusions, this Los Alamos study  
18 has been sponsored by OSHA and are accept by the  
19 OSHA as an independent study.

20 Also, this test program can screen poor  
21 performing respirators. The test aerosol is not  
22 too small to cause excess leakage of N-95 filters.

1           And all test has been passed under our  
2 test protocol except SCBA. So the ten test  
3 protocol can be used to test other devices.

4           And results correlate well with WPF  
5 studies.

6           High temperature and the high humidity  
7 meet NIOSH criteria for work case test scenario.  
8 It is a fair test, fair test condition for all  
9 respirators.

10           To reduce the development time, NIOSH  
11 should adopt the LANL TIL test protocol.

12           Thank you. Questions?

13           MS. BARNARD: Hi. I'm Stacy Barnard, and  
14 I represent the Interagency Board's program office.

15           You indicated the temperature extremes,  
16 and most manufacturers are now giving limits in  
17 their user instructions.

18           Do you know if the worst case scenario  
19 should be set at the height of the manufacturer's  
20 extreme or at a uniform extreme?

21           MR. BIEN: I don't know what the  
22 manufacturers test by the temperature humidity. If

1 the -- the temperature humidity, we want to even go  
2 lower, such as the human test panel say that you  
3 can allow it.

4 I don't know whether that answer your  
5 question.

6 This try to be most reliable to be used  
7 for human test subjects.

8 MR. BERNDTSSON: Goran Berndtsson of the  
9 SEA Group.

10 You exclude testing breathing apparatus.  
11 Why?

12 MR. BIEN: We didn't test it.

13 MR. BERNDTSSON: How about your proposal  
14 here? It says all respirators except for breathing  
15 apparatus.

16 Why not test all respirators?

17 MR. BIEN: No. We didn't test it.

18 I said under the Los Alamos program, we  
19 didn't test SCBA.

20 MR. BERNDTSSON: Okay. I thought you  
21 proposed to --

22 MR. BIEN: No, I'm sorry.



1                   Maybe I misunderstood this.

2                   MR. NEWCOMB: Ching, do you have a copy  
3 of this study that you can put on the docket?

4                   MR. BIEN: Yeah, sure. I can send you  
5 the whole report.

6                   MR. NEWCOMB: Okay, thank you.

7                   MS. SOLANO: Celin Solano,  
8 Kimberly-Clark.

9                   I would just like NIOSH to keep under  
10 consideration the workplace environment for  
11 healthcare workers.

12                   MR. BERNDTSSON: Goran Berndtsson from  
13 SEA.

14                   I think that what you propose here is  
15 almost all the way there, but there's a lot of  
16 things in there who could be measured a little bit  
17 better. Or did I misunderstand it?

18                   I thought you proposed that this was one  
19 way we would be doing it instead of the old way.

20                   Isn't that what you said?

21                   MR. BIEN: I didn't hear.

22                   MR. BERNDTSSON: That you proposed this

1 is a test procedure we could adopt.

2 Didn't you say that?

3 MR. BIEN: Yeah.

4 MR. BERNDTSSON: For example, some of the  
5 works you are doing in -- are you proposing that  
6 the exercising could be done in sort of a situation  
7 where it is measurable?

8 In other words, using treadmills or bikes  
9 where we could see the metabolic rate, or so we  
10 could maintain the same kind of workload from  
11 person to person to test the protocol?

12 That's possible today to do that.

13 MR. BIEN: I know you are asking that,  
14 but if we use ten test subject, to maybe redo some  
15 variations.

16 We just try to simulate the work that  
17 move -- workers move in the workplace.

18 Yeah, treadmill is a greater way to do  
19 it. I think OSHA has sponsor another project on  
20 treadmill, just see how those -- how, in the heavy  
21 workload, when does the respirator goes negative  
22 pressure.

1 MR. NEWCOMB: Do you know whether this  
2 test was -- the study was included in the original  
3 rewrite of 19 -- of Part 84, when it to Part 84?

4 MR. BIEN: I believe OSHA didn't submit  
5 the report, so I cannot recall. That's long time  
6 ago. I cannot remember the details.

7 It's too long time. My memory getting  
8 bad. We are getting old.

9 MR. NEWCOMB: Thank you.

10 MR. BOORD: Thank you. Any other  
11 questions?

12 Okay. That brings us to the part of  
13 today's program where we had planned and have  
14 identified a panel discussion.

15 And what we will do is the panel -- the  
16 NIOSH panel is obviously the presenters at the  
17 front table, and we would open up for any continued  
18 questions and comment.

19 But first I would like to summarize in a  
20 perhaps a brief but overall perspective some of the  
21 things that we have discussed today, heard today,  
22 and documented.

1           And what I'm going to mention as a  
2 summary is by no means all inclusive or permanent,  
3 but only some scribbled down notes from my  
4 handwriting here.

5           And basically, I think there is six  
6 things that I have identified.

7           And first, is full support for the NIOSH  
8 effort to develop a TIL performance requirement for  
9 personal protective equipment, respirators and  
10 protective garment work.

11           I think I haven't heard any real  
12 opposition to the program and the goal that we have  
13 identified for a TIL effort. So I think the sense  
14 that we are getting here is support for that  
15 program.

16           Secondly, I think that we are hearing  
17 that there can be benefits to the -- to a  
18 successful program. And those benefits are both  
19 from a worker health perspective as well as a  
20 potential economic benefit to continued use of  
21 respirators in the work environment.

22           Third, I think we have heard that there

1 are some -- there have been some concerns expressed  
2 about the test methods -- the concept test methods  
3 that we have identified, that being the PortaCount.

4 And the concerns that I have quickly  
5 jotted down here are concerns relative to the  
6 ambient concentration and the area controls that  
7 are administered while testing.

8 And secondly, I think we had a concern  
9 expressed relative to any attempt to extend the  
10 applicability of the concept test methods to other  
11 respirators and PPE.

12 So I think in general, some concerns have  
13 been expressed relative to the concept of using the  
14 PortaCount.

15 Next, I jotted down some notes relative  
16 to the concept for the fit test panel. And the  
17 things that I think I'm indicating or sensing is  
18 that the -- there seems to be a general recognition  
19 of the inadequacies associated with the existing  
20 LANL panel as -- the Los Alamos National Laboratory  
21 panel, as it applies to the diverse population that  
22 we need to deal with in the U.S. work force.

1           So I think I have heard support relative  
2 to that work and that concept.

3           I think we have also heard that there may  
4 be a need to look at some -- and I think the  
5 terminology was some subsets or some subset  
6 populations, that one of the commenters had  
7 mentioned that there are perhaps work areas or  
8 regions where you may have exclusively populations  
9 using respirators that maybe even fall outside, or  
10 are a subset of what we have identified as the --  
11 under the concept panel.

12           And then thirdly, I have heard comments  
13 relative to the application of the panel, the  
14 concept panel, to respirators of multiple sizes.  
15 And I think there was some comments generated and  
16 suggested relative to how those would be applied,  
17 and some thoughts in those areas.

18           And then, another big area that we have  
19 heard here in some of the later presentations and  
20 discussions, was this aspect of the practical  
21 application of work related factors as they might  
22 apply to a TIL program or respirator use in

1 general.

2           And I think with that, I would like to  
3 ask Rich if he has some further insight he wants to  
4 give there.

5           MR. METZLER: Some of the issues raised  
6 by the labor representatives present -- in their  
7 discussions before lunch indicated the advocacy for  
8 practical work related factors being implemented  
9 into the standard: Environmental conditions like  
10 cold, heat, humidity; reliability conditions like  
11 strap elasticity and how long will the straps hold  
12 up; physiologic work load; different body positions  
13 for work being performed.

14           And typically, an engineering standard  
15 will take in a number of these unknown factors by  
16 increasing a safety factor. In other words, the  
17 Total Inward Leakage measurement might be set at  
18 200 rather than 100 or some other factor.

19           What I would like to have -- or I would  
20 like to invite additional discussion on the issues  
21 of delays that there may be in additional research  
22 to come to the establishment of a standard for

1 these other factors, as well as a development of  
2 the test procedures -- additional time will be  
3 needed -- versus continuing to move forward with  
4 what can be defined today with state-of-the-art by  
5 perhaps increasing a safety factor rather than  
6 better understanding some of these other issues.

7           It's important for us to have your  
8 insights.

9           So at this point we would like to invite  
10 additional discussion and points of view on that  
11 topic.

12           MR. BERNDTSSON: Goran Berndtsson, from  
13 the SEA Group.

14           I think to get this right, it is probably  
15 quite a bit of work to be done in develop a  
16 protocol and validating that protocol.

17           I think it would be advisable to maybe do  
18 this in a two-step program, not to hold up the  
19 progress that you have started, where we make it  
20 very clear, you go out in the beginning saying that  
21 this is going to be a two-step.

22           We are going to look on down the track to



1 have this as a more like simulated work test and --  
2 but to get it off the ground, we will start with a  
3 protocol who has been established.

4 But if that's made very clear in the  
5 beginning, no one will misunderstand it. And if it  
6 die off with the first step, oh, well.

7 There's probably going to be a lot of  
8 discussions about what the standard tests will  
9 include. But if there is a lot of talk about that,  
10 that could be coordinated here.

11 MR. SAWICKI: Jack Sawicki, Global  
12 Security.

13 I might suggest that you consider having  
14 two categories of respirators that a manufacturer  
15 could submit to you, one low stress, one high  
16 stress, and that you use the SCBA protocol that is  
17 already well established and the methodology well  
18 documented on the high-stress protocol to provide a  
19 more strenuous work environment test, as you do the  
20 aerosol test.

21 MR. KOJOLA: Well, as you mentioned,  
22 Rich, you know, the labor presentations this

1 morning really did try to emphasize that as part of  
2 the certification requirements, it would be useful  
3 for NIOSH to incorporate as many elements of that  
4 certification program, that it attempted to reflect  
5 how respirators are used in the workplace.

6           Because ultimately, in a scare-all  
7 (phonetic) laboratory condition with a very narrow  
8 range of tests or criteria that don't really  
9 reflect what goes on in the workplace, you may be  
10 missing out on a lot of situations where  
11 respirators are passing in the laboratory, but then  
12 failing in the workplace. And then that doesn't  
13 really advance work protection issues.

14           Now, that being said, I think it would be  
15 useful to have NIOSH and this entire community look  
16 at ways of incorporating some additional elements  
17 into your test protocol sooner rather than later we  
18 have a relative comfort level in terms of our  
19 understanding -- scientific understanding of the  
20 validity of incorporating those.

21           But I think this two-stage process is an  
22 intriguing idea where there may be some issues

1 where, you know, we are not on real solid footing  
2 and some additional work or research needs to be  
3 done.

4 So that's an intriguing idea that, you  
5 know, may have some traction.

6 But the only problem with doing a  
7 two-stage, the flip side is is that once the first  
8 stage has moved forward, it tends to crystallize,  
9 and the second stage becomes sort of a forgotten  
10 element. And it gets pushed back on the agenda.  
11 And then maybe ten or 15 years from now, and then,  
12 you know, we sort of revisit it.

13 So, you know, I think that if we are  
14 going to move in that direction, we need to make  
15 some very solid commitments amongst ourselves and  
16 as an agency to make that a fairly aggressive  
17 two-stage process.

18 And I think that the issues that Jim  
19 Platner and Jeff Shine raised, I think, are  
20 really -- are really critical from a worker  
21 protection point of view that we ought to seriously  
22 consider.

1           And I think that coming out of this  
2 process, you know, if we decide to move to a  
3 two-stage process, that's good.

4           We should also, coming out of this stage,  
5 is identify those issues for which additional  
6 research is necessary, you know, identify those  
7 issues. And if they could get even some general  
8 sense of what the priority is because we are --  
9 this agency is not going to be able to do  
10 everything that's identified in its future  
11 research.

12           So what are the critical issues? What's  
13 the priorities? And maybe we can give some  
14 direction to the agency on where to move.

15           And it would be nice, I think, to  
16 provide -- provide some time frames for all of  
17 these matters.

18           MR. WEEKS: Hi. Jim Weeks from the  
19 United Mine Workers.

20           I think this issue raises something  
21 about -- inherent about respirators, that there are  
22 inherent limitations to what respirators can do to

1 protect workers. And I think it would be important  
2 in some way or another to place the work on  
3 respirators in the context of saying that there are  
4 other ways of controlling hazards.

5 And when we get to the point where  
6 respirators simply don't provide that kind of  
7 protection, we have to turn to methods of control.

8 I know that's beyond the scope of this,  
9 but I think we need to keep that perspective in  
10 mind.

11 MR. PFRIEM: I have some questions, and  
12 I'm probably going to underline what has been said  
13 before.

14 But I came here, and I'm kind of  
15 surprised and in a state of shock because I fell  
16 into that state of assumption which we should never  
17 fall into. And I'm kind of shocked to hear for the  
18 first time now that we are considering a test  
19 protocol based on PortaCount Plus when I was in my  
20 own mind thinking that NIOSH would go down a  
21 different road.

22 We have heard probably resounding

1 recommendations and shortcomings of going down the  
2 road of PortaCount Plus with an ambient,  
3 uncontrolled atmosphere and not taking into account  
4 both preconditioning of respirators and also in  
5 suit to testing of fit factors with environmental  
6 challenges, low and high temperature, low and high  
7 humidity effects on fit factor performance.

8           So I would urge NIOSH, if we are not too  
9 far down this six-month program that we are already  
10 into and stuck in a train of thought that's with  
11 PortaCount Plus in an uncontrolled challenge  
12 atmosphere, to revisit these factors.

13           I think we have heard a lot of evidence  
14 that it definitely needs to be revisited, and it's  
15 a fundamental flaw not to revisit these things.

16           And then I did have a question.

17           Rich, you may have covered this because I  
18 got here a little bit late. But in the first phase  
19 program, which we are now coming to a close to  
20 where it was assigned that there was going to be a  
21 peer review kind of committee formed of  
22 manufacturers, academia, varied interested parties

1 besides NIOSH personnel, where the concept would be  
2 developed, did you cover when I was not here what  
3 that peer review team was -- the composition of  
4 that peer review team, how they came on settling on  
5 a PortaCount type fit test protocol for TIL?

6 I would be interested to know that. If I  
7 missed it or if I didn't miss it, I would still be  
8 interested in that and how the team came to the  
9 path that it's now on.

10 And just hope that -- we are six months  
11 into this, and we have got -- we have kind of got a  
12 caveat because we have got concurrent events in the  
13 planning of this where we have got established test  
14 facilities, benchmark testing, and continued  
15 concept developments overlapping a concept  
16 development where it seems to me where the concept  
17 is already pretty much formed and hopefully I'm  
18 just praying that it's not stuck to because there  
19 is fundamental flaws in it.

20 And we are already down a Phase 2 path  
21 where we are establishing a test facility and  
22 continuing on a concept development that at least I

1 feel has some fundamental flaws in it.

2 MR. METZLER: Let me start the answer,  
3 and then I will have Bill add a couple of comments  
4 as the program manager.

5 I think some of the confusion is coming  
6 from the fact that the Total Inward Leakage concept  
7 for PPE goes well beyond half-mask, as the  
8 discussion started this morning.

9 So part of the discussion, or the  
10 comments that were made on us developing a Total  
11 Inward Leakage facility has a broader scope in mind  
12 in manned and simulant testing for fully  
13 encapsulated suits.

14 And we have started the literature  
15 search, have started the building specifications,  
16 the size that you would need and what kind of  
17 equipment would be needed in it. But that's from  
18 the broader perspective of the full range of PPE  
19 evaluations.

20 It might involve corn oil or other  
21 aerosols that might be used for making measurements  
22 on different types of PPE.



1           So some of the confusion on comments that  
2 were made on a TIL facility, one where a PortaCount  
3 does not need a special facility, could be  
4 confusing, but that was what was driving us on the  
5 TIL facility, the broader concepts of testing a  
6 full range of personal protective equipment, not  
7 just half-mask.

8           Then when we come to the respirators and  
9 half-mask, our focus has been on the use of the  
10 PortaCount.

11           But that was not driven by peer review.

12           The team working on the TIL concept for a  
13 half-mask came up with the initial protocol and a  
14 description of the program and invited these  
15 programmatic peer reviewers to look it over.

16           We are just now receiving the comments  
17 from the peer reviewers and haven't had an  
18 opportunity to go into the comments we have  
19 received. So it would be wrong to say that peer  
20 reviewers advocated the use of the PortaCount.  
21 They did not.

22           We advocate the use of the PortaCount,

1 and peer reviewer comments that are coming in to us  
2 will be evaluating their comments.

3 So we are not stuck on PortaCount. And  
4 we are open minded and are -- will be looking very  
5 shortly at the peer reviewers' comments.

6 MR. PFRIEM: Will the peer review  
7 comments of the members be made available publicly,  
8 who those participants are?

9 MR. METZLER: Yeah. I think we can make  
10 them available now, but I would ask Bill to state  
11 who they are because I'm likely to miss a couple.

12 MR. NEWCOMB: You expect me to remember?

13 MR. METZLER: Well, together we will  
14 remember.

15 Jim Johnson from Lawrence Livermore was  
16 an at-large scientific contributor.

17 MR. NEWCOMB: Warren Meyers.

18 MR. METZLER: Warren Meyers from  
19 academia. Jeff Bertner was an at-large industrial  
20 hygienist.

21 Craig Colton for the ISEA. Bill Kojola,  
22 who is here today for -- representing AFL-CIO. And

1 John Steelnack representing OSHA.

2 Was that six?

3 MR. PFRIEM: Thanks.

4 MR. BERNDTSSON: Goran Berndtsson.

5 For the benefit of those who don't know  
6 what's going on in the ISO arena, can we talk a  
7 little bit about that? Because that lines up with  
8 what we proposed here.

9 We all -- sounds as if we are really  
10 starting to get back to the people you are talking  
11 to.

12 MR. BOORD: Well, come up -- come up to  
13 the -- I hesitate to invite you onto the podium  
14 because you know you are in a public meeting.

15 He may not leave if this is how you look  
16 like.

17 MR. BERNDTSSON: I have been very active  
18 representing as one of the specialists in the  
19 United States area, and I have been looking very  
20 carefully, for all of the reasons we heard here  
21 today, how the next generation of respirator  
22 standards for the world is going to look like.

1           And one very important thing is that we  
2 all agree about it is going to be based on the  
3 physiological requirement of man, and it is going  
4 to be built to protect people who has to use the  
5 equipment.

6           So what we are going to do, or what we  
7 all have already agreed about is that we are going  
8 to look on four -- four industrial work rates based  
9 on the international standard of metabolic rate.

10           And without having the document in front  
11 of me, it goes somewhere from 65 up to 275 watts  
12 per square meter body surface. That's how we are  
13 measuring metabolic rate.

14           Then on top of that, we are going to have  
15 three levels of purchase, one with a higher  
16 metabolic rate. One who sustains -- so all this  
17 performance is sustainable for eight hours. And  
18 the other three is going to be a two hour, 15  
19 minutes, and 5 minutes work rate.

20           How we are visualizing that, we are going  
21 to test respirators at those work rates for the  
22 required time and determine how they perform.

1           And then this work has come quite a long  
2 way. So it doesn't necessarily mean that it would  
3 be a long delay if NIOSH was going to wait for some  
4 of that coming out and see if that would be  
5 applicable to put into its test protocol.

6           That I thought may be worthwhile to know  
7 that that's going on.

8           MR. METZLER: The only thing that I would  
9 challenge in what you said is, you know, it has  
10 taken about two years to get to the point that the  
11 international community has been settling in on the  
12 physiologic work rates, and it may be another two  
13 years before the various subcommittees understand  
14 how to incorporate that into the variety of  
15 different standards.

16           So from a timing perspective, when you  
17 said it may not be a very long time, I think we are  
18 talking about in term of years.

19           MR. BIRKNER: Jeff Birkner with Moldex.

20           I just want to -- it seems that people  
21 are thinking that a year to complete this whole  
22 program is a very short time.

1           And I would just, you know, ask NIOSH to  
2 consider carefully that whatever you come up with,  
3 we -- everybody will have to live with that for  
4 presumably a long time.

5           So I guess what I'm trying to say is, you  
6 know, don't rush to judgment. Just take your time  
7 and allow the public to make their comments, et  
8 cetera, et cetera.

9           I think that's important if you want to  
10 end up with a good standard, you know, that will  
11 benefit everyone.

12           MR. WEED: Jeff Weed with TSI. I have  
13 two comments.

14           One, we are talking about the environment  
15 that the fit testing is done in, and we have talked  
16 about particle concentration. And the study that  
17 Dr. Zhuang did showed that that wasn't a major  
18 factor.

19           But I think particle size certainly could  
20 be, especially if we are measuring Total Inward  
21 Leakage and not just fit factor, because it's going  
22 to depend on the filter penetration.

1           So this -- I think because of that and  
2 just because we want to eliminate as many variables  
3 as possible -- because we want to do testing today  
4 and next year with repeatability and in your  
5 facility and the respirator manufacturers'  
6 facility, and other test lab facilities -- we  
7 should consider defining some range of particle  
8 size and concentration, just to keep things the  
9 same so that the issue doesn't come up.

10           The other comment I have is -- I'm not a  
11 respirator manufacturer, but it seems to me this --  
12 this idea that you have presented of making sure  
13 that a small mask fits the smaller range of the  
14 panel and the medium fits the medium and the large  
15 fits the large is going to have some problems.

16           You know, to me, the one deficiency in  
17 the standard now is that somebody could -- you  
18 could -- you may have to certify a respirator that  
19 doesn't fit anybody on the planet. That's possible  
20 right now.

21           And the workplace fit testing is supposed  
22 to catch that.

1           And this is something that I imagine you  
2 don't like at all, and it makes sense.

3           So to me, what you should worry about is  
4 does a particular mask fall in the envelope of  
5 fitting humans.

6           MR. METZLER: That would be good.

7 Thanks.

8           MR. WEED: And not worry about whether  
9 it's -- a medium actually fits the medium -- the  
10 middle of this, and the small actually fits low  
11 end.

12           It just has to fit somebody. And this  
13 workplace testing that's required will take care of  
14 the rest of it.

15           I mean, to me, what you don't want to do  
16 is certify a mask that couldn't possibly fit  
17 anybody, but meets the criteria that we have now.

18           As another example, what if a respirator  
19 manufacturer wanted to market a mask that was  
20 designed for people with a flatter nose bridge?  
21 Which part of the panel would you use for  
22 certification if they did that?



1           And what if a manufacturer has a  
2 one-size-fits-all mask, and you found it only fit  
3 the middle of the panel? Could they resubmit it as  
4 a medium without a small and a large as part of the  
5 package and get it certified?

6           I mean, are you insisting now that they  
7 cover the whole range with a set of respirators?  
8 What if they wanted to market one that was just for  
9 large faces and not offer one for medium and small?

10           So I see that you are, you know,  
11 requiring that if the labels fit in these baskets  
12 on panels is going to lead to some problems down  
13 the road if you are not careful.

14           MR. NEWCOMB: If I may address that.

15           One of the things we do not want to do is  
16 to limit the design of respirators and respirator  
17 facepieces.

18           And if someone wants to make -- a  
19 manufacturer wants to make a facepiece that fits a  
20 certain segment of the population and does that  
21 well, then they should be able to get a  
22 certification by NIOSH for that respirator.

1           And what we are looking for is for the  
2 manufacturer to tell us what population that's  
3 designed to fit, and that's the one we will attest  
4 it to.

5           Now, if a manufacturer came up and said  
6 we made one to fit only flat nose bridges, and  
7 defined in their instructions how the user would  
8 make that decision, then we could use that to --  
9 within our test panel as well.

10           So I guess, you know, the proposal is  
11 that we don't want to stifle design at all, but we  
12 are looking for the manufacturer to tell us who  
13 that respirator is designed to fit.

14           And then we would test it against that.  
15 At least that's the proposal at this time.

16           MR. BERNDTSSON: Goran Berndtsson, SEA.

17           Comment on that. What I think we need to  
18 do is to think a little bit about it before we make  
19 any decisions at the end of the day.

20           Physiologically wise, should try to get  
21 the smallest respirators that a person can get away  
22 with because that can give you lower work rate, a

1 lower air space, and et cetera, et cetera.

2 And we don't want to push large  
3 respirators unless you have to have large  
4 respirators on people's faces.

5 So we need to --I think that we shouldn't  
6 make any decisions here today how we want to  
7 interpret, and I think we should think a little bit  
8 about it and come back at a later stage and say  
9 this is how we are going to incorporate it.

10 MR. BOORD: Any other comments,  
11 questions, suggestions?

12 MR. PFRIEM: Just one, and I'll make it  
13 quick, promise.

14 It could be that we don't have a  
15 one-size-fits-all fit test protocol. It could be  
16 that there could be -- and it could even be the  
17 PortaCount. I don't know.

18 But you know, a PortaCount could be  
19 applicable, could be applicable to filtering  
20 facepieces.

21 Because if we look at environmental  
22 challenges and what people commonly use a filtering

1 facepiece for, the environmental challenge for that  
2 type of facepiece certainly is nowhere close to  
3 what somebody would typically wear an elastomeric  
4 half-mask for.

5           So you may want not to have a  
6 one-size-fits-all fit test protocol because it may  
7 not be applicable. You may want to choose a fit  
8 test protocol that NIOSH utilizes per the perceived  
9 channels or the perceived risk of when somebody is  
10 wearing that respirator.

11           And certainly a perceived risk on a  
12 filtering facepiece is different than a half-mask  
13 when we could have, you know, any variety of filter  
14 cartridges. And then, again, on a full facepiece,  
15 we are going to have yet a different level of  
16 perceived risk, and you may want to step up that  
17 protocol.

18           And I think as we step up that protocol,  
19 we have to consider environmental challenges and  
20 take these into account in fit tests, fit testing.

21           MR. NEWCOMB: I can't obviously speak for  
22 OSHA.

1           But OSHA assigns -- or proposed to assign  
2     the same protection factor for a half-mask,  
3     regardless of whether it's a filtering facepiece or  
4     an elastomeric.

5           So that the -- although people might  
6     perceive a difference in the -- in protection or  
7     other things concerning the two of them, OSHA is  
8     looking at them the same, and we have designed a  
9     protocol -- or tried to -- that will be able to  
10    evaluate a half-mask the same, whether it's an  
11    elastomeric or whether it's a filtering facepiece.

12           MR. PFRIEM: And if we are stuck in that  
13    kind of a paradigm, I don't know if we need to --  
14    if you guys need to have that alignment.

15           But if you do, and you are stuck in that  
16    paradigm, then I think by default, you are forced  
17    to go the higher level route.

18           MR. NEWCOMB: Thank you.

19           MR. BOORD: Okay. Any other comments?

20           I think what we would like to do then is  
21    bring the meeting to a conclusion. There are a few  
22    things I would like to just talk on before we do

1 that.

2 The docket information -- the docket  
3 information to contact us is on screen and I think  
4 in everybody's packet. So we do encourage  
5 submittals to the docket, and any information,  
6 comments, questions are certainly welcome. They do  
7 provide further insight into what we are doing.

8 The program concept, as we mature our  
9 thinking and our process, that concept will be  
10 revised and maintained on our website. And I think  
11 everybody here probably has access to it already.

12 So I would encourage you to watch that for  
13 additional changes to the concept as time goes by.

14 And finally, I would like to call  
15 everybody's attention to the survey that's in the  
16 information packet. Please take the time to fill  
17 that out. That does provide us input, valuable  
18 input on how to structure and conduct these public  
19 meetings.

20 And with that, I will take one last  
21 attempt to ask if the -- first of all, does the  
22 panel have anything further they want to address

1 the audience with at this point?

2 MR. NEWCOMB: I would just like to thank  
3 everybody for ensuring my longevity with this  
4 organization.

5 MR. BOORD: You know there is a natural  
6 reply to that.

7 MR. METZLER: Yeah. I would like add my  
8 thanks for your attendance, and in particular I  
9 want to thank the labor organizations who came to  
10 this meeting.

11 We have held a large number of public  
12 meetings over the past few years developing  
13 standards, and your attendance today shows your  
14 strong interest and commitment in solving this  
15 problem. We see it. We recognize it. We thank  
16 you for coming.

17 And I would end by saying that the  
18 laboratory operates on the principle that quality  
19 partnerships enhance safety and health.

20 So your input in this process is  
21 extremely important in helping us create the best  
22 standard we can. I thank you for attending.

1 MR. BOORD: Yes, thank you all for  
2 attending. And I have said many times, the input  
3 is valuable, and we do appreciate it. Thank you.

4 (Whereupon, the proceedings in the  
5 above-captioned matter were concluded at 2:37 p.m.)

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## A

- abatement** 114:4  
**ability** 10:4 19:9 28:7  
 28:12,14 90:14 93:8  
 96:15  
**able** 26:8 42:12 60:18  
 88:3 94:1 104:3  
 113:9 140:9 153:21  
 157:9  
**abolished** 19:5  
**about** 9:15,21 10:1 13:2  
 13:19 18:7 19:7  
 26:12,19 31:9 40:10  
 42:16 44:12,16,21  
 45:10 46:4,8,9,12  
 47:8 50:16 51:10,18  
 51:19 55:18 56:7  
 60:17 64:17 70:17,22  
 71:10 72:6 79:11  
 86:19 87:13 89:14  
 91:15 93:7 95:2,3  
 98:6,17,20 100:16,20  
 101:7 106:14 107:9  
 107:10 108:2,20  
 109:4,8 110:14 113:4  
 116:10,15 119:4  
 120:5 125:16 128:13  
 133:2 137:8,9 140:21  
 140:21 147:7 148:2,7  
 149:10,18 150:14,16  
 152:3,8 154:18 155:8  
**above-captioned** 160:5  
**absence** 81:14  
**absolutely** 42:14  
**absorb** 99:20 107:7  
**absorbed** 99:19  
**academia** 11:15 24:3  
 142:22 146:19  
**academic** 117:11  
**accept** 126:18  
**acceptable** 25:8  
**acceptance** 87:10  
**accepted** 20:21 45:8  
**access** 158:11  
**accommodate** 48:18  
**according** 38:15 81:7  
 82:22  
**account** 57:7 77:1  
 142:3 156:20  
**accreditation** 87:10  
**accuracy** 70:11  
**accurate** 28:12 125:5  
**accurately** 80:6  
**acetate** 18:21 19:9,13  
 20:21  
**achieve** 20:14 40:21  
 92:12 121:14  
**across** 83:18
- action** 161:8,13  
**actions** 3:19  
**active** 147:17  
**actively** 17:3  
**actual** 20:22 22:20  
 26:17 29:12 34:1  
 54:9 122:17  
**actually** 21:16 36:6  
 39:7 41:6 78:14  
 80:16 83:5 84:16  
 90:9 93:15 95:7  
 97:22 104:11 152:9  
 152:10  
**add** 22:1,6 32:14 34:13  
 36:13 37:21 49:4  
 144:3 159:7  
**addition** 19:1 40:6  
**additional** 4:8 92:11,19  
 135:20,21 136:2,10  
 138:16 139:2 140:5  
 158:13  
**address** 6:2,2 7:18 21:9  
 32:8 90:11 153:14  
 158:22  
**addressed** 7:22  
**addressing** 12:17 24:4  
**adequacy** 91:22  
**adequately** 100:2  
**administered** 133:7  
**administration** 26:5  
**ado** 17:14  
**adopt** 119:13 127:11  
 130:1  
**adopted** 124:6  
**adults** 48:6  
**advance** 138:13  
**advantageous** 53:19  
**advertising** 43:12  
**advisable** 136:17  
**advocacy** 135:7  
**advocate** 145:22  
**advocated** 145:20  
**Aerodynamic** 124:17  
**aerosol** 40:14 124:13  
 124:14 126:21 137:20  
**aerosols** 123:1 144:21  
**Affairs** 31:20  
**affect** 21:17 103:15,19  
 103:21  
**affected** 79:1  
**affects** 97:22 113:16  
 114:6,8  
**affiliated** 95:2  
**afforded** 22:20  
**AFL-CIO** 89:3 95:1  
 146:22  
**African-American**  
 51:6,9,12,17 57:1
- 69:9,20  
**after** 3:12 17:11 18:12  
 46:16 56:12 64:19  
 66:4 105:18 112:9  
 113:15 115:4  
**afternoon** 90:1,3  
**again** 16:20 21:22  
 48:14 73:7 85:1 86:7  
 117:13 156:14  
**against** 6:18 58:22  
 154:14  
**age** 52:4,6,15 57:2 58:9  
 58:9  
**agency** 89:16 90:2,8  
 105:15 139:16 140:9  
 140:14  
**agenda** 4:20,21,22 5:7  
 88:10 139:10  
**agent** 87:16  
**agents** 26:20  
**aggressive** 139:16  
**ago** 71:7,20 108:6,19  
 131:6  
**agree** 20:7 36:18  
 122:13 148:2  
**agreed** 25:2,22 73:15  
 148:7  
**ahead** 39:14 43:2  
**aim** 10:7  
**air** 23:2,2 28:9 47:18  
 47:19 48:3,5 50:2,10  
 51:4,7,10 52:11 54:1  
 54:15 60:1 106:15,22  
 107:15 108:14 114:16  
 114:17 122:10 155:1  
**Alabama** 73:1  
**Alamos** 45:7 46:6,16  
 47:16 48:1 120:17  
 122:4 125:7,11  
 126:10,17 128:18  
 133:20  
**algorithm** 67:7  
**alignment** 157:14  
**Allen** 50:4,5 73:13  
**allocated** 79:16  
**allow** 83:20 126:15  
 128:3 150:7  
**allowed** 98:10  
**allows** 27:2  
**almost** 21:19 95:5  
 117:21 120:16 129:15  
**alone** 37:14  
**along** 19:3 87:22  
**already** 17:6 34:14,18  
 36:15 39:20 41:10  
 50:8 67:18 91:8  
 99:19 112:1 137:17  
 142:9 143:17,20
- 148:7 158:11  
**altered** 19:18  
**although** 23:17 157:5  
**always** 102:10 104:20  
 105:8 109:13 111:17  
 111:17  
**ambient** 38:2,12 39:2,4  
 40:13,14 133:6 142:2  
**America** 109:5  
**American** 22:16 54:16  
 118:4  
**Americans** 97:5  
**among** 47:12  
**amongst** 139:15  
**amount** 45:17 76:15  
 99:3 106:15  
**amounts** 76:22  
**analysis** 65:5,7 66:20  
 66:20 67:5 80:11  
**and/or** 86:14  
**ann** 1:11 2:17,17  
**annually** 53:4  
**another** 30:19 60:19  
 62:3 68:13 72:13  
 74:21 77:9 81:18  
 95:9 113:20 120:5  
 125:17 126:1 130:19  
 134:18 141:2 149:12  
 152:18  
**ANSI** 22:16  
**ANSI/OHSA** 20:21  
**answer** 3:15 14:1 104:3  
 106:1 115:1,2,9 128:4  
 144:2  
**anthropometer** 57:22  
**anthropometric** 46:13  
 56:10 60:2 124:6  
**anthropometrically**  
 10:10  
**anthropometrics** 45:18  
**anthropometry** 48:5  
 54:16  
**anticipate** 11:6 12:3,19  
 33:3 35:16 86:6  
**anticipated** 27:19  
**antsy** 102:19  
**anxious** 111:18  
**anybody** 151:19 152:17  
**anymore** 113:13  
**anything** 9:6 88:18  
 100:14 109:6 158:22  
**anywhere** 103:14  
**APF** 16:8 22:18 25:9  
 32:4 46:21 89:14,17  
 89:21 119:6  
**APFs** 16:9 25:4 33:12  
 34:22 89:11  
**apparatus** 128:10,15
- applaud** 73:20 117:13  
**applicability** 50:17  
 56:13 73:22 74:3  
 133:10  
**applicable** 58:18 149:5  
 155:19,19 156:7  
**application** 21:6  
 134:13,21  
**applications** 45:6 46:15  
**applied** 15:1 134:16  
**applies** 12:14 89:20  
 104:22 133:21  
**apply** 10:8 45:18  
 104:21 134:22  
**appreciate** 94:7 160:3  
**apprentice** 101:22  
 112:6  
**approach** 23:9 56:18  
 56:20 66:18,20  
**approaching** 87:19  
**appropriate** 28:1 32:10  
 36:19 43:22 61:10  
 89:17  
**appropriately** 90:10  
**appropriateness** 46:6  
**approval** 64:22 87:3  
 92:3  
**approved** 18:6,18  
 85:18 105:13 109:3  
**approving** 19:1  
**area** 32:19 37:8 46:10  
 53:13,17,19 63:5 83:8  
 89:10 98:6,17 133:6  
 134:18 147:19  
**areas** 8:1 10:8 11:4  
 12:19 22:18 56:8  
 72:16 105:2 111:12  
 111:16 114:9 134:7  
 134:17  
**arena** 110:3 147:6  
**argument** 87:18  
**Arlington** 1:22  
**arm** 55:2 94:22  
**Army** 75:22 77:17  
**around** 4:9 17:22  
 105:19 111:7,11  
 112:21,22 113:11,22  
 114:7 125:9  
**arrange** 13:13  
**asbestos** 101:17 105:11  
 105:19 108:7,17,19  
 114:4  
**asking** 130:13  
**aspect** 134:20  
**aspects** 7:20 9:16,22  
 11:1 45:1  
**assess** 22:11  
**assessing** 26:3 33:9

**assign** 157:1  
**assigned** 2:13 22:2,21  
 25:3 26:15 33:13  
 121:19 142:20  
**assigns** 157:1  
**associated** 21:9 86:13  
 86:20 99:7 133:19  
**Association** 101:16  
**assume** 33:16 85:18  
**assumed** 34:10 48:4,5  
**assumption** 141:16  
**assurance** 105:19 106:1  
**assure** 20:17 91:11  
**atmosphere** 142:3,12  
**atomizing** 19:4  
**attempt** 133:9 158:21  
**attempted** 138:4  
**attendance** 159:8,13  
**attended** 9:3  
**attending** 159:22 160:2  
**attention** 158:15  
**attest** 154:3  
**attic** 106:8  
**attorney** 161:11  
**at-large** 146:16,19  
**audience** 3:10 45:4  
 101:12 115:21 159:1  
**August** 1:7 18:7 30:11  
**authority** 32:10  
**available** 16:2 43:17,19  
 44:8 47:21 50:13  
 66:22 78:4 97:20  
 108:9 120:19 146:7  
 146:10  
**award** 95:8  
**awarded** 95:8  
**away** 105:20 106:2  
 154:21  
**a.m** 1:21

---

**B**


---

**back** 18:5 43:4 52:1  
 59:17 64:22 66:21  
 72:10 74:8,12 75:12  
 75:22 80:9 81:10  
 84:5 88:2,7 96:19  
 101:11 112:20 113:21  
 139:10 147:10 155:8  
**backdrop** 89:9,10  
**background** 119:14  
**bad** 31:8 105:12 111:16  
 131:8  
**bag** 108:20  
**ball** 78:21  
**Baltarosa** 124:21  
**barnard** 127:13,13  
**arrier** 6:12,22  
**Barry** 120:7

**bars** 51:14  
**base** 51:22  
**based** 14:22 15:5,10,15  
 16:2,11 22:3 25:3  
 26:15,15,16 37:5 40:8  
 40:13,13 47:17,20  
 48:22 49:22 75:20  
 76:2,7 79:14 83:21  
 87:10 97:2 121:21  
 141:19 148:2,8  
**baseline** 10:15  
**basically** 2:8 5:2 6:10  
 38:12 48:7 50:12  
 57:5 61:6 67:10,14,21  
 132:5  
**basics** 46:20  
**baskets** 153:11  
**batteries** 99:2  
**become** 11:8 45:8 119:5  
**becomes** 12:5 34:5 62:9  
 139:9  
**before** 1:10 18:9 25:16  
 31:12 43:7 47:3 50:7  
 54:12 58:3 88:4 91:5  
 91:5 99:21 101:21  
 107:10 135:7 141:13  
 149:13 154:18 157:22  
**begin** 2:9 23:10 43:7  
 88:7 93:19  
**beginning** 105:12  
 136:20 137:5  
**begun** 30:3 34:14 35:10  
**being** 4:12 7:21 8:12  
 11:22 15:2 16:9 19:6  
 29:22 34:19 44:5  
 59:20 102:4 103:17  
 119:4 125:17 133:3  
 135:8,13 138:14  
**believe** 5:17 27:1 89:16  
 107:17 109:18 113:10  
 114:22 131:4  
**benchmark** 9:5,6,11  
 15:18 24:8,12 27:11  
 30:3,15 39:19 41:19  
 45:13 63:12 81:4  
 82:15,19 86:1,4  
 143:14  
**benchmarks** 41:16  
**benefit** 14:3,9,12,15,19  
 33:14,20 132:20  
 147:5 150:11  
**benefits** 132:17,18  
**benefitted** 14:13  
**berndtsson** 41:22,22  
 42:22 71:2,2 84:22,22  
 85:11 115:22,22  
 117:22 128:8,8,13,20  
 129:12,12,22 130:4

136:12,12 147:4,4,17  
 154:16,16  
**berry** 1:11 2:17,17  
**Bertner** 146:19  
**besides** 143:1  
**best** 16:1,2 21:5 27:9  
 29:3 47:21 159:21  
**better** 33:17 40:2,3  
 66:16 68:8 74:4  
 83:14 104:20 108:5  
 116:5 117:16,16  
 118:9 123:19 129:17  
 136:6  
**between** 6:13 52:14  
 56:16 60:7 77:2  
 79:11 125:16  
**beware** 109:8  
**beyond** 8:18 141:8  
 144:7  
**bias** 124:2  
**bien** 37:2,2 38:16 88:8  
 119:2,3 127:21  
 128:12,17,22 129:4  
 129:21 130:3,13  
 131:4  
**Bien's** 118:15  
**big** 94:17 102:15 105:1  
 106:20 112:2 134:18  
**bigger** 114:19  
**biggest** 37:6  
**bigonial** 61:1 66:11  
**bikes** 130:8  
**bill** 1:15 2:22 5:5 8:13  
 17:5,6,10,15,20 36:18  
 81:10 89:2 91:15  
 94:6 118:5 144:3  
 146:10,21  
**bins** 125:16  
**birkner** 39:6,6,15 41:9  
 41:12 149:19,19  
**bit** 17:13 39:16 40:7  
 58:12 71:5 96:14,20  
 98:18 101:11 106:4  
 116:13 126:11,11  
 129:16 136:15 142:18  
 147:7 154:18 155:7  
**bivariied** 68:6  
**bizygomatic** 76:17  
**black** 18:14 69:12  
 114:11  
**bless** 109:5  
**blew** 114:10  
**block** 125:22  
**blocks** 106:17  
**blower** 97:20  
**blowers** 98:21  
**blowing** 40:16  
**blown** 18:19

**board** 64:16,17 125:20  
 126:3  
**Board's** 127:14  
**Bob** 108:11  
**body** 54:21 97:16,21  
 98:7 135:12 148:12  
**boiler** 103:20  
**boilers** 112:22  
**boord** 1:12 2:2,14 3:2,2  
 31:16 43:7 87:21  
 88:21 94:6 101:10  
 115:11 117:21 118:12  
 119:1 131:10 147:12  
 155:10 157:19 159:5  
 160:1  
**boots** 124:10  
**both** 10:8 11:7,9 23:2  
 29:18 34:16 62:5  
 83:20 87:17 89:16,17  
 89:19 132:18 142:4  
**bothered** 105:8  
**bottom** 112:11,13  
 113:5  
**box** 81:19,20,21,22  
 83:18 105:9,20  
**box's** 105:10  
**branch** 2:16,18,19  
 45:16  
**breadth** 61:1 66:11  
 73:2 76:18 78:15  
 79:3  
**break** 43:3 88:2,4,6  
 118:14,19  
**break-through** 98:13  
**breath** 107:1,12 113:6  
**breathe** 110:20  
**breathing** 7:1 111:6,14  
 114:4 128:10,14  
**bridge** 1:22 72:15  
 152:20  
**bridges** 154:6  
**brief** 8:4 118:19 131:20  
**bring** 68:11,13 157:21  
**bringing** 106:16  
**brings** 85:17 131:12  
**broader** 78:22 144:11  
 144:18 145:5  
**broadly** 95:13 98:5  
**broken** 99:18  
**brought** 87:5  
**building** 92:19 93:3  
 94:22 101:4 144:15  
**buildings** 106:7  
**builds** 92:10  
**built** 93:17 148:4  
**bulkier** 19:20  
**burden** 100:9,9,16  
**Bureau** 18:6,22 53:20

**business** 17:11  
**buy** 109:5  
**buyer** 109:8

---

**C**


---

**CAESAR** 55:15 75:21  
**calculate** 67:21  
**calculation** 66:22 67:2  
**calculations** 70:7  
**California** 57:13  
**caliper** 57:21,22  
**calipers** 78:13,22  
**call** 53:1 63:19 158:14  
**called** 52:22 66:19  
 119:20  
**came** 19:3 141:14 143:4  
 143:8 145:13 154:5  
 159:9  
**camera** 55:5  
**campbell** 1:13 2:9,10  
**capabilities** 10:3,5  
 12:13 15:21 16:4  
 23:22 25:7 26:3 33:9  
**capability** 7:14 8:17  
 15:11 34:10  
**capable** 10:3 20:6  
 25:12 84:16  
**care** 57:17 152:13  
**career** 17:7  
**careful** 153:13  
**carefully** 147:20 150:2  
**cartridge** 96:9 98:10,12  
 99:19 107:6 109:2  
**cartridges** 156:14  
**case** 19:22 39:15 88:22  
 99:8 122:21 123:2  
 126:16 127:7,18  
**cases** 98:11  
**catch** 151:22  
**categories** 49:11  
 120:20 137:14  
**category** 61:15 70:21  
 76:21 82:3  
**cause** 78:14 126:22  
**caveat** 109:8 143:12  
**cavities** 18:14  
**cavity** 108:22  
**cc** 38:13,14  
**Celcius** 121:4  
**Celin** 129:7  
**cell** 49:14,15,21 59:1,2  
 59:12 61:15,17 62:13  
 76:20  
**cells** 62:14,17,19,21  
 63:14,21 76:21 82:9  
 82:11  
**Celsius** 121:11  
**census** 51:5,14 52:5,8

- Center** 65:17 94:13,21 101:4
- certain** 71:17 78:1 153:20
- certainly** 9:17 16:22 44:19 97:17 101:3 115:17 150:19 156:2 156:11 158:6
- CERTIFICATE** 161:1
- certification** 16:15 18:5 20:16 21:21 22:7 23:7 27:3 30:5 32:10 32:15 33:10 34:2,5,8 37:20 47:8 82:18 87:14 89:8 90:5,8,17 91:3,6 92:3,8,13,15 93:18 138:2,4 152:22 153:22
- certifications** 120:2
- certified** 14:8 26:7 39:20 40:3 41:10 90:2,5 93:1,4 153:5
- certify** 119:13 151:18 152:16 161:2
- cetera** 26:21 28:16,22 71:18,18 150:8,8 155:1,1
- chair** 102:20
- challenge** 42:11 100:22 123:13 142:11 149:9 156:1
- challenges** 142:6 155:22 156:19
- chamber** 28:20 121:1 123:14 125:2,4 126:1 126:1
- change** 27:20 35:3 40:13,20 53:18 56:1 64:6,7 76:22 100:10 102:7 121:13
- changed** 50:20 102:9
- changes** 34:21 35:2 37:15 158:13
- channels** 156:9
- characteristic** 12:21 15:4
- characteristics** 14:5 15:14 20:18 28:6
- charcoal** 108:20
- charge** 73:14
- chart** 59:19 85:21
- check** 2:4 93:8,14,15,21 99:13 100:12,15,17
- checking** 21:6
- checks** 99:15 100:7
- chemical** 106:6
- chemicals** 52:22
- Chicago** 101:20
- chief** 2:18
- Ching** 129:2
- Ching's** 39:8
- Ching-tsen** 37:2
- choice** 29:3 73:16
- choose** 66:1 156:7
- chose** 73:5
- cinder** 125:22
- civilian** 46:2 48:13 50:18 51:2 54:15 56:14 58:18
- clarification** 43:9,14
- clarifications** 5:21
- clarify** 44:10 85:2
- clarity** 3:18
- class** 15:1,5,17,21 16:15 26:9 27:12 32:14
- classes** 7:15,21 12:18 28:2 102:3 106:11
- classified** 49:11
- clean** 28:21
- clear** 11:9 136:20 137:4
- clearly** 4:13 95:20 99:5
- climb** 113:22,22
- climbing** 111:8
- clog** 107:13 114:16
- clogged** 106:22
- close** 62:2 69:18 76:8 101:8 112:16 142:19 156:2
- closely** 16:6 101:3
- closing** 5:15
- clothing** 35:8,11
- coal** 18:8,12,18 19:4,9
- coefficient** 67:22
- cold** 103:19 111:4 113:2 135:10
- colder** 103:8
- colleagues** 117:14
- collect** 77:11
- collected** 36:11 38:5,6 38:11 52:1 54:18,20 56:12 58:16 74:15,16 75:15 80:10
- collecting** 15:19 36:21 65:2
- collection** 65:3
- Colorado** 53:2
- Colton** 146:21
- combination** 60:11,18 67:20
- come** 19:17 43:4 68:14 72:3,8 82:17 85:3 88:2 96:4 99:14 106:19,22 109:17 110:13 112:20 115:4 135:22 145:8 147:12 147:12 149:1 150:2 151:9 155:8
- comes** 74:4 84:15 85:7
- comfort** 138:18
- coming** 16:20 77:13 103:2 140:1,4 142:19 144:5 146:1 149:4 159:16
- Commencing** 1:21
- commend** 32:17
- comment** 4:1,4,8 5:20 37:3,21 39:7,8,10 73:8 131:18 151:10 154:17
- commenters** 134:6
- comments** 3:20 13:12 17:1 29:15 32:3,5 64:15,21 65:13 73:17 87:17 94:7 119:19 134:12,15 144:3,10 145:1,16,18 146:1,2,5 146:7 150:7,13 155:10 157:19 158:6
- commercial** 106:7
- commission** 2:11 71:15 120:14
- commitment** 159:14
- commitments** 139:15
- committee** 142:21
- common** 46:21 47:12
- commonly** 155:22
- community** 138:15 149:11
- companies** 38:7
- company** 50:3 52:21,21 77:11 87:1
- compare** 55:13 69:11
- compared** 27:22 28:6 48:2 54:1
- competitive** 95:8
- complaints** 37:10
- complete** 14:20 30:20 149:21
- completed** 30:4 31:3
- completion** 21:11
- component** 8:15 10:12 18:4 21:21 66:19 67:17,18 68:1,2
- components** 8:6 9:11 67:12
- composed** 24:2
- composition** 51:21 123:14 143:3
- compute** 67:8
- computer** 66:22 118:16
- conceivable** 98:13
- conceive** 39:10 86:17
- concentration** 22:3 37:12,13 38:2,12,15 38:22 39:2,5 42:3,5 42:12 124:15 125:4 133:6 150:16 151:8
- concentrations** 37:18 123:19
- concept** 5:9 8:8 9:4 10:11 11:12 23:19 24:4,14,20 30:12 31:4 33:7 40:20 133:2,10 133:13,16 134:2,11 134:14 143:1,15,15 143:16,22 144:6 145:12 158:8,9,13
- concepts** 3:17 6:4 12:9 44:14,21 94:11 145:5
- conceptual** 44:12,16 45:2
- concern** 48:15 90:7 93:11 107:2 133:8
- concerned** 3:8 10:1 39:16 40:7 85:9
- concerning** 9:16 11:12 29:15 43:15 157:7
- concerns** 11:3 19:7 21:5 50:16 90:13 93:6 116:11 133:1,4,5 133:12
- concluded** 53:18 54:8 160:5
- conclusion** 29:1 61:9 122:4 157:21
- conclusions** 27:22 126:17
- concurrent** 143:12
- concurrently** 23:17
- condition** 127:8 138:7
- conditions** 99:12 121:22 123:11 125:10 135:9,10
- conduct** 27:10 120:7 158:18
- conducted** 25:19 29:9 29:22
- conducting** 21:2,16 24:18
- conference** 119:21 120:4
- confidence** 14:17 33:15 70:18
- confident** 68:6 70:9
- confirmed** 122:16
- conform** 96:16
- confuse** 102:10
- confused** 39:16 105:18
- confusing** 145:4
- confusion** 144:5 145:1
- congratulate** 89:4
- consider** 30:13 41:19 50:13 70:14 73:7 78:10 80:12 81:5 83:4 96:21 97:11,14 98:7 99:10 106:13 137:13 139:22 150:2 151:7 156:19
- considerable** 45:17 93:9
- consideration** 7:4 27:12 71:12 92:18 111:9,22 112:4 113:20 129:10
- considered** 12:18 56:21 57:5 68:4 72:14,17 109:15 110:4 111:14
- considering** 141:18
- consistency** 24:17 77:15
- consists** 24:18
- construct** 20:1
- constructed** 49:8,19
- construction** 29:6 57:17 95:1,5 97:17 99:4 101:6 102:13,17 102:21 103:14 104:19 110:3 115:13
- constructive** 4:18
- construed** 44:4
- consultant** 38:6 120:5
- consultant's** 120:4
- consulting** 17:9 37:3
- consume** 101:6
- contact** 13:12 158:3
- contained** 92:9
- content** 11:17
- context** 141:3
- continuation** 23:8
- continue** 24:13 65:7 73:8 95:8
- continued** 131:17 132:20 143:14
- continuing** 136:3 143:22
- continuously** 125:18
- contract** 87:16
- contractor** 2:12 50:3
- contractors** 87:13 95:4
- contribute** 99:2
- contribution** 55:4
- contributor** 22:15 146:16
- control** 42:5 141:7
- controlled** 120:11
- controlling** 141:4
- controls** 133:6
- controversial** 89:13
- coordinated** 137:10

- copy** 129:2  
**core** 35:22  
**corn** 144:20  
**correct** 10:10 110:10  
 124:1  
**corrected** 74:8,9,10,12  
**correction** 74:18 75:16  
**correctly** 79:16 85:16  
 108:9 114:2  
**correlate** 42:9,13 127:4  
**correlated** 60:10,21  
 65:21 77:4  
**correlating** 72:10  
**correlation** 21:4 56:16  
 60:6,6 61:3 66:8 76:3  
 78:3,7 79:11 123:20  
**corresponding** 14:14  
**cost** 28:19 86:9,13 87:5  
**costs** 86:19 104:11  
**counsel** 161:7,11  
**count** 57:3 90:3  
**couple** 71:7 90:22 96:2  
 144:3 146:11  
**course** 42:11 72:4 93:9  
 117:6  
**Court** 161:17  
**cover** 63:9 67:7 72:5  
 85:12 143:2 153:7  
**coverage** 109:19  
**coverages** 109:20  
**coveralls** 124:10  
**covered** 142:17  
**co-exist** 82:12  
**Craig** 146:21  
**create** 159:21  
**criteria** 23:7 26:13 34:8  
 92:3,5 127:7 138:8  
 152:17  
**criterion** 126:8  
**critical** 72:9,16 91:16  
 139:20 140:12  
**critique** 11:21  
**crucial** 9:5  
**crystallize** 139:8  
**cubic** 124:15  
**current** 16:10 27:1  
 46:1,17 47:15 52:19  
 53:8 60:3  
**currently** 6:6 8:21  
 11:16 87:15  
**customary** 17:13  
**customer** 37:6  
**customers** 116:6  
**cut** 92:22  
**cutting** 106:15
- D**
- Dale** 73:19  
**damp** 114:3  
**dangerous** 102:22  
**data** 15:19,19 25:20  
 27:7 34:1,4 36:8,10  
 37:19 38:5,6,8,9,11  
 39:13 41:14 43:15  
 44:3 46:20,20 47:21  
 47:21 50:13,22 51:5  
 51:14 52:5,8,11 54:1  
 54:5,14,18,19 55:9,12  
 55:12 56:12 57:4  
 58:16 59:9,11 60:1  
 63:7 65:2,3,5,7 74:8,9  
 74:10,13,18 75:15  
 76:1,2 77:11 78:3  
 79:21 80:7,10 86:3  
 96:20 97:2 125:8  
**database** 52:1 56:10,19  
 57:19 58:7 69:21  
**date** 12:6 31:10  
**dates** 30:10  
**day** 16:5 75:7 99:9  
 118:4 154:19  
**days** 105:4  
**dead** 99:2  
**deal** 113:14 133:22  
**dealing** 31:22  
**debate** 22:19  
**debates** 26:19  
**decade** 21:19  
**decades** 26:22  
**decide** 25:16,18 26:12  
 140:2  
**decided** 19:8 23:9 50:8  
 102:7  
**decision** 154:8  
**decisions** 33:4 154:19  
 155:6  
**deemed** 27:6  
**default** 157:16  
**defense** 71:21  
**deficiency** 151:16  
**deficient** 91:20  
**define** 9:8 20:20 25:1  
 53:8 62:4 82:20  
 99:22  
**defined** 77:16 100:2  
 136:4 154:7  
**defining** 61:11 151:7  
**definitely** 84:1 142:14  
**degree** 92:11  
**degrees** 121:11  
**delay** 86:10 149:3  
**delays** 135:21  
**deliberately** 4:13  
**deliver** 3:11 5:10,14  
**delivered** 8:20  
**delivering** 4:19 5:6  
**demographics** 50:19  
**denny** 31:14,18,18  
**densities** 77:5  
**density** 76:16,22 79:2  
**Department** 31:20 89:3  
 95:1  
**depend** 40:15 150:22  
**dependable** 99:14  
**deposition** 124:20  
**Deputy** 3:3  
**described** 15:18 96:14  
**description** 106:18  
 145:14  
**design** 15:12 27:15  
 47:4 50:1,9 58:15,15  
 68:9,15 81:19 84:21  
 96:17 153:16 154:11  
**designed** 25:13,14 83:7  
 84:3 112:15 152:20  
 154:3,13 157:8  
**desired** 28:10  
**despite** 26:22  
**detail** 46:8 96:15  
**detailing** 56:11  
**details** 119:12 131:6  
**detection** 125:9  
**deteriorated** 121:9  
**determination** 27:13  
**determine** 10:7 43:22  
 70:5 79:15 80:5  
 91:22 123:4 148:22  
**determined** 27:9 49:3  
**determines** 106:21  
**determining** 7:4 10:15  
 25:11  
**develop** 8:10 9:18 42:8  
 44:20 46:17 47:20  
 48:17 66:17 73:9  
 90:16 95:13 97:12  
 132:8 136:15  
**developed** 11:22 16:1  
 47:16 50:4 56:10,17  
 60:4 64:12 65:8 75:8  
 76:2 100:7 143:2  
**developing** 3:17 5:9  
 23:11 24:3,14 34:14  
 94:11 144:10 159:12  
**development** 9:4 46:12  
 47:4 73:14 98:18  
 127:10 136:1 143:16  
 143:22  
**developments** 143:15  
**develops** 12:5  
**deviation** 48:10 49:5  
 122:1 124:18  
**deviations** 41:14 49:7  
**device** 121:16 123:3  
**devices** 14:17 22:20  
 23:2 127:3  
**diagram** 83:6  
**dialogue** 94:2  
**Diameter** 124:17  
**die** 137:6  
**difference** 157:6  
**differences** 48:11 70:15  
 78:8 112:3  
**different** 8:3 17:13  
 27:6 28:1,2,3 35:13  
 35:13,14,15 42:8 48:8  
 51:22 54:4 57:12  
 62:14 81:6,8 85:13  
 86:15 96:5 100:14  
 109:20 110:2 116:13  
 117:2 121:5,22  
 135:12 141:21 144:22  
 149:15 156:12,15  
**differential** 96:10  
**differing** 76:22  
**difficult** 93:13 110:19  
 113:5 115:3  
**difficulties** 116:9  
**dimension** 50:11,15  
 54:20 56:16 60:7,19  
 60:19 61:1 67:14,19  
 67:22 68:9,10,12,13  
 72:21 73:2 76:5  
**dimensions** 46:14 48:22  
 53:8 60:9 67:11  
 79:12  
**diminished** 114:17  
**direct** 29:2 101:13  
**direction** 139:14  
 140:14  
**directly** 31:10 45:11  
**director** 2:20 3:3 13:1  
 22:4 107:18  
**dirt** 107:14 114:11  
**disapproval** 92:4  
**discharge** 18:13  
**discovered** 76:14  
**discuss** 4:7 9:11  
**discussed** 5:22 10:11  
 89:13 91:8 93:9  
 131:21  
**discussing** 44:14  
**discussion** 4:7,9 5:8,15  
 56:6 91:15 94:2  
 118:20 131:14 135:20  
 136:10 144:8,9  
**discussions** 3:16 10:17  
 11:8 12:7 13:11  
 44:13 117:4 134:20  
 135:7 137:8  
**dispute** 89:19  
**distance** 125:16  
**distinction** 75:19  
**distortion** 96:6  
**distressed** 110:9  
**distributed** 58:21  
**distribution** 48:9 51:4  
 52:4 54:2,4 56:11  
 60:2 61:18,21 68:7  
**disturbing** 28:15  
**diverse** 51:15 133:21  
**diversity** 51:1  
**divided** 49:10  
**Division** 53:2  
**docket** 5:19 6:1 13:12  
 31:10 116:10 129:3  
 158:2,2,5  
**document** 34:20 148:10  
**documented** 131:22  
 137:18  
**doing** 37:1 38:7 40:4,17  
 53:5 71:13 77:2  
 104:2,5 107:21  
 117:10,17 129:19  
 130:5 139:6 158:7  
**don** 1:13 2:9 63:17  
**done** 41:20 42:17 80:11  
 84:13 87:11 91:2  
 104:16 117:20 130:6  
 136:15 139:3 150:15  
**donned** 18:10  
**donnings** 63:16 93:19  
**dose** 103:9  
**doubt** 36:18  
**Dow** 52:22  
**down** 17:6 38:22 45:6  
 68:14 72:3,8 96:3  
 106:15 113:5 125:13  
 132:3 133:5,15  
 136:22 141:20 142:1  
 142:9 143:20 153:12  
**Dr** 5:10 25:19 31:12  
 44:15 45:10,15 72:22  
 85:22 87:21 96:14,21  
 150:17  
**draft** 23:20 24:15 30:10  
 30:18 56:1,5  
**dramatic** 112:18  
**driven** 145:11  
**driving** 145:4  
**drove** 115:18  
**dry** 111:4  
**due** 28:15  
**dumped** 125:17  
**duplication** 28:17  
**during** 4:10 98:7  
 120:11,22 122:11,15  
 122:17 124:22  
**dust** 18:8,12,19 19:2,4  
 19:9,14 102:6 105:10  
 106:17,18 107:14

108:19 112:7  
dusty 106:10

## E

each 15:17,21 16:14,18  
23:18 32:13 49:14,20  
52:9 58:14 61:16  
62:17 63:16,22 67:18  
67:19,22,22 70:8,21  
79:15 108:15 120:21  
124:7  
earlier 26:14 47:16  
59:17 65:3 66:17  
89:13 93:10 119:6  
early 12:4 36:20 38:4  
52:20  
ease 28:17,21  
easier 33:22 79:2  
economic 14:9,12,14  
33:20 132:20  
editing 75:13  
edition 34:15  
educate 103:6  
educated 107:20  
education 103:3  
effect 38:1,3,9,11 78:14  
96:9 112:18 113:2  
121:18 122:8,9,11  
123:5 124:20  
effective 93:13,20  
effectively 108:10  
effectiveness 20:4,20  
effects 142:7  
efficacy 21:10 41:2  
efficiency 19:15 113:3  
effort 8:12 21:17 94:16  
94:17 95:9,10 115:8  
132:8,13  
efforts 32:18  
eight 57:12 66:5,9 73:4  
148:17  
either 20:20 22:10 31:9  
34:3 84:16 101:13  
elasticity 135:11  
elastomer 40:10  
elastomeric 89:18  
107:3 156:3 157:4,11  
element 9:2 19:14  
91:16 139:10  
elements 9:13 19:17  
28:9 138:3,16  
eliminate 16:17 151:2  
eliminated 20:4,13  
email 6:2  
embarked 22:11  
emphasize 138:1  
employed 161:8,11  
employee 18:1 48:2

52:21 161:10  
employers 93:4  
emtor 109:8  
encapsulated 36:14  
144:13  
encapsulating 6:17  
encapsulation 22:13  
encourage 3:13,20  
40:19 95:12 116:10  
158:4,12  
end 30:14 82:2 108:15  
117:7,11,16,18 118:4  
150:10 152:11 154:19  
159:17  
ending 37:12  
endorsement 44:4  
enforcement 57:18  
engage 94:1  
engineering 135:14  
enhance 159:19  
enough 21:17 116:18  
122:5 123:13  
ensure 16:18 40:1  
ensuring 159:3  
enter 75:9  
entering 110:3  
entire 17:2 27:17 71:22  
72:5 138:15  
entitled 21:12  
envelope 152:4  
environment 6:13  
37:17 39:11 110:22  
129:10 132:21 137:19  
150:14  
environmental 6:20  
135:9 142:5 155:21  
156:1,19  
environments 7:3  
111:4 121:5 123:9  
envision 7:19 33:1  
equation 76:3  
equipment 6:8,12,14  
7:6,15 10:5 12:12,15  
23:22 28:16,19 33:5  
36:9 45:19 54:10  
107:22 108:8 124:8  
132:9 144:17 145:6  
148:5  
equipped 19:17  
equivalent 99:9  
error 68:19,22 69:1,14  
70:1 76:10 77:16,19  
115:4  
especially 45:19 76:16  
76:17 78:15 121:10  
150:20  
essentially 91:2  
establish 7:12 8:16,21

8:22 10:7 12:12  
24:12 26:13 92:3  
established 10:14 16:10  
50:8 89:8 92:8 137:3  
137:17 143:13  
establishing 7:5 15:20  
24:5,8 143:21  
establishment 135:22  
estimate 70:1,9,10  
et 26:21 28:16,22 71:18  
71:18 150:7,8 155:1,1  
ethnics 56:22  
Europe 54:19  
European 54:16  
evaluate 8:2 56:13  
100:4,11,15 157:10  
evaluated 19:21 91:5  
96:12  
evaluating 8:11 100:3  
146:2  
evaluation 14:20 25:7  
98:12  
evaluations 10:17  
144:19  
even 18:9 53:15 73:22  
81:2 86:16 95:21  
97:9,15 99:1 106:8  
112:16 113:1,6 128:1  
134:9 140:7 155:16  
events 143:12  
eventual 34:1  
eventually 26:10 34:4  
107:13  
ever 26:7  
every 37:8 79:18 86:3  
118:3  
everybody 2:4 4:16,21  
45:4 100:13 107:19  
150:3 158:11 159:3  
everybody's 158:4,15  
everyone 4:17 26:9  
73:12 77:14 94:8  
150:11  
everything 140:10  
evidence 52:18 142:13  
exact 12:6 53:12  
exactly 60:17 76:6  
91:12  
equipped 93:19  
examined 18:14  
example 25:14 34:22  
80:21 83:17 97:3,20  
130:4 152:18  
examples 6:15 111:21  
Excellent 83:12  
except 120:18 127:2  
128:14  
excess 110:21 126:22

exchange 13:16 17:1  
exclude 68:12 128:10  
excluded 96:22  
exclusively 134:8  
Excuse 31:16  
exercise 92:14 121:6  
123:12,22 125:12  
exercises 10:15 18:20  
26:21 28:15 29:8,15  
92:20 122:5  
exercising 130:6  
exhalation 41:2 110:18  
110:18 113:18  
exhale 113:5  
existed 32:8  
existing 23:20,21,22  
133:19  
expect 32:21 48:17  
65:9 86:9 100:10  
146:12  
expected 98:8  
experience 37:5 71:5  
80:15 87:1 102:1,5  
106:4  
experts 11:16,20 22:19  
expiration 113:7  
explain 67:13,17  
exposed 104:12  
exposure 6:19 99:3,6,7  
99:21 114:6  
exposures 6:19 99:5  
expressed 133:1,9,13  
expression 94:2  
extend 8:18 133:9  
extended 96:7  
extensive 54:8  
extent 32:20  
extreme 127:20,20  
extremely 14:2 110:7  
159:21  
extremes 23:5 127:15

## F

F 101:19  
face 17:21 18:14,19  
19:5,22 20:18 21:10  
22:14 23:1 25:17,18  
47:11 48:22,22 49:1,8  
49:10,18 51:1 53:9,9  
54:3,3,21,22,22 55:11  
55:11 56:11 58:3,5  
59:7,8,10,10 61:1,2  
61:10,10 62:3,4,8,9  
62:11 63:6,7 66:1,2,7  
66:7,13,14 70:3,3,4  
71:10 73:15,15 78:18  
79:1,2 90:10 95:19  
96:6,13,15,16 97:16  
98:7 100:21 103:20  
104:2,13 105:3  
109:19 110:2 111:17  
112:17 114:1,7,8  
123:13  
facemasks 72:4,11  
facepiece 40:9,11 53:15  
66:15 89:15,18,21  
90:2,18 93:16 97:21  
102:8 107:5 112:1  
114:10 153:19 156:1  
156:2,12,14 157:3,11  
facepieces 28:9 90:4,14  
90:20 91:18 93:7,12  
107:15 114:12 153:17  
155:20  
faces 7:20 25:16,17  
90:21 93:1 153:9  
155:4  
face-to-mask 110:6  
face-to-respirator  
110:11  
facial 39:3 46:13 48:4  
53:7 56:16 60:6,7,8  
61:1 79:12 124:4  
facilities 9:1 106:6  
143:14 151:6  
facility 24:6,7,9,19 29:6  
29:7 30:12,15,20  
36:16 143:21 144:11  
145:2,3,5 151:5,6  
fact 3:13 33:16 48:12  
66:13 70:4 107:20  
109:4 110:9 144:6  
factor 15:22 16:13  
20:14 22:2 31:15,22  
38:2,15 39:1,4,17  
40:20 46:21 57:6,6  
60:10 65:22 87:3  
95:22 111:13 121:11  
121:19,20 126:14  
135:16,18 136:5  
142:7 150:18,21  
157:2  
factors 16:9 22:21 25:4  
26:16 40:5 56:20  
60:21 61:4 65:21  
71:8 72:11 92:7  
95:15 96:1,18 122:15  
134:21 135:8,15  
136:1 142:5,12  
fail 99:16  
failed 84:7 91:19 99:16  
100:4 126:16  
failing 138:12  
failure 97:7 98:13  
100:1,5  
failures 98:21 99:1,11

- 100:21  
**fair** 127:8,8  
**fairly** 51:1 139:16  
**faith** 107:20  
**fall** 83:10 134:9 141:17  
152:4  
**falling** 53:17  
**familiar** 17:21 45:4,6  
94:21  
**family** 103:5 105:16  
**fan** 38:16,17  
**far** 2:9 3:7 82:5 85:8  
142:9  
**fast** 106:21  
**father** 104:19  
**fax** 6:3  
**features** 124:4  
**February** 30:17  
**federal** 17:7 18:1 64:20  
**feed** 60:7 103:6  
**feel** 13:10 17:3 43:22  
54:6 66:15 68:5  
77:17 105:14 110:6  
144:1  
**feelings** 31:8  
**feet** 108:3 125:16  
**feiner** 68:17,17 69:3,6  
**fell** 141:15  
**felt** 20:11 32:8  
**female** 49:6 51:10,12  
51:16,17 52:12 54:11  
56:22 58:8,12 69:13  
110:2  
**females** 51:11,20  
**few** 13:2,21 17:21 43:8  
44:16 67:9 90:6  
93:15 105:19 157:21  
159:12  
**fewer** 14:12,12  
**fiberglass** 106:10 112:8  
**field** 6:7 25:20 33:22  
34:11 38:5,7 40:2,3  
97:15 98:21 99:11,14  
100:7,14,17 101:21  
124:9  
**figure** 51:3 102:9  
**files** 43:19  
**fill** 4:17 158:16  
**filter** 40:9,11,12 96:9  
106:17,21 107:6  
108:14 114:6,15  
122:21 150:22 156:13  
**filtering** 19:14,17,22  
23:1 28:8 89:14,17,21  
90:1,4,14,18,19 91:18  
93:7,11,16 102:8  
107:5,14 111:22  
114:10,12 155:19,22  
156:12 157:3,11  
**filters** 19:15 39:20  
41:10,11 126:22  
**final** 4:11 9:13 24:19,20  
31:4 34:22 57:3  
64:22 71:11 72:3  
82:17,21 84:19 86:5,7  
**finalized** 30:7  
**finally** 4:14 10:14  
119:5 158:14  
**financially** 161:12  
**find** 6:4 17:19 41:18  
48:11 53:20 59:18  
60:18 61:7 73:1  
80:16 99:4  
**finding** 31:21 60:8  
**findings** 59:22  
**fine** 37:12  
**finish** 65:9  
**finished** 46:16 65:3,6  
**finishes** 17:7  
**firefighter** 57:17  
**Firms** 21:13  
**first** 2:6 7:21 8:7,10  
12:2,16 25:1 30:1  
43:10 50:19 58:16  
62:1 68:1 73:20 75:4  
88:8 92:21 93:2  
119:14 125:12 131:19  
132:7 137:6 139:7  
141:18 142:18 158:21  
**fit** 5:8 14:11 15:22  
16:18 18:8 19:11,20  
20:7,10,14,16,21 21:6  
21:6,10,16,20 22:7,14  
25:13,15 26:2,4,5,8,8  
26:17,18 27:5,7,14,15  
27:21 28:15 29:10  
31:15,22 33:9,21 34:4  
34:9,12,12 37:9 38:2  
38:14 39:1,4,17 40:2  
40:3,4,20 41:3 45:4  
46:1 53:4,5 56:14,17  
60:3,10,21 61:4 65:21  
74:7 78:19 79:12  
80:16,17 81:1,2,14,19  
81:20,21,21 82:8,9,10  
82:20 83:7,19 84:4  
86:13 90:10,15,17,20  
92:7,22 97:1,7 100:11  
110:15 113:16 114:8  
114:12 117:6 121:11  
122:6 124:4 133:16  
142:5,7 143:5 150:15  
150:21 151:19,21  
152:12,16 153:2,11  
154:3,6,13 155:15  
156:6,7,20,20  
**fits** 25:17 41:8 79:20  
86:16 151:13,14,15  
152:9,10 153:19  
**fitting** 14:4,13 15:4,14  
16:3,19 19:10,10  
20:11,12,18 21:18  
22:14 25:12 33:17  
82:1,2,7 83:21 84:16  
85:4 112:17 122:10  
122:14 152:5  
**five** 8:6 62:14 64:13  
68:12 80:2 95:9  
125:13,14,19 126:2,4  
126:4  
**five-matrix** 82:9  
**fix** 104:17 119:5  
**flat** 53:1 78:21 154:6  
**flatter** 152:20  
**flaw** 142:15  
**flawed** 91:20  
**flaws** 143:19 144:1  
**flexible** 107:4  
**flip** 139:7  
**flipping** 107:11  
**flow** 122:22  
**foam** 108:13,18  
**focus** 7:9 145:9  
**Focusing** 95:19  
**follow** 81:12,22 88:9  
91:12 104:6  
**followed** 5:14 91:21  
**following** 4:5 28:5 82:5  
118:15,18  
**footing** 139:1  
**force** 47:18,19 48:3,5  
50:2,10 51:4,7,10  
52:11 54:2,15 60:1  
133:22  
**forced** 18:13 157:16  
**forefront** 6:16  
**foregoing** 161:3  
**foreman** 101:22  
**forget** 118:1  
**forgotten** 139:9  
**form** 4:15 32:21 107:4  
**formal** 13:8  
**formed** 142:21 143:17  
**forum** 13:15 44:18  
117:13  
**forward** 71:11 78:12  
89:5 91:9 94:3,4  
95:10 101:5 136:3  
139:8  
**found** 20:6 39:13 48:4  
53:11 54:3 55:14  
60:8,9 61:3,6 66:7  
104:21 108:15 109:12  
115:3 122:4 153:2  
**four** 10:22 11:4 55:5  
56:8,22 58:10 66:8  
148:8,8  
**frames** 140:16  
**Frank** 31:17,18  
**frantically** 94:8  
**free** 13:10 17:3  
**freedom** 43:17 44:9  
**freeze** 98:22 113:19  
**freezes** 110:19  
**freezing** 113:4  
**frequency** 66:9  
**frequently** 34:21 61:3  
**friends** 13:5  
**from** 2:9,11 3:8,9,10  
7:3 8:12 10:6 14:14  
20:13 27:7,8 29:20  
30:16 34:1 35:21  
36:9,21 38:5,5,9  
40:16,17,20 41:22  
49:1,13,14,15,15,20  
50:6 51:13,14,21,22  
52:6,8 54:4,14,14,18  
57:16 58:13,14 62:9  
62:15,17 63:14 65:17  
71:2 83:13 84:22  
87:18 88:18 94:13  
96:5,20 97:1 101:16  
103:20 106:19 107:1  
107:1,15,16 108:7  
110:21 115:21,22  
116:17 117:6,11  
119:2 120:4 125:22  
129:12 130:10 132:3  
132:19 136:12 139:11  
139:20 140:18 144:6  
144:17 145:17 146:15  
146:18 148:11 149:16  
**front** 2:8 94:8 131:17  
148:10  
**Frost** 101:17  
**FSphotometer** 125:6  
**full** 18:12 53:15 56:6  
66:14 72:4,11 81:14  
109:21 132:7 144:18  
145:6 156:14  
**fully** 36:14 144:12  
**full-facepiece** 46:19  
48:21 55:13 62:5  
**fume** 19:15  
**fun** 18:16 102:22  
106:13  
**function** 39:4 67:19  
**fundamental** 142:15  
143:19 144:1  
**further** 4:7 17:14 43:9  
135:3 158:7,22 161:9  
**Furthermore** 20:9  
**future** 7:22 73:18 80:11  
104:10,11 140:10

## G

- garment** 132:10  
**garments** 6:16,17,18  
7:16 8:3 12:20 36:14  
**gas** 103:18  
**gathering** 23:20  
**gauge** 9:7  
**gave** 38:8  
**gender** 56:21  
**general** 43:17 44:7,7  
50:17 68:20 69:11,13  
96:20 97:10,21  
133:12,18 135:1  
140:7  
**generally** 20:18 34:2,10  
111:1 122:13  
**generated** 134:15  
**generation** 147:21  
**gentlemen** 13:5  
**gently** 18:19  
**geometric** 122:1 124:17  
**gets** 103:10 106:21  
114:7 139:10  
**getting** 87:3 131:7,8  
132:14  
**give** 28:12 46:11 75:10  
76:21 82:1 135:4  
140:13 154:22  
**given** 3:12 29:8,17 34:2  
91:14 92:19 108:16  
**giving** 13:15 127:16  
**glad** 16:22 87:4  
**glasses** 124:10  
**Global** 35:5 79:9 83:13  
137:11  
**gloves** 124:11  
**go** 4:1,20 5:4 17:18  
33:21 38:22 39:14  
59:2 65:8 66:16 75:6  
75:11 80:9,22 88:12  
96:2 100:19 106:8  
118:18,20 121:11  
128:1 136:20 141:20  
145:18 157:17  
**goal** 7:7,10 12:11 71:1  
132:12  
**goals** 40:21  
**God** 109:5,5  
**goes** 76:11 81:10 87:8  
110:20 130:21 138:9  
144:7 148:11 158:13  
**going** 3:6 15:15 24:10  
24:10 37:19 38:18  
40:8,13,14 41:12,13  
41:15 42:4,5 44:15

46:3 47:6 49:13  
 62:16 71:6 74:18  
 78:22 81:11 82:4,19  
 84:2,9,18 85:5,18  
 86:7,13,20 92:6 95:16  
 103:5 114:18,20  
 116:14,18,20 117:10  
 118:2,3,5,9 121:7  
 132:1 136:21,22  
 137:7 139:14 140:9  
 141:12 142:1,20  
 147:6,22 148:2,3,6,7  
 148:14,18,20 149:3,7  
 150:21 151:15 153:12  
 155:9 156:15  
**gone** 98:4  
**good** 2:2 13:4 14:13  
 17:20 20:18 31:8  
 34:11 42:22 47:13  
 54:6 57:3,19 64:8  
 70:18 88:21 94:14  
 101:18 104:13 105:14  
 109:20 112:2 114:20  
 116:18 122:5 140:3  
 150:10 152:6  
**Goran** 41:22 71:2  
 84:22 115:22 128:8  
 129:12 136:12 147:4  
 154:16  
**government** 11:15  
 17:12 24:3 105:15,17  
 109:11  
**grabbed** 116:7  
**grabs** 84:19  
**grapple** 92:5  
**gravel** 125:15,17  
**greater** 25:9 130:18  
**ground** 3:5 137:2  
**group** 42:1 51:19 52:6  
 52:10,16 54:11 58:9,9  
 65:8 70:8,10 71:3,8  
 85:1 116:1 128:9  
 136:13  
**groups** 57:1,2 58:10  
 97:10,13  
**growing** 118:4  
**guess** 22:9 48:8 66:4  
 78:9,11 80:8 81:16  
 84:6 87:6 97:6 150:5  
 154:10  
**guest** 4:6 5:12 88:3  
**guidance** 27:17 82:1  
**Guide** 34:15  
**guidelines** 81:12  
**guy** 84:8 88:19  
**guys** 41:9 46:10 72:22  
 157:14  
**guy's** 82:3

**H**

**Hagg** 50:5 73:13  
**half** 62:10,10,11,11  
 63:4 95:3 109:21  
**half-face** 102:6  
**half-mask** 7:18 8:5,5,15  
 8:19 9:12,17,19 10:9  
 10:12,20 11:1,17 12:3  
 12:17 13:19 22:22  
 23:11 25:10 28:4,5  
 29:4 30:2,8 33:4  
 46:18 49:17 53:14  
 61:12 62:5 89:18  
 91:17 120:1 121:10  
 121:15,18 122:2  
 144:7 145:7,9,13  
 156:4,12 157:2,10  
**half-masks** 7:21 28:8  
 72:12 90:19,20  
**Hall** 108:2  
**hammer** 126:4  
**handkerchief** 114:11  
**handwriting** 132:4  
**happen** 109:9 112:4  
 113:12  
**happening** 116:22  
**happens** 114:14 115:15  
**happy** 115:9  
**hard** 80:9  
**hardhat** 124:9  
**hardly** 21:16 52:15  
**harm** 102:14  
**haul** 3:18  
**having** 7:19 14:10,20  
 15:7 42:17 137:13  
 148:10  
**hazardous** 111:12  
**hazards** 6:13,20 141:4  
**head** 71:17 112:10,12  
**health** 13:6 14:3 19:6  
 21:5 29:17 31:19  
 57:17 89:3 104:10,14  
 105:13,15 108:7  
 118:5 132:19 159:19  
**healthcare** 129:11  
**HEALTH/NATION...**  
 1:2  
**hear** 103:1 105:12  
 129:21 141:17  
**heard** 96:5 116:12  
 131:21 132:11,22  
 134:1,3,12,19 141:22  
 142:13 147:20  
**hearing** 21:22 42:20  
 93:10 116:3,17 119:6  
 124:22 132:16  
**heart** 101:8  
**heat** 101:17 103:20

112:18 135:10  
**heated** 112:21  
**heavier** 19:20 76:16  
**heavy** 98:2 111:7  
 123:21 130:20  
**height** 55:1,1 58:1  
 72:15 127:19  
**heights** 71:17  
**held** 12:4 21:22 159:11  
**help** 3:18 9:8 44:20  
 90:11 104:14 105:17  
**helped** 108:5,8 115:7  
**helper** 101:22 105:9  
**helping** 77:11 159:21  
**her** 59:10  
**hesitate** 147:13  
**Hey** 75:10  
**Hi** 32:16 127:13 140:18  
**high** 19:15 41:13 96:8  
 97:6,13 99:7 109:7  
 121:8,20 122:2,12  
 123:3 126:12 127:6,6  
 137:15 142:6,6  
**higher** 26:16 53:16  
 148:15 157:17  
**highest** 66:9 122:22  
**high-stress** 137:18  
**him** 50:6  
**hired** 22:9  
**Hispanic** 51:6,17 57:1  
 69:8,12,21  
**hold** 42:3 109:13  
 135:11 136:18  
**holds** 106:17  
**hole** 108:15  
**home** 115:19  
**hood** 122:9  
**hoods** 71:18  
**hood/helmet** 23:1  
**hope** 30:5 88:13 104:21  
 104:22 115:7 143:10  
**hopefully** 28:17 33:14  
 33:21 104:14 143:17  
**hot** 111:4 117:1  
**Hotel** 1:22  
**hotter** 103:9  
**hour** 113:15 121:6  
 126:7 148:18  
**hours** 148:17  
**house** 103:6  
**houses** 106:7  
**huge** 100:16  
**human** 29:17 64:16,17  
 71:8 76:10 128:2,7  
**humans** 19:7 152:5  
**humidity** 121:4,9  
 122:12 123:4 126:9  
 126:13 127:6,22

128:1 135:10 142:7  
**hundred** 67:13 75:6  
**hurt** 103:17 108:1  
**hygienist** 146:20

**I**

**ICS** 73:19  
**idea** 72:4 92:5 138:22  
 139:4 151:12  
**ideas** 12:9  
**identification** 24:15  
**identified** 6:2 8:7 11:13  
 12:6 29:21 100:5  
 131:14 132:6,13  
 133:3 134:10 140:10  
**identify** 4:2 7:8 8:22  
 9:8 15:21 31:17  
 97:12 115:18 140:5,6  
**identifying** 24:1 115:12  
**Illinois** 57:14  
**illustrated** 7:10  
**imagine** 152:1  
**immigrant** 104:19  
**impact** 15:12 35:4  
 114:19  
**impactor** 124:20  
**imperfect** 26:18  
**implement** 32:12  
**implementation** 24:16  
 24:18,20 30:6,19 31:2  
 31:3 34:22  
**implemented** 91:6  
 135:8  
**implementing** 5:9  
**importance** 10:18 46:4  
**important** 3:16 5:16  
 6:8 7:4 11:10,10  
 12:21 13:7 14:2 42:2  
 44:2 72:13 80:14  
 89:6 91:10 93:2  
 95:16,17,21,22 96:1  
 97:11 101:2 110:7  
 118:10 136:7 141:1  
 148:1 150:9 159:21  
**importantly** 118:7  
**imposed** 26:10  
**impossible** 20:1 67:1  
**improper** 96:7  
**improve** 14:4,5,6 80:9  
**improved** 15:13 104:17  
**improving** 13:5 91:17  
**inability** 20:14  
**Inabnet** 161:2,16  
**inadequacies** 133:19  
**inadequate** 97:17  
**inappropriate** 27:6  
**include** 41:2 47:6 59:21  
 68:11,16 71:15 96:6

111:6 137:9  
**included** 59:20 92:21  
 110:11,17 111:4,7  
 131:2  
**including** 7:15 42:18  
**inclusive** 132:2  
**incorporate** 64:14  
 138:3 149:14 155:9  
**incorporated** 92:14  
**incorporating** 138:16  
 138:20  
**increase** 14:16  
**increased** 98:14  
**increases** 96:10,11  
**increasing** 14:10  
 135:16 136:5  
**indeed** 11:2 90:18  
**independent** 23:17  
 126:19  
**indicated** 15:16 21:15  
 32:11 36:10 55:17  
 83:6 122:5 127:15  
 135:7  
**indicating** 133:17  
**indicators** 98:9,10,14  
**individual** 13:13 16:18  
 16:19 20:10 21:7  
 26:2,4 84:17  
**individuals** 14:11 18:10  
 76:16 97:4  
**industrial** 34:15 146:19  
 148:8  
**industry** 11:14 17:22  
 45:8,9,13 46:5 57:16  
**influence** 33:3  
**informal** 13:9  
**information** 4:16,22  
 5:16,18,19,20 13:17  
 17:2 23:21 32:22  
 33:2 36:21 39:12  
 43:9,12,15,16,18,18  
 43:21 44:3,8,9,15,19  
 45:1 56:6 75:9 86:19  
 88:14 116:19 119:15  
 158:2,3,5,16  
**inhalation** 6:22 110:17  
 110:21  
**inherent** 140:21,22  
**initial** 7:17,17 14:11  
 24:3 26:5 63:11 64:5  
 145:13  
**initially** 34:12 46:16  
**initiated** 36:20  
**initiative** 89:5 90:11  
**input** 4:18 13:20 29:19  
 31:6 94:11 158:17,18  
 159:20 160:2  
**insight** 135:3 158:7



- insights** 94:10 136:8  
**insisting** 153:6  
**instance** 83:6  
**instances** 113:1  
**instead** 19:9 39:17  
 49:18 129:19  
**institute** 1:1 108:12  
**instruction** 82:7 105:6  
**instructions** 10:19  
 27:16,19 81:13 82:1,6  
 83:1 85:4 91:13,20,21  
 92:1 127:17 154:7  
**instrument** 35:17 125:6  
**instrumentation** 16:2  
**Insulators** 101:17,19  
**intake** 114:16  
**intend** 85:6  
**intended** 7:2  
**intent** 34:19 40:1  
**intention** 11:20  
**Interagency** 127:14  
**interest** 89:9 159:14  
**interested** 5:20 13:16  
 31:21 142:22 143:6,8  
 161:12  
**interesting** 75:17  
**interim** 21:3  
**international** 101:16  
 148:9 149:11  
**interpret** 155:7  
**intervals** 99:7  
**inter-correlation** 77:2  
**intralab** 28:18  
**intriguing** 138:22  
 139:4  
**introduce** 2:7 12:22  
 17:15 45:15 100:14  
**introduced** 18:22  
 100:10  
**introduction** 45:21  
**invaluable** 31:5  
**investigative** 23:19  
**investigative/concept**  
 30:10  
**investigator** 77:10  
**invincible** 102:16  
**invite** 87:17 135:20  
 136:9 147:13  
**invited** 145:14  
**involve** 144:20  
**involved** 32:2  
**involvement** 31:14  
**inward** 2:3 5:4 6:8,10  
 7:3,12 8:16,22 10:20  
 12:14,21 13:17 18:3,4  
 22:12,15 23:5,10 25:2  
 25:22 27:18 29:3  
 33:10 41:5 42:17
- 45:5 47:7 56:7 95:14  
 96:11 98:15 104:2  
 105:2 109:16 116:16  
 117:2,5,8 119:8 120:1  
 122:19 135:17 144:6  
 144:11 150:20  
**ISEA** 146:21  
**islanders** 97:5  
**ISO** 71:6 73:10 147:6  
**isoamyl** 19:8,13 20:21  
**isomyl** 18:21  
**issue** 21:20 25:4,6 29:7  
 33:8 76:22 87:5  
 89:12,13,20 90:12  
 93:9 94:3 110:7  
 119:20 140:20 151:9  
**issues** 3:19 4:8 21:9  
 71:9 82:14 91:1 96:4  
 135:5,20 136:6  
 138:13,22 139:18  
 140:5,7,12  
**itched** 111:17,18  
**item** 5:7 44:5  
**items** 43:8 45:2
- J**
- J** 101:18  
**Jack** 35:5 79:9 81:16  
 83:13 115:11 116:8  
 137:11  
**Jean** 32:16  
**Jeff** 39:6 40:22 139:19  
 146:19 149:19 150:12  
**Jim** 65:17 94:12 101:10  
 116:8 139:18 140:18  
 146:15  
**job** 17:9 75:7 100:4  
 103:9 106:2 107:11  
 107:12 108:16 114:15  
**John** 85:14 147:1  
**Johnson** 146:15  
**joined** 17:12  
**joint** 78:21  
**jointly** 120:13  
**Joseph** 161:2,16  
**jotted** 133:5,15  
**journeyman** 101:22  
**judging** 15:11 90:9  
**judgment** 14:9 150:6  
**jump** 76:20 98:1  
**just** 8:4,18 9:15 30:2  
 36:1 37:3 38:8 39:12  
 40:21 41:7 48:9  
 50:21 51:9,21 53:6  
 54:21 58:4 59:19  
 64:7 65:16 66:1 67:1  
 67:8 71:4,7 76:8,22  
 77:7 79:13 81:5 83:2
- 85:2,3,16 87:5 88:17  
 90:22 95:7 97:2 99:1  
 100:21 102:10 110:12  
 119:5,10,11 120:3,3,8  
 124:5 125:10 126:6  
 126:10 129:9 130:16  
 130:20 143:10,18  
 145:7,16 149:20  
 150:1,6,21 151:2,8  
 152:12 153:8 155:12  
 157:22 159:2
- K**
- keep** 44:22 61:14 129:9  
 141:9 151:8  
**Ken** 72:22  
**key** 1:22 10:12,22 62:3  
**kicking** 107:7  
**Kimberly-Clark** 129:8  
**kind** 17:16 38:17 53:5  
 71:1 75:13 76:2,2  
 77:18 81:10 92:4  
 99:1 130:10 141:6,14  
 141:17 142:21 143:11  
 144:16 157:13  
**kinds** 100:7  
**knew** 105:7  
**know** 15:5 31:8 35:13  
 36:4 38:20,21 40:15  
 40:16 62:18 69:7  
 70:21 71:6 72:21,22  
 76:8 84:20 87:15  
 89:4 91:4,5 94:1,4  
 95:17 99:17 101:1  
 103:4,11 104:4,5  
 105:22 106:22 113:4  
 117:9 119:15 124:1,5  
 127:18,21 128:4  
 130:13 131:1 137:22  
 139:1,5,12,13 140:2,6  
 141:8 143:6 147:5,14  
 149:6,9 150:1,6,10  
 151:16 153:10 154:10  
 155:17,18 156:13  
 157:13 159:5  
**knowledge** 98:17  
**known** 19:7  
**knows** 100:13 102:11  
**kojola** 88:13,17,22 89:2  
 137:21 146:21
- L**
- lab** 2:21 120:17 151:6  
**label** 105:10,13  
**labels** 105:14 153:11  
**labor** 11:15 135:6  
 137:22 159:9  
**laboratories** 42:9
- laboratory** 1:3 7:13 9:1  
 14:22 15:10 22:6  
 23:4 25:7 38:10 45:7  
 45:16 46:7 47:17  
 133:20 138:7,11  
 159:18  
**labs** 73:19 87:16  
**lack** 15:7 21:20  
**lacking** 21:3 27:17  
**ladders** 111:8  
**ladies** 13:4  
**landmark** 58:3  
**LANL** 45:7 50:17  
 53:14,18 55:16 56:13  
 58:18 59:12 62:15  
 66:14 73:14,22  
 127:11 133:20  
**LANL/NIOSH** 124:4  
**LAO** 37:2  
**large** 64:4 72:2 75:11  
 75:19 76:15 81:22  
 82:10 97:9 121:1  
 151:14,15 153:4,9  
 155:2,3 159:11  
**largely** 96:22  
**larger** 41:14 103:10  
**last** 35:20 50:20 71:19  
 101:20 116:8 158:20  
**late** 142:18  
**later** 25:20 31:10 46:8  
 48:15 104:14 134:19  
 138:17 155:8  
**latter** 23:3 30:21  
**laughed** 109:4  
**law** 57:18  
**lawnmower** 108:14  
**Lawrence** 23:4 124:19  
 125:7 146:15  
**lay** 113:21  
**lead** 105:11 109:18  
 153:12  
**leading** 8:21  
**leak** 105:3 114:20  
**leakage** 2:3 5:4 6:8,10  
 7:3,12 8:16 9:1 10:20  
 12:14,21 13:18 18:3,4  
 22:12,15 23:5,6,10  
 25:3 26:1 27:18 29:3  
 33:10 39:3 41:5  
 42:17 45:5 47:7 56:7  
 95:14 96:11 98:6,15  
 105:2 109:16 116:16  
 117:3,5,8 119:8 120:1  
 122:19 126:22 135:17  
 144:6,11 150:21  
**learn** 8:19 24:11  
**least** 5:13 25:9 61:16  
 62:1 78:1 89:20 90:3
- 92:15 115:1,1 143:22  
 154:15  
**leave** 104:20 147:15  
**led** 8:12 27:1  
**left** 62:14 114:9  
**leg** 55:2  
**length** 49:1,9,18,22  
 50:9,14 53:9,10 54:3  
 54:22 55:2,11 59:8,10  
 61:2,10,10 62:3,9  
 63:7 66:2,7,14 70:3,4  
 72:8 73:15 93:10  
**les** 1:12 3:2 15:15 32:11  
 45:20  
**less** 38:12 58:12 124:18  
**lessens** 114:5  
**let** 31:8 37:21 75:3  
 83:14 104:17 107:21  
 109:9 144:2  
**letter** 91:22  
**let's** 73:8 85:18 88:6,12  
 88:16 101:11 118:21  
 119:14  
**level** 34:8 138:18  
 156:15 157:17  
**levels** 121:4 148:15  
**life** 118:10  
**Light** 111:7  
**like** 2:6 3:4 4:17,20  
 12:22 13:21 16:6  
 17:14 18:16 34:21  
 38:4 39:10,11 40:6  
 43:8 44:10 45:14  
 49:14 50:19 51:19  
 52:11,14,14 53:12,12  
 55:1,8 59:2,3,3,6,9,13  
 60:8,19 61:14,16,18  
 61:19,21,22 62:13,20  
 63:1 64:6 65:12,20  
 66:4,10,15 67:4,6,10  
 67:16 69:19 70:19,20  
 70:22 73:5,7,15 75:5  
 75:6,13,20,21,22 76:4  
 76:4 77:7,13,18,21  
 78:5,19 79:20 80:1,8  
 81:6 83:6 88:1 94:12  
 98:9 99:13 101:13  
 102:19 108:14 110:1  
 116:2 119:5 129:9  
 131:19 135:2,9,10,19  
 135:20 136:9 137:1  
 147:16,22 152:2  
 157:20,22 158:14  
 159:2,7  
**likelihood** 14:10  
**likely** 25:8 41:18 95:21  
 96:11 99:11,16,20  
 146:11

**limit** 49:1,3 77:19  
 125:9 153:16  
**imitations** 140:22  
**limited** 80:2 98:11,16  
**limits** 49:8,18 55:15,21  
 62:9 78:2 127:16  
**line** 39:8 83:18  
**linear** 67:19  
**lines** 147:7  
**lip** 49:17,22 50:9,14  
 53:9 61:9  
**listed** 88:9  
**listen** 16:6  
**listened** 102:4  
**listening** 117:15  
**listing** 43:12 108:3  
**literature** 36:15 52:17  
 61:6 73:5 144:14  
**little** 9:15 17:13 33:22  
 39:16 40:7 43:2  
 58:12 71:4 83:14  
 101:11 102:22,22  
 103:1 116:13 121:18  
 126:7,10,11 129:16  
 142:18 147:7 154:18  
 155:7  
**live** 87:16 104:22 150:3  
**Livermore** 23:4,14  
 124:19 125:7 146:15  
**ives** 104:15  
**load** 135:12  
**loaded** 88:15 118:16  
**loading** 96:10  
**logger** 125:8  
**logic** 34:15,18 35:3  
**London** 71:8  
**long** 3:18 77:17 99:9  
 103:15 107:5 108:3,6  
 108:13 111:11 113:9  
 113:11,19 131:5,7  
 135:11 149:1,3,17  
 150:4  
**longer** 105:20  
**longest** 87:2  
**longevity** 159:3  
**look** 10:19 11:3 38:12  
 39:1,3 41:1 48:8  
 52:10 55:12,19 56:16  
 56:21,22 58:20 60:6  
 60:13,14,14,22 66:18  
 69:19 70:2,3,7 72:18  
 73:4 77:12,14 78:6,7  
 79:5 80:5 90:1 94:3  
 95:9,13 97:15 101:3,5  
 102:14 114:5 134:4  
 136:22 138:15 145:15  
 147:15,22 148:8  
 155:21  
**looked** 20:5 38:1,8,10  
 38:21 39:12 48:10  
 54:2,13 61:7 72:2  
 76:1 108:14  
**looking** 11:17 12:16  
 17:8 36:16 39:22  
 40:4 41:5 69:1,3  
 71:10,14 72:12 80:18  
 82:21 102:15 105:15  
 117:5,6 146:4 147:19  
 154:1,12 157:8  
**looks** 38:4  
**loose** 19:10 113:15  
 122:10,14  
**loosen** 113:13  
**Los** 45:7 46:6,16 47:16  
 48:1 120:17 122:4  
 125:7,10 126:10,17  
 128:18 133:20  
**lot** 11:2 18:16 37:9 38:6  
 79:8 81:17 95:15  
 98:2 102:1,3,16 105:6  
 114:5 115:17 129:15  
 137:7,9 138:10  
 142:13  
**low** 69:10 88:19 96:8  
 121:19 122:15 137:15  
 142:6,6 152:10  
**lower** 41:15 49:5,8 82:8  
 126:11 128:2 154:22  
 155:1  
**lowest** 122:22  
**LRPL** 74:2  
**lunch** 88:5 118:14,15  
 135:7  
**lung** 124:20  
**lungs** 106:16 107:7  
**Lynn** 68:17  


---

**M**

---

**made** 13:22 35:2  
 105:14 109:13 124:21  
 137:4 144:10 145:2  
 146:7 154:6  
**mail** 6:1  
**main** 13:21 40:1 55:4  
**mainly** 51:8  
**maintain** 130:10  
**maintained** 158:10  
**major** 22:14 48:11  
 150:17  
**majority** 25:13,15  
**make** 2:4 21:17 57:10  
 75:19 76:9 77:21  
 84:14 91:1 109:14  
 110:16 111:3 136:19  
 139:14,16 146:9  
 150:7 153:18,19  
 154:8,18 155:6,12  
**makes** 152:2  
**making** 16:3 33:2 58:3  
 92:22 144:21 151:12  
**male** 48:1 49:4 51:8,16  
 51:17,20 52:12,13  
 53:21,22 54:7 56:21  
 58:8,11 69:12 110:2  
**man** 148:3  
**manage** 42:3 65:8  
**management** 8:13  
**manager** 3:1 13:13  
 18:2 31:19 144:4  
**mandate** 29:18 82:7  
**mandated** 26:2  
**mandatory** 18:8  
**manned** 37:1 144:12  
**manufacture** 10:19  
**manufacturer** 25:6  
 26:11 36:8 43:11,21  
 47:1 82:5 83:2,5,16  
 84:3 85:2,17 91:13  
 137:14 151:11 152:19  
 153:1,19 154:2,5,12  
**manufacturers** 24:2  
 31:6 34:3 35:21 36:2  
 116:5 127:16,22  
 142:22 151:5  
**manufacturer's** 81:12  
 81:22 83:1 91:19  
 92:1 127:19  
**manufacturer/NIOSH**  
 33:8  
**manufacturing** 11:14  
 57:16 106:6  
**many** 20:5 38:17 46:15  
 46:18 47:9 59:13  
 86:6 90:1 97:4 102:4  
 102:5 104:21 105:4  
 109:17 113:17 119:19  
 138:3 151:2 160:2  
**March** 30:10  
**margin** 93:3  
**market** 152:19 153:8  
**marketplace** 20:13  
 21:17  
**Marriott** 1:21  
**Martinotti** 108:11  
**mask** 78:18 80:18 98:3  
 104:12 105:9,10  
 107:3 108:19 109:19  
 111:2,15 112:2 113:4  
 113:7,12,15,22 114:7  
 151:13 152:4,16,19  
 153:2  
**masks** 50:1,2,10 102:6  
 104:6 107:13,18  
 109:12 112:7,9 113:1  
 113:10,11  
**Mass** 124:16  
**match** 61:18,22 62:2  
**matrix** 82:11 83:9  
**matter** 11:15 26:9 32:5  
 57:7 61:8 103:15  
 109:4 117:8 160:5  
**matters** 140:17  
**mature** 12:5 44:21 68:5  
 158:8  
**maximum** 22:2  
**may** 23:17 27:5,5,20  
 30:16 38:9 50:22  
 52:19 63:18 64:6,7  
 65:6,14 66:10 70:14  
 72:22 79:5 81:5,8  
 88:3 96:1,17 98:4,14  
 99:2,6 103:12 134:3,8  
 135:21 138:9,22  
 139:5 142:17 147:15  
 149:6,12,17 151:18  
 153:14 156:5,6,7,16  
**maybe** 38:13 52:14  
 67:17 70:21 71:5  
 72:18 77:7 80:1  
 83:14 88:21 93:18  
 129:1 130:14 134:9  
 136:17 139:11 140:13  
**MC2Ps** 80:19  
**mean** 33:1 42:6 48:2,3  
 48:7,10 49:4,6 70:2  
 74:9,14 75:5 109:10  
 121:22 122:1 149:2  
 152:15 153:6  
**means** 132:2  
**measurable** 130:7  
**measure** 28:7 48:1 53:6  
 53:7 54:20,22 55:1,3  
 58:1,5,7 70:15 75:6  
 75:10 77:22 124:12  
**measured** 52:20,22  
 121:2 129:16  
**measurement** 13:17  
 16:14 58:4 72:2,13  
 74:7 75:2,14 77:14  
 78:16 125:8 135:17  
**measurements** 16:3  
 53:13 55:10 74:12  
 77:3,3,4 144:21  
**measurer** 58:3 77:8  
**measuring** 27:21 29:3  
 76:17 148:13 150:20  
**mechanical** 98:20 99:1  
**mechanisms** 100:3  
**media** 115:5,6  
**Median** 124:16  
**medical** 104:11,14  
**medium** 64:3 80:2,22  
 81:1,21 82:9,10 83:19  
 83:20 84:10,10  
 106:17 107:6 110:8  
 110:12 151:14,14  
 152:9,9 153:4,9  
**medium-large** 63:19  
**meet** 127:7  
**meeting** 1:3 2:3 3:6  
 4:11,14 12:4 13:8,10  
 22:4 30:20 31:9  
 44:18 71:7,20 86:18  
 120:9 147:14 157:21  
 159:10  
**meetings** 4:19 9:4,14  
 12:1,2 13:14 16:21  
 30:2,13 158:19  
 159:12  
**meets** 152:17  
**melted** 113:1  
**members** 64:18 96:6  
 108:4 146:7  
**memory** 131:7  
**mention** 96:2 122:8  
 132:1  
**mentioned** 33:19 47:16  
 59:17 74:6 81:11  
 115:17 119:7 120:9  
 134:7 137:21  
**mentions** 119:8  
**mesh** 19:2  
**message** 27:4  
**metabolic** 130:9 148:9  
 148:13,16  
**meter** 124:15 148:12  
**method** 22:6 25:11 26:3  
 27:10 28:5 29:8 30:6  
 42:8 97:12 100:18  
 123:6  
**methodology** 26:20  
 35:8 137:17  
**methods** 8:2 27:21 28:1  
 29:9 35:12,13 44:14  
 95:13 133:2,2,10  
 141:7  
**metzler** 1:14 2:20,20  
 13:1,4 22:4 32:3  
 34:13 36:6,13 42:21  
 86:18 87:12 88:12  
 119:7 135:5 144:2  
 146:9,13,18 149:8  
 152:6 159:7  
**Meyers** 146:17,18  
**micrometer** 124:16  
**microphone** 4:2  
**mid** 120:14  
**middle** 4:2 83:18 84:9  
 152:10 153:3  
**might** 83:19 88:17 89:1

- 96:22 97:3,6 98:11  
134:21 135:17 137:13  
144:20,21 157:5  
**milestones** 30:9,11,18  
31:2  
**military** 48:12 50:21,22  
54:5 80:18 87:16  
**mill** 114:13  
**milligram** 124:15  
**millimeter** 49:2 70:11  
70:16  
**millimeters** 62:10  
**million** 55:18,19 72:6  
95:3  
**mills** 106:6  
**mind** 44:22 96:5 101:1  
141:10,20 144:11  
**minded** 87:12,19 146:4  
**mine** 53:21 140:19  
**Mines** 18:6,22 53:21  
**minimal** 34:8  
**minimized** 120:11  
**minimum** 34:8 62:18  
**minus** 68:19 69:14  
125:3  
**minute** 9:15  
**minutes** 18:12 44:16  
113:15 125:13,14,18  
125:19,21 126:2,2,4,5  
126:6 148:19,19  
**mirror** 92:16  
**miss** 143:7 146:11  
**missed** 143:7  
**missing** 89:7 138:10  
**mist** 19:15  
**mistake** 95:20  
**misunderstand** 129:17  
137:5  
**misunderstood** 129:1  
**mode** 29:2 100:5  
**model** 15:6,6 60:11,15  
60:15 63:13,18,20  
80:17  
**models** 60:13 64:2  
**moderate** 18:11 123:21  
**modes** 100:1  
**modular** 23:8  
**module** 21:10  
**moisture** 107:7,12,12  
**Moldex** 39:6 149:19  
**momentum** 98:2  
**money** 103:5 118:2,3  
**months** 143:10  
**moot** 30:22  
**more** 9:15 11:9 12:5  
15:3 16:21 33:15  
51:14 53:11 54:8  
55:20 59:3 62:12,20  
64:6 65:4 68:5 70:20  
74:1 84:15 86:19  
92:8,20 97:14 98:5  
101:3 110:2 115:9  
116:19 118:7 125:3  
137:1,19  
**morning** 2:2 13:4 17:20  
94:14 101:18 119:4  
124:5 138:1 144:8  
**most** 6:15 22:19 25:8  
29:9 41:18 61:2  
70:22 95:17,21 99:6  
105:8 113:14 124:8,8  
127:16 128:6  
**motion** 97:16,22 98:7  
**mounted** 97:21  
**mouth** 72:9  
**move** 45:3 94:12 98:1  
101:15 102:20 125:15  
125:22 130:17,17  
136:3 139:14 140:2  
140:14  
**moved** 139:8  
**moves** 17:8 114:1  
**moving** 87:22 89:5 91:9  
94:4  
**much** 9:6 29:20 44:12  
68:8 71:10 79:1,2  
94:5 143:17  
**much-needed** 94:16  
**multi** 86:16  
**multiple** 7:20,20 80:5  
93:19 134:14  
**must** 37:16 91:11 92:8  
109:9 112:3  
**M-40s** 80:19
- N**
- nails** 125:20  
**name** 3:2 4:3 17:20  
52:21 54:15 89:2  
101:18 102:7  
**names** 102:10  
**naming** 102:7  
**narrow** 138:7  
**nasal** 18:13,13 73:1  
108:21  
**national** 1:1 2:21 22:5  
23:4 45:7 46:6 47:17  
57:11 71:21 120:17  
133:20  
**nationwide** 57:12  
**Native** 97:5  
**natural** 159:5  
**nature** 26:18  
**necessarily** 41:7 56:4  
95:18 149:2  
**necessary** 21:11 42:14  
140:6  
**necessity** 91:21  
**neck** 112:11  
**need** 9:22 16:17,21  
28:20 47:4 67:12,14  
68:1 70:17,22 90:15  
90:16 92:2 97:14  
98:5 99:13 100:2,20  
104:14 107:1 111:3,6  
124:12 133:22 134:4  
139:14 141:9 144:16  
145:3 154:17 155:5  
157:13,14  
**needed** 36:22 54:10  
60:4 74:2 136:3  
144:17  
**needs** 90:16 92:18  
93:17 139:2 142:14  
**negative** 100:12 130:21  
**neither** 161:7  
**never** 42:12 102:12,13  
107:10 141:16  
**new** 5:9 18:5 34:15  
35:1 45:22 56:17  
57:14 60:3 62:6 63:8  
100:6,7,17 113:13  
117:14 124:6  
**newcomb** 1:15 2:22,22  
5:5 8:14 17:5,6,15,16  
17:20 33:6 35:10  
36:2 40:22 41:11,18  
43:1 82:13 83:11,22  
84:12 85:7,21 86:12  
129:2,6 131:1,9  
146:12,17 153:14  
156:21 157:18 159:2  
**Newcomb's** 91:15  
**next** 12:4 17:5 23:12  
26:12 30:5 65:10  
76:12 86:18 88:13  
98:19 110:16 112:18  
125:15 133:15 147:21  
151:4  
**nice** 111:1 140:15  
**NIOSH** 2:3,7,12 3:8  
4:5 5:15 6:1 7:7,11  
14:8 15:6 16:16 18:2  
19:3,6,8 20:19 21:2,9  
21:14 22:11 23:6  
25:1,6 27:8,15 30:2  
31:22 32:3,12 33:8  
34:3,7,13 35:22 36:1  
36:5,9,10 42:17 43:15  
43:16 44:3,4,7 46:9  
46:11 55:17 56:4,9  
62:7 64:15,17 85:17  
87:9,11 89:4,8,16,20  
89:22 90:11,16 91:7,9  
92:6,8,12 94:4,17  
95:4,8 105:14 107:19  
109:4,9,13,14 116:13  
117:14,15,15 119:7  
119:12,17,19,20,22  
120:8,15 122:20,21  
124:5 127:7,10 129:9  
131:16 132:7 138:3  
138:15 141:20 142:8  
143:1 149:3 150:1  
153:22 156:8  
**NIOSH's** 22:5 23:8  
31:14  
**NIOSH/NPPTL** 1:3,10  
**none** 20:6  
**nonprofit** 94:22  
**non-toxic** 124:14  
**non-validated** 20:3  
**normal** 126:9  
**North** 68:17 85:14  
**nose** 61:2 65:20 66:10  
72:15,21 97:21  
108:22 111:17 114:11  
152:20 154:6  
**note** 4:11 44:2  
**notes** 132:3 133:15  
**nothing** 18:5 88:19  
110:20  
**November** 65:1  
**nowadays** 67:3 68:9  
**nowhere** 156:2  
**NPPTL** 2:11,13,16 3:3  
6:4 7:11 8:5 13:1  
24:8 87:11  
**NRC** 119:11 120:14  
**nuclear** 106:7 120:14  
**number** 36:16 40:19  
49:12,19 55:20 63:14  
64:1,4,7 69:9 70:13  
72:2 75:11 80:3  
85:22 98:11 135:15  
159:11  
**numbers** 6:3  
**N-95** 126:22
- O**
- objectives** 23:18 30:9  
**observation** 78:7 97:3  
**observer** 77:16  
**obsolete** 119:5  
**obtain** 27:10  
**obtained** 27:7 34:9  
43:18  
**obvious** 6:15  
**obviously** 12:1 29:12  
30:21 43:16 86:12  
131:16 156:21  
**occupational** 1:1 31:19  
**occur** 99:6,11  
**off** 3:4 38:17,17 72:1  
103:17 114:10 116:15  
137:2,6  
**offer** 14:6 153:9  
**office** 37:9,9,10 127:14  
**officer** 57:18  
**official** 4:22  
**officially** 73:17  
**often** 46:14 80:16 99:4  
**oftentimes** 19:19  
**oh** 69:16 74:16 81:4  
137:6  
**Ohio** 57:13  
**OHSA** 10:14 16:10  
20:9 25:3,4 26:1  
29:10 33:12,13  
**OHSA's** 31:15,22  
34:22  
**oil** 106:5 144:20  
**oiled** 125:15  
**okay** 17:18 35:19 37:16  
43:7 45:20 65:12  
66:4 69:5,16 74:17,22  
76:13 78:21 79:7  
80:13,20 81:4 84:5,8  
85:13 101:15 106:10  
109:2,12 113:19  
119:1 128:20 129:6  
131:12 157:19  
**old** 129:19 131:8  
**older** 52:13 103:1  
**OMB** 64:21  
**omission** 32:8  
**omitted** 18:20  
**once** 57:6 58:16 68:12  
75:15 106:9 139:7  
**one** 10:2 19:12 20:7  
32:8,20 37:3 40:19,22  
41:4 43:10 49:11  
50:19 51:9 59:9,9  
60:13,15,18,19 65:16  
65:19 66:10,11,19  
68:9 70:16,21 71:9  
73:13 76:4,20 77:7  
79:13,20 81:9 82:15  
83:21 84:7,15,16 85:2  
85:3 86:15 106:8  
110:14 111:22 117:7  
117:22 121:6,17  
125:12,17,22 126:7  
126:15 129:18 134:6  
137:5,15,15 145:2  
147:18 148:1,15,16  
150:14 151:16 153:8  
153:9,15 154:3,6  
155:12 158:20  
**ones** 29:10 95:17 103:2

- 104:7  
**one-by-two-inch** 78:20  
**one-inch** 108:15  
**one-size-fits-all** 63:13  
 153:2 155:15 156:6  
**one-third** 52:9  
**only** 19:12 21:15 26:3  
 52:11 53:7 54:19,21  
 58:22 59:6,21 63:19  
 67:14 68:1,10 70:17  
 80:1 85:4 92:16  
 95:19 96:13 111:19  
 112:16 115:5 117:7  
 132:3 139:6 149:8  
 153:2 154:6  
**onto** 147:13  
**open** 4:8 87:12,19  
 131:17 146:4  
**opened** 87:9  
**opening** 5:2,3 118:1  
**operate** 114:1  
**operates** 159:18  
**opportunity** 13:16 14:6  
 94:15 145:18  
**opposition** 132:12  
**ORC** 32:17  
**order** 19:18 47:13  
 57:10 62:12  
**organic** 19:1,14,17  
 109:1  
**organization** 4:3 19:6  
 159:4  
**organizations** 159:9  
**organized** 23:15 54:14  
**original** 112:20 131:2  
**Originally** 38:1  
**OSHA** 21:22 22:17  
 26:15 37:5,6,6 89:19  
 92:9 93:10 108:12  
 116:16 119:10 120:13  
 121:18 124:22,22  
 126:18,19 130:19  
 131:4 147:1 156:22  
 157:1,7  
**OSHA's** 89:11 92:17  
 119:6  
**Ostenstead** 72:22  
**other** 3:10 6:5,17 7:21  
 9:3 11:2 12:18,19  
 22:12 33:4 34:7 41:3  
 42:15 43:1 50:14  
 54:11 59:6 60:5,12,12  
 61:7 62:16 65:20,20  
 66:18 67:6,6 68:12  
 69:12 73:18 76:5  
 81:9 82:16 83:2  
 84:17 90:20 96:1,17  
 109:19 111:21 121:15  
 127:3 130:8 131:10  
 133:10 135:16,18  
 136:1,6 141:4 144:20  
 148:18 151:6,10  
 155:10 157:7,19  
**others** 15:6 51:6,18,20  
 57:2 113:17 117:11  
**otherwise** 37:18 42:6  
 161:12  
**ought** 92:20 93:21  
 139:21  
**ourselves** 30:13 139:15  
**out** 4:17 31:21 41:19  
 48:15 65:19 67:4  
 74:4 75:6 90:19  
 95:16 101:1 102:9  
 105:15 107:8,11,12  
 110:20 115:15 116:6  
 116:8,20 118:6  
 136:20 138:10 140:1  
 140:4 149:4 158:17  
**outcome** 161:13  
**outline** 46:2  
**outside** 53:13,17 55:15  
 55:21 59:7 134:9  
**over** 3:18 4:20 18:1  
 23:16 50:20 97:4  
 112:1 126:7 145:15  
 159:12  
**overall** 11:3,11 12:11  
 23:5 33:17 121:21,22  
 131:20  
**overcome** 103:18  
**overhead** 7:11 125:20  
**overlap** 84:13  
**overlapping** 143:15  
**overview** 8:4  
**own** 38:10 54:12 55:9  
 69:14 73:6 141:20  
**oxygen** 50:1,2,9
- 
- P**
- 
- Pacific** 97:5  
**package** 64:21 67:4,6  
 153:5  
**packet** 5:1 8:8 158:4,16  
**packets** 4:16 5:18  
**paid** 118:5  
**Palley** 120:7  
**panel** 1:10 3:9 4:7 5:8  
 5:10,15 10:11 27:5,14  
 27:17 34:9 45:8,11  
 46:11,12 47:7,20  
 48:16,17,17,20 49:16  
 50:4,8,17 52:19 53:9  
 53:14,18 55:13,16  
 56:14,18 58:18,22  
 59:12,20,21 60:4  
 61:11,13,19 62:4,7,15  
 63:8,11 64:13 66:14  
 66:18 68:15 73:14,22  
 79:18 81:7,7,15 83:4  
 83:9 87:2 94:8  
 118:20 124:4,6 128:2  
 131:14,15,16 133:16  
 133:20,21 134:11,13  
 134:14 151:14 152:21  
 153:3 154:9 158:22  
**panels** 46:1,5,7,13,17  
 46:18 47:1,5,10,15  
 79:19 153:12  
**paper** 19:1  
**PAPR** 98:21  
**PAPRs** 97:20 109:21  
 121:18 122:15  
**paradigm** 157:13,16  
**parallel** 56:15  
**parameter** 6:11,11 7:9  
 50:9 70:4  
**parameters** 65:20 66:2  
**Pardon** 74:20  
**part** 7:17 9:5 13:8  
 16:15 20:2,15 21:20  
 27:13 47:7 53:3 59:7  
 63:6 86:7 90:5 92:2  
 93:21 94:17 95:10  
 98:12 118:11 131:3,3  
 131:12 138:1 144:9  
 152:21 153:4  
**participants** 146:8  
**participate** 13:10 17:3  
**particle** 37:12,13 38:13  
 38:14 123:16 124:16  
 125:4 150:16,19  
 151:7  
**particles** 106:20 121:2  
**particular** 23:1 34:20  
 63:20 70:10,19 72:19  
 152:4 159:8  
**particularly** 44:1 89:12  
 91:18 93:7  
**particulate** 19:15  
**particulates** 18:15 42:6  
**parties** 5:20 13:16  
 142:22 161:8,11  
**partner** 95:6  
**partners** 13:5  
**partnerships** 159:19  
**pass** 14:11 81:1,2 83:20  
 84:10,10 124:13  
 126:12  
**passage** 97:16  
**passed** 23:6 108:4  
 127:1  
**passing** 126:8,13  
 138:11  
**pass/fail** 15:20  
**past** 15:8 43:4 45:12  
 104:16 110:12 159:12  
**path** 143:9,20  
**peer** 9:14 11:5 24:1  
 29:18,21 30:12,19  
 31:2 34:19 56:2  
 64:13 65:9,10 73:11  
 86:2,8 142:21 143:3,4  
 145:11,15,17,19  
 146:1,5,6  
**pel** 99:10  
**penetration** 40:12  
 150:22  
**Pennsylvania** 57:13  
**people** 3:9 25:13 36:16  
 50:4 53:1 72:7 73:18  
 75:6 77:2,4 82:20  
 85:19 102:5,11,12,15  
 102:16 103:2,12,22  
 104:2,12 107:17,20  
 108:3,5 110:5,13,22  
 111:10 112:19,21  
 113:6,9,14,21 114:14  
 116:6 117:1 118:7  
 147:10 148:4 149:20  
 152:20 155:22 157:5  
**people's** 155:4  
**per** 38:13,14 124:15  
 148:12 156:8  
**perceive** 157:6  
**perceived** 156:8,9,11  
 156:16  
**percent** 21:15 48:18  
 51:8,9,9,11,11,15,16  
 51:18,19 53:11,12,16  
 55:14,19 58:22 59:4  
 59:20,21 63:1,4 67:13  
 67:17 68:11,13,14,16  
 69:20,20,21 70:8 97:7  
 125:3  
**percentage** 62:13,22  
 63:3 69:22  
**percentile** 68:10 70:9  
 70:12  
**percutaneous** 6:19  
**perfect** 22:10  
**perform** 10:4 24:12  
 93:15 148:22  
**performance** 6:11 7:5  
 7:13 9:18,19,21 10:2  
 10:6,16,20 12:13  
 14:22 15:10,11 16:14  
 24:4,13 26:13 43:13  
 64:8 119:16 121:10  
 123:5 132:8 142:7  
 148:17  
**performed** 135:13  
**performing** 123:7  
 126:21  
**performs** 41:7  
**perhaps** 131:20 134:7  
 136:5  
**period** 23:16  
**periodic** 26:5  
**periods** 18:11  
**permanent** 132:2  
**person** 4:1 6:11 49:14  
 49:14,15 77:22,22  
 114:17 130:11,11  
 154:21  
**personal** 1:2 2:21 6:7  
 6:16 7:5,14 8:3 12:12  
 12:14 45:18 54:9  
 56:3 97:2 132:9  
 145:6  
**personnel** 48:13 50:21  
 143:1  
**perspective** 131:20  
 132:19 141:9 144:18  
 149:16  
**perspectives** 94:3  
**pfriem** 73:19,19 74:11  
 74:17,20 75:1,17 76:6  
 76:11,14,20 78:3,11  
 78:18 79:8 81:9 83:9  
 83:12 87:4 141:11  
 146:6 147:3 155:12  
 157:12  
**phase** 23:19 24:7,17  
 30:9,14,15 31:1  
 125:15 142:18 143:20  
**phases** 23:16,16,18  
**phone** 6:3  
**phonetic** 50:5 68:6  
 72:22 99:10 108:11  
 124:21 138:7  
**photometer** 121:2  
**physiologic** 135:12  
 149:12  
**physiological** 148:3  
**Physiologically** 154:20  
**picture** 52:3 58:2  
**pie** 59:19  
**piece** 5:16 44:3 64:11  
 89:6 107:22 108:13  
 108:18  
**pieces** 19:22 23:1  
**pipes** 112:22  
**pivot** 78:21  
**place** 10:17 108:5,6  
 111:1,19,20 141:2  
**placed** 34:20 69:14  
**placement** 26:20  
**places** 102:14  
**plan** 24:16,20 30:5,19

- 31:2,3 86:1,8  
**planet** 151:19  
**planned** 4:21 12:2 30:1  
 131:13  
**planning** 143:13  
**plans** 30:3 80:4  
**plants** 106:6  
**plaque** 108:2  
**platform** 125:13  
**platner** 65:16,17 94:13  
 94:14 139:19  
**please** 13:10 17:3 44:22  
 158:16  
**pleased** 93:22 94:1  
 116:3  
**pledged** 22:6  
**plus** 17:10 29:2 68:19  
 69:14 73:6 125:3  
 141:19 142:2,11  
**podium** 147:13  
**point** 8:13 10:6 30:22  
 40:17 44:17 45:14  
 48:14,16 57:4 59:9  
 62:3 66:15 67:1  
 71:14 72:17 84:1,20  
 86:17 92:15 116:8  
 117:7,12 118:13  
 136:9 139:21 141:5  
 149:10 159:1  
**pointing** 65:19  
**points** 13:22 86:3 91:1  
 115:16,17 136:10  
**police** 57:18  
**pool** 11:16  
**poor** 20:12 21:18  
 102:18 123:7 126:20  
**population** 48:13,14,19  
 49:4 50:20,22 51:2,15  
 54:9,11 56:15 57:9  
 61:20,21 63:9 66:3  
 68:21 69:7,12,13  
 71:22 72:5,6 74:7  
 96:20 97:10 133:21  
 153:20 154:2  
**populations** 134:6,8  
**PortaCount** 29:2,5  
 35:7,16 36:19 37:3,7  
 37:8 42:4 133:3,14  
 141:19 142:2,11  
 143:5 145:2,10,20,22  
 146:3 155:17,18  
**PortaCounts** 37:16  
**portion** 3:15 27:14  
 32:14 33:9  
**positions** 135:12  
**positive** 100:12 116:4  
**possible** 29:20 62:2  
 85:5 130:12 151:3,19  
**possibly** 72:13 92:20  
 97:15 152:16  
**posted** 8:9  
**potential** 132:20  
**pounding** 125:20 126:3  
**pounds** 97:4  
**power** 106:7  
**powered** 23:2 122:10  
**PPE** 6:11 7:2 12:16,19  
 13:18 14:21 17:11  
 22:13 35:15 36:14,20  
 120:22 124:7,8  
 133:11 144:7,18,22  
**practical** 114:21  
 134:20 135:8  
**practices** 114:3  
**praying** 143:18  
**preamble** 20:15  
**preclude** 35:21  
**preconditioning** 142:4  
**predicted** 76:5 79:14  
 80:17,22 81:3  
**predicting** 20:22 80:6  
**prediction** 76:8  
**preliminary** 59:22 60:8  
 90:22  
**preparation** 28:21  
**prepare** 65:5  
**present** 17:15 23:7  
 45:11 86:2 135:6  
**presentation** 3:12 5:4,6  
 5:11 31:13 33:7,19  
 45:22 56:2 118:16,17  
 118:19 119:2 124:21  
**presentations** 3:7,8,11  
 3:16 4:5,10 5:14 8:20  
 9:10 12:8 16:7  
 134:19 137:22  
**presented** 5:22 44:5  
 96:21 151:12  
**presenters** 2:7 3:10 4:6  
 4:6 101:14 131:16  
**presenting** 3:17 4:19  
 25:20 55:22 56:5  
**presently** 21:2  
**president** 77:10  
**pressure** 96:10 121:15  
 130:22  
**presumably** 33:20  
 39:20 150:4  
**presume** 35:12  
**pretest** 124:12  
**pretty** 9:5 106:10 112:1  
 143:17  
**previous** 80:15 101:13  
**previously** 27:7  
**primarily** 3:9 90:14  
**primary** 8:6 11:1,4  
**principal** 66:19 67:11  
 68:2 77:9,10  
**principle** 159:18  
**priorities** 140:13  
**priority** 140:8  
**private** 17:8 21:13 87:9  
**probably** 23:12 34:5  
 35:14 39:22 94:18  
 97:17 136:14 137:7  
 141:12,22 158:11  
**probe** 26:20 79:4 124:2  
**probes** 26:20 28:16  
**problem** 19:12 36:7  
 37:10,20 52:19 54:13  
 77:20 99:21 104:18  
 108:7 115:3 139:6  
 159:15  
**problems** 109:14,15  
 110:18 113:8 151:15  
 153:12  
**procedure** 16:11 39:19  
 130:1  
**procedures** 21:7 32:13  
 91:4 136:2  
**proceedings** 2:1 160:4  
 161:3,6,9  
**process** 13:9 17:2 20:5  
 27:3,20 30:3 33:10,18  
 34:5 65:10 73:11  
 75:14 82:18 87:14  
 89:8 90:8,17 92:2  
 93:18 100:20 104:6,8  
 138:21 139:17 140:2  
 140:3 158:9 159:20  
**product** 14:8 36:3 44:1  
 44:5 84:3 96:17  
**production** 47:3  
**products** 23:6 31:7  
 33:15 68:18 85:15  
**profusely** 103:21  
**program** 3:1 5:5 6:5  
 7:7,8,12,18,19 8:5,6,8  
 8:13,16,19,21 9:2,12  
 9:13,17 10:13 11:1,3  
 11:6,10,11,12,18 12:3  
 12:5,10,11 13:20 16:7  
 16:16 17:15 18:3,5  
 20:17 21:8 22:11  
 23:10 25:21 26:1  
 30:21 31:18 32:15  
 35:11 36:17 44:11  
 45:1,3 53:4 56:7  
 71:21 87:20 91:6  
 126:20 127:14 128:18  
 131:13 132:12,15,18  
 134:22 136:18 138:4  
 142:9,19 144:4  
 145:14 149:22 158:8  
**programmatically** 11:7  
 29:22 145:15  
**programmatically**  
 29:19  
**programs** 6:5  
**progress** 136:19  
**progression** 32:1  
**project** 2:22 13:13 18:2  
 23:12,15,18 25:2,3  
 28:4,5 29:18 30:2,8  
 31:9 32:18 54:14,15  
 130:19  
**projects** 34:16  
**promise** 155:13  
**promulgated** 20:2  
**promulgation** 21:20  
 87:8 89:11  
**proper** 82:2  
**properly** 16:19  
**properties** 119:4  
**proportional** 69:19  
**proposal** 64:5 65:13  
 128:13 154:10,15  
**propose** 119:7 122:18  
 124:14 126:8 129:14  
**proposed** 22:1,18 46:11  
 61:13 62:6 63:8  
 89:11,21 119:18,22  
 122:20,21 124:3  
 128:21 129:18,22  
 147:8 157:1  
**proposing** 27:4 92:16  
 130:5  
**protect** 6:18 7:2 65:17  
 94:13,21 101:4 108:7  
 117:10 141:1 148:4  
**protecting** 104:10  
**protection** 6:21 14:6,7  
 14:18 16:13 17:11  
 20:22 22:2,17,20,21  
 25:4 26:16 34:16  
 46:21 53:4 71:16  
 72:10 89:12 92:11  
 105:5 121:19,20  
 122:15 126:13 138:13  
 139:21 141:7 157:2,6  
**protective** 1:2 2:21 6:7  
 6:12,16,17,18 7:6,14  
 7:16 8:3 12:12,15,20  
 22:5 45:19 54:10  
 132:9,10 145:6  
**protocol** 3:5 8:11 24:5  
 24:21 29:11 64:12,14  
 64:15,20 91:4,11  
 92:15 93:21 116:17  
 119:13 127:2,3,11  
 130:11 136:16,16  
 137:3,16,18 138:17  
 141:19 143:5 145:13  
 149:5 155:15 156:6,8  
 156:17,18 157:9  
**protocols** 8:2 21:4  
 24:15  
**prototype** 47:2  
**protrusion** 61:2 65:20  
 66:10  
**prove** 26:11 58:17 85:5  
**provide** 3:18 4:8,18  
 5:20 15:3 32:21 43:8  
 46:14 137:18 140:16  
 140:16 141:6 158:7  
 158:17  
**provided** 4:15 5:18  
 20:22 32:3 82:6  
 91:13  
**provides** 6:12,22  
**providing** 14:21 15:22  
**psychological** 111:13  
**public** 1:3 2:3 9:14 12:1  
 12:2 13:8,9,15 14:3  
 16:21 19:6 21:22  
 30:1,13,20 32:6 34:3  
 34:6 43:17,20 44:8,18  
 64:20 86:18 87:18  
 93:10 147:14 150:7  
 158:18 159:11  
**publicly** 146:7  
**publish** 35:22 36:2  
 46:19  
**published** 18:7 21:14  
 36:1 64:19  
**publishing** 35:22 36:8  
 43:11  
**purchase** 148:15  
**purchased** 37:8  
**purchasing** 33:3  
**purifying** 28:9 122:11  
**purpose** 20:16 21:3  
 56:5  
**push** 155:2  
**pushed** 108:22 139:10  
**put** 47:3 71:21 73:5  
 83:17 85:22 103:22  
 107:19 108:21 112:8  
 112:9,12,13 114:3,18  
 115:6 129:3 149:5  
**putting** 106:16  
**p.m** 160:5

## Q

- quadrupling** 74:1  
**qualification** 20:10  
**qualify** 19:9  
**qualifying** 22:6  
**quality** 21:7 118:9  
 159:18

**quantifying** 20:7  
**quarter** 43:4 65:10  
 109:21  
**quarter-masks** 28:8  
**question** 3:15 4:1,4  
 5:21 14:1 32:20  
 35:20,20 39:7 43:1,10  
 74:21 75:4 76:11,12  
 81:9 84:6 87:6 105:1  
 105:21 114:22 116:2  
 128:5 142:16  
**questionable** 20:3  
**questioning** 69:7  
**questions** 3:13,14,21  
 31:12 35:6 74:5  
 101:12 104:1 115:8  
 115:21 127:12 131:11  
 131:18 141:11 155:11  
 158:6  
**quick** 65:16 67:8 68:14  
 99:14 155:13  
**quickly** 133:4  
**quite** 48:7 51:22 52:9  
 54:4 69:1 90:6 96:14  
 98:18 121:12 136:15  
 149:1

## R

**race** 51:3 56:22  
**racial** 54:11 58:10  
**rainbow** 97:16  
**raised** 4:10 21:22 43:11  
 50:16 105:16 135:5  
 139:19  
**raises** 140:20  
**range** 79:14 80:18 81:3  
 83:19 84:9 85:6  
 95:22 100:20 138:8  
 144:18 145:6 151:7  
 151:13 153:7  
**rate** 52:4 68:19,22 69:1  
 69:14 70:1 122:22  
 130:9 148:9,13,16,19  
 154:22  
**rates** 117:2 148:8,21  
 149:12  
**rather** 135:18 136:5  
 138:17  
**ratio** 39:2,3 51:21  
**reached** 27:22 29:1  
**read** 42:16  
**reading** 29:2  
**readjust** 113:16  
**real** 67:8 68:14 115:15  
 125:8 132:11 139:1  
**realistic** 97:15  
**realities** 115:12,13,14  
**reality** 102:16

**realize** 26:19 100:8  
 119:3  
**really** 7:8 8:18 9:7,22  
 33:7 40:4 42:2,2 45:8  
 78:14 82:13 90:8  
 92:21 96:12 100:1  
 101:1 115:15,18  
 116:3,4,4,7 117:13  
 118:10 121:9 138:1,8  
 138:13 139:20,20  
 147:9  
**reason** 81:18 111:15  
**reasonable** 37:19  
**reasons** 41:4 147:20  
**recall** 81:13 131:5  
**receive** 14:7 37:9 99:9  
 99:20 105:6  
**received** 119:19 145:19  
**receiving** 14:18 145:16  
**recent** 55:17  
**recently** 2:11 95:7  
**receptive** 17:1  
**recess** 43:6 88:11  
 118:22  
**recognition** 133:18  
**recognize** 9:4 99:17  
 159:15  
**recommendations** 30:7  
 142:1  
**recommended** 61:11  
**record** 32:6 93:14  
 161:6  
**recorded** 4:12  
**recruit** 47:10  
**recruited** 57:15  
**redo** 130:14  
**redonning** 26:21  
**reduce** 121:12 124:20  
 127:10  
**reduced** 161:4  
**references** 46:15  
**referring** 32:5  
**refineries** 106:5  
**reflect** 138:4,9  
**reflective** 60:2  
**regard** 36:14  
**regarding** 43:9  
**regardless** 28:9 157:3  
**regards** 116:16  
**regimen** 18:11  
**regions** 134:8  
**Register** 64:20  
**regulation** 82:22 84:19  
 86:5 87:8  
**regulations** 108:6  
 119:17  
**regulators** 31:6  
**Regulatory** 120:14

**Rehak** 8:21  
**related** 35:20 45:11  
 96:18 99:5 134:21  
 135:8 161:7  
**relationship** 32:1  
**relative** 12:9 43:11,12  
 44:6,13 133:5,9,13,15  
 134:1,13,16 138:18  
 161:10  
**release** 78:10  
**reliability** 135:10  
**reliable** 128:6  
**relied** 46:14  
**rely** 27:15 37:11 47:1  
 84:2  
**remain** 26:4  
**remarks** 5:3,15 32:11  
**remeasure** 75:12  
**remeasurement** 76:9  
**remember** 108:11  
 109:7 111:15 131:6  
 146:12,14  
**removed** 19:13  
**render** 119:7  
**repeatability** 151:4  
**repeatable** 28:12  
**reply** 159:6  
**report** 53:19 65:5  
 71:11 120:4 129:5  
 131:5  
**reporter** 161:1,17  
**represent** 4:3 51:1 56:4  
 59:12 68:2 127:14  
**representative** 11:14  
 48:6 57:8 58:14  
 123:8  
**representatives** 135:6  
**representing** 46:1  
 146:22 147:1,18  
**represents** 56:3 59:9  
**reproducibility** 28:18  
**reproducible** 29:9  
 123:15  
**require** 29:5 88:14  
 100:7  
**required** 3:20 8:2 20:10  
 20:14 28:10,14 33:11  
 54:10 55:18 92:16  
 148:22 152:13  
**requirement** 8:11,12  
 9:18,19 10:21 19:4  
 26:14 82:17 132:8  
 148:3  
**requirements** 7:13 9:9  
 10:16 12:13 18:17  
 22:7 23:11 24:4,14,21  
 26:10 33:12 36:17  
 90:5 138:2

**requires** 97:1  
**requiring** 153:11  
**rescue** 53:21  
**research** 8:1 12:19 15:5  
 21:2,11 25:19 27:1  
 43:15 54:13 94:22  
 95:5 135:21 139:2  
 140:6,11  
**researchers** 47:9,12  
**researching** 45:17  
**resounding** 141:22  
**Resources** 54:17  
**respirable** 123:16  
**respirator** 2:18 5:8  
 6:21 7:1 10:2,3,9  
 12:17,18 14:13 15:17  
 15:21 16:3,15,19  
 19:16,19,21 21:8,13  
 21:21 22:20 23:13,21  
 24:13 25:5,8,12,14  
 26:4,7,8,17 27:15  
 32:13 34:11,14,18  
 41:1,7 45:9 46:1,18  
 46:19 47:2,3,4 48:21  
 49:17 53:14 55:14  
 56:11,14,17 60:3,7,11  
 62:5 63:17 64:2  
 79:12,13 82:2,6,8  
 83:7 84:15,21 85:7,12  
 85:17 86:4 89:7,12  
 91:14 92:10,17 97:1  
 99:16 100:15 103:13  
 106:13,14 110:6  
 113:3 117:9 119:16  
 120:1,21 121:9  
 122:11 123:5,10  
 125:1 130:21 134:22  
 147:21 151:5,11,18  
 152:18 153:16,22  
 154:13 156:10  
**respirators** 6:20 7:15  
 7:18,22 9:20 13:19  
 14:5 15:1,4,12,13  
 18:6,9,10 19:1,2,11  
 20:11,12,17 21:18  
 22:8,12,14,22 23:11  
 25:10 27:11,20 28:2,2  
 29:4 33:4,13,17 35:9  
 35:14 40:2 42:19  
 45:19 46:15 61:12  
 71:22 80:5 81:18  
 82:20 83:17 90:2,6,9  
 90:18 91:17,19 92:12  
 92:22 93:4,16 97:19  
 100:6 101:7 102:2,6  
 105:5 106:4,5 109:17  
 110:13 113:18 115:14  
 116:5,9,19 117:19

118:8,8 119:13  
 120:18 121:15 122:8  
 123:7 124:2 126:21  
 127:9 128:14,16  
 132:9,21 133:11  
 134:9,14 137:14  
 138:5,11 140:21,22  
 141:3,6 142:4 145:8  
 148:21 153:7,16  
 154:21 155:3,4  
**respiratory** 6:21 14:21  
 17:11 22:17 34:16  
 53:3 71:16  
**respond** 75:3  
**respondents** 21:15  
**rest** 18:11 109:22  
 125:14,19 126:2,4  
 152:14  
**restricted** 114:18  
**restrictive** 84:21  
**resubmit** 153:3  
**result** 27:20 33:17,18  
 37:14,18 41:14 55:22  
 72:3 98:14 123:20  
**resulting** 19:19  
**results** 27:10 28:11,13  
 36:3,5 37:11,19 38:18  
 42:10,13 66:5 78:1  
 121:7 122:3,13 127:4  
**resume** 88:3 118:21  
 119:2  
**retired** 2:11  
**retirement** 17:12  
**retraining** 100:9,17  
**retrials** 126:15  
**reverse** 112:14  
**review** 9:14 11:5,19,21  
 24:2 29:22 30:12  
 31:3 56:2 61:5 64:13  
 64:14,16,16,17,22  
 65:9,10 73:11 86:2,8  
 142:21 143:3,4  
 145:11 146:6  
**reviewed** 29:18 34:19  
**reviewer** 146:1  
**reviewers** 11:13,16,20  
 29:21 64:13 145:15  
 145:17,20 146:5  
**reviewing** 23:21,22  
 30:8 66:5  
**reviews** 11:7,9,12 30:19  
**revised** 119:17 158:10  
**revising** 23:20  
**revision** 124:22  
**revisions** 22:1  
**revisit** 139:12 142:12  
 142:15  
**revisited** 142:14

- rewrite** 22:16 131:3  
**rewriting** 117:18  
**re-emphasize** 44:11  
**rich** 1:14 2:20 13:1  
 17:22 22:4 33:19  
 135:3 137:22 142:17  
**right** 2:5,9 38:20 59:15  
 73:16 76:19 87:22  
 111:20 136:14 151:20  
**Rights** 65:18 94:13,22  
 101:5  
**rigorous** 92:20 123:12  
**rise** 76:21  
**risk** 97:13 103:12 156:9  
 156:11,16  
**road** 141:21 142:2  
 153:13  
**Rocky** 53:1  
**roland** 1:11 2:17  
**room** 2:5 4:2 18:12  
**root** 73:1  
**roughly** 51:15 52:9  
**route** 157:17  
**routine** 75:14  
**rubber** 108:13 112:19  
**rulemaking** 13:9 16:10  
 32:4,9  
**rules** 3:5 105:7 114:5  
**run** 23:17 30:16 37:14  
 37:16 120:15,18  
**running** 43:2  
**rush** 150:6
- 
- S**
- safety** 1:1 13:6 31:19  
 35:6 68:17 85:15  
 89:3 93:3 107:18  
 121:15 124:10,10  
 135:16 136:5 159:19  
**same** 27:5 70:15 72:1  
 77:22,22 103:1  
 120:16 123:10 125:10  
 130:10 151:9 157:2,8  
 157:10  
**sample** 49:13 57:8  
 69:19 70:5  
**sampling** 56:20 68:20  
 69:4,15,16 70:19  
 97:12  
**samplings** 71:1  
**SAS** 67:4  
**sat** 87:4  
**save** 118:2,3  
**saving** 104:11  
**saw** 94:7  
**sawicki** 35:5,5,19 36:12  
 79:9,9 80:4,13,21  
 83:13,13 84:5 137:11
- 137:11  
**saying** 14:3 81:17  
 83:15,18 85:11  
 136:20 141:3 159:17  
**says** 83:3 85:8 128:14  
**scaffolds** 111:8  
**scale** 79:2  
**scan** 55:6 79:3  
**scanner** 55:4,5  
**scared** 111:18  
**scare-all** 138:6  
**scatter** 59:7 63:6  
**SCBA** 127:2 128:19  
 137:16  
**scenario** 122:22 123:3  
 127:7,18  
**schedule** 18:7 43:3 88:1  
**schedules** 22:18  
**school** 103:3 109:7  
 112:6  
**science** 11:21 13:20  
**scientific** 11:7,19,20  
 50:12 52:18 138:19  
 146:16  
**scientifically** 29:19  
 58:17  
**scope** 141:8 144:11  
**screen** 5:17 88:14  
 126:20 158:3  
**screening** 123:6  
**scribbled** 132:3  
**SEA** 42:1 71:3 85:1  
 116:1 128:9 129:13  
 136:13 154:16  
**seal** 93:8,14,15,20  
 95:19 96:6,13,15  
 97:22 98:3 99:13,18  
 100:12 103:21 104:13  
 110:6,11 114:21  
 115:6 123:13  
**sealed** 100:21  
**sealing** 104:2  
**seals** 41:2 114:19  
**search** 52:18 144:15  
**searches** 36:15  
**seated** 2:8  
**SEBA** 120:19  
**second** 8:15 12:4 35:19  
 44:10 53:20 65:10  
 139:9  
**secondly** 10:4,10 11:19  
 132:16 133:8  
**seconds** 67:9  
**sector** 17:8 21:13 87:9  
 101:7  
**Secure** 35:5 79:10  
 83:14  
**Security** 137:12
- see** 38:3,11,17 40:8  
 41:6 51:7,13 52:8,15  
 58:8,13,21 59:1,13  
 62:8,12 63:9 73:3,11  
 77:3 78:5 81:5,17  
 105:1 107:9 116:5,22  
 121:8 122:2 130:9,20  
 149:4 153:10 159:15  
**seem** 121:17  
**seems** 133:18 143:16  
 149:20 151:11  
**seen** 51:2  
**sees** 16:16  
**segment** 7:17 153:20  
**select** 33:13 62:17 93:4  
 121:3 123:2  
**selected** 49:22 62:4  
 120:17  
**selection** 16:11 25:5  
 34:14,18 35:2 53:13  
 53:17,18 63:4  
**self-identify** 99:15  
**send** 13:12 129:4  
**sense** 132:13 140:8  
 152:2  
**sensing** 133:17  
**sensitivity** 28:10  
**separate** 21:10  
**September** 65:4  
**sequence** 88:9  
**serious** 90:13 92:18  
 93:6,11 122:7  
**seriously** 139:21  
**served** 21:5  
**serviceman** 47:18  
**Services** 29:17  
**set** 4:6 41:16 46:21 55:9  
 55:12 76:1,16 127:19  
 135:17 153:7  
**settling** 143:4 149:11  
**seven** 60:12 61:7 73:6  
 120:18  
**seven-inch** 108:13  
**several** 60:12 66:18  
 67:6 88:4 120:7  
**shape** 62:14 96:13  
 112:20  
**shapes** 110:14  
**share** 12:8 13:1 71:4  
 119:10  
**shared** 71:19  
**sharing** 115:12  
**shield** 103:20  
**shifted** 62:13  
**shine** 101:16,18,19  
 139:19  
**shock** 141:15  
**shocked** 141:17
- short** 99:6 149:22  
**shortcomings** 142:1  
**shortly** 146:5  
**shoveled** 125:17  
**show** 46:10 52:18 58:4  
 59:11,19 70:7 106:12  
 119:12 121:7  
**showed** 23:5 93:14  
 150:17  
**showing** 52:3 58:2  
 108:12  
**shown** 108:21  
**shows** 21:15 51:3  
 159:13  
**side** 107:16 126:1,1  
 139:7  
**sides** 87:18 107:2  
**signatory** 95:3  
**signed** 5:14  
**significant** 38:3 60:20  
 61:3 66:8 73:2 96:16  
 99:3,20 100:5,8  
**significantly** 60:9,20  
 65:21 98:2  
**silicone** 112:19  
**similar** 18:17 59:16,18  
 61:20 69:22 78:1  
 116:19  
**similarly** 49:7,19  
**simple** 99:14  
**simply** 48:9 49:22  
 50:10 141:6  
**simulant** 144:12  
**simulate** 29:12 130:16  
**simulated** 16:12 20:8  
 37:1 119:9,11 120:5  
 120:11 122:16 126:13  
 137:1  
**since** 7:2 18:22 20:9  
 21:19 56:1 73:22  
 74:1 78:13 87:22  
 88:18 109:12  
**single** 68:8  
**sit** 102:20  
**site** 100:4 103:14  
 115:13  
**sites** 103:9  
**sits** 113:5  
**sitting** 55:1,7  
**situation** 113:21 130:6  
**situations** 138:10  
**six** 121:5 125:16 132:5  
 143:10 147:2  
**six-month** 142:9  
**size** 25:15 46:20 47:11  
 49:10,11 51:1 56:11  
 60:11,15,16 63:18,19  
 63:22 64:4 69:4,15,17
- 79:13,16,20,22 80:3,5  
 80:6,22 81:1,2,3,6,8  
 82:8 83:10 84:7,15,16  
 85:3,3,5,8,9,10 86:16  
 86:16 110:15 111:22  
 112:3,5 123:16,17  
 124:16,17 125:4  
 144:16 150:19 151:8  
**sizes** 60:16 70:5 71:10  
 71:17 79:15 83:17  
 85:13,19,20 109:17  
 109:19 110:14 134:14  
**sizing** 46:14  
**skin** 6:19  
**sledge** 126:3  
**slide** 5:17 113:22  
**slides** 17:19 42:7 65:19  
 114:7  
**sliding** 57:21  
**small** 25:15,16,16,17,18  
 35:3 64:3 75:11,18  
 80:2 81:2,20 82:8  
 83:3,4,19,20 84:7  
 85:3,5,8,9,10 108:20  
 112:2 123:1 126:22  
 151:13 152:10 153:4  
 153:9  
**smaller** 72:20 110:4  
 151:13  
**smallest** 154:21  
**small-medium** 63:19  
**smellier** 103:9  
**sneak** 107:1  
**soft** 107:4  
**software** 66:22 67:8  
 75:5,8  
**solano** 129:7,7  
**sold** 101:8 108:19,21  
**solely** 87:11  
**solicit** 31:5  
**solid** 107:4 139:1,15  
**solutions** 115:4  
**solve** 77:20  
**solving** 159:14  
**some** 3:5 9:3 10:15,16  
 11:21 17:10 19:10  
 20:12 25:20 27:19  
 38:5 42:9 43:8 46:11  
 48:15 52:13,17,18  
 55:9 59:14 60:15,15  
 60:16 67:6 71:5,20  
 74:18 75:10,21 76:2  
 77:13 80:3,21 81:18  
 90:13 92:3,18,19 93:6  
 94:18 96:4 97:3,7,19  
 99:22 111:21 112:8  
 113:6 115:14 116:19  
 117:4 119:14 120:3

- 121:16 126:16 130:4  
130:14 131:20 132:3  
133:1,1,12,15 134:4,5  
134:5,15,17,19 135:3  
135:5,18 136:6  
138:16,22 139:2,5,15  
140:7,13,16 141:2,11  
144:1,5 145:1 149:3  
151:7,15 153:12  
**somebody** 99:21 106:2  
151:17 152:12 156:3  
156:9  
**someone** 17:7 102:7  
103:21 153:18  
**something** 68:4 70:17  
76:10 78:9,12 100:13  
109:10 116:4 118:5  
140:20 152:1  
**sometimes** 70:14 76:21  
**somewhat** 39:8  
**somewhere** 27:8  
107:16 148:11  
**soon** 99:16  
**sooner** 74:3 138:17  
**sorbent** 107:7  
**sorry** 18:6 74:16  
128:22  
**sort** 36:20 37:1 92:21  
99:22 130:6 139:9,12  
**ought** 30:7  
**sounds** 18:16 147:9  
**source** 44:19  
**sources** 36:22  
**space** 155:1  
**speak** 4:12 84:18 94:15  
102:12 156:21  
**speaker** 17:5 88:7,13  
**speakers** 5:12,13 13:22  
88:3 116:8  
**speaking** 94:9  
**special** 145:3  
**specialists** 147:18  
**specialized** 29:6  
**specific** 15:5 27:14  
**specifically** 13:18 32:7  
**specification** 24:6  
**specifications** 24:1  
30:12 144:15  
**spent** 17:10 45:16  
**split** 98:22 99:18  
**sponsor** 130:19  
**sponsored** 119:11  
120:13 126:18  
**spots** 99:21  
**spreading** 57:21  
**spring** 30:5  
**autum** 18:13  
**square** 148:12  
**stable** 37:13,17,17  
39:11 123:14,18  
**Stacy** 127:13  
**stage** 139:8,9 140:4  
155:8  
**stakeholder** 13:14  
**stakeholders** 29:20  
**stand** 24:22  
**standard** 14:22 22:17  
35:17 41:14 48:10  
49:5,6 72:17 73:10  
92:10,17 108:17  
117:16 122:1 124:17  
125:1 135:9,14,22  
137:8 148:9 150:10  
151:17 159:22  
**standardized** 14:20  
15:8 29:14 32:9,13  
**standards** 15:20 23:9  
102:2 117:18 147:22  
149:15 159:13  
**standing** 55:1,6 98:4  
**start** 3:4 14:2 42:16  
72:10 100:13 101:2  
104:9,17 109:20  
115:2 118:17 137:2  
144:2  
**started** 18:9 36:15 65:2  
72:1 105:6,9 116:15  
120:15 136:19 144:8  
144:14,15  
**starting** 104:7 108:16  
147:10  
**starts** 114:15,16  
**state** 64:9 141:15,16  
146:10  
**stated** 20:15 26:14  
**states** 57:13 147:19  
**state-of-the-art** 10:7  
15:16 24:13 27:11  
136:4  
**statistical** 16:12 67:3,4  
**Stay** 103:2  
**steam** 112:22  
**steel** 106:5 114:13  
**Steelnack** 147:1  
**Stenotype** 161:4  
**step** 78:11 91:10 93:3  
96:19 125:12 137:6  
156:16,18  
**steps** 35:3  
**stick** 103:7  
**sticks** 110:21  
**stifle** 154:11  
**still** 33:11 56:2 64:1  
65:7 68:8 98:4,16  
100:15 106:1 143:7  
**stopped** 77:19  
**storage** 96:7  
**strange** 119:4  
**strap** 112:10,10,11,13  
135:11  
**straps** 113:12,13  
135:11  
**strata** 70:19  
**stratified** 56:19  
**stratifying** 66:2  
**stratum** 58:14  
**strenuous** 137:19  
**stress** 137:15,16  
**stressed** 117:1  
**stringent** 92:9  
**strong** 102:15 159:14  
**structure** 158:18  
**structured** 7:8 87:11  
**structures** 83:10  
**struggling** 73:21  
**stuck** 142:10 143:18  
146:3 157:12,15  
**students** 102:18 106:12  
112:7  
**studied** 15:2  
**studies** 16:12,13,13  
20:20 36:21 45:5  
60:13 61:7 66:9 74:7  
120:8 122:14 127:5  
**study** 21:12 23:3,14  
53:20 56:1,15 59:17  
60:5,14 66:5,6 72:19  
73:2,3,4,6,6 77:1,2  
79:17 80:9,11 126:17  
126:19 129:3 131:2  
150:16  
**styles** 28:8  
**subcommittees** 149:13  
**subject** 11:15 23:3,13  
47:13,14 48:2,5 49:20  
49:20 52:5,14,15  
53:16 55:6,6,15 56:1  
57:16 58:7,11,20 59:1  
59:8,9 61:8,15,19,19  
63:3,7,13,15,16 64:5  
64:16,17 70:16 77:13  
77:18 79:15,18,18  
84:11 87:2 120:22  
130:14  
**subjecting** 19:7  
**subjects** 47:10 49:12,13  
51:5 59:13 61:16  
62:1,16,20 63:4 64:1  
74:2 79:21 80:1,3  
85:20,22 91:12  
120:22 124:3 128:7  
**subject's** 18:19 19:5  
**submicron** 121:1  
**submit** 131:4 137:15  
**submittal** 87:3  
**submittals** 86:10,11  
158:5  
**submitted** 64:15,21  
**subpopulations** 96:22  
97:8  
**subset** 48:13 50:22  
134:5,10  
**subsets** 134:5  
**substitute** 26:1  
**subtracting** 49:6  
**success** 11:11  
**successful** 132:18  
**suck** 114:17  
**sudden** 105:18  
**suggest** 110:1 137:13  
**suggested** 134:16  
**suggestions** 155:11  
**suit** 142:5  
**suits** 6:17 22:13 42:17  
42:18 144:13  
**sum** 59:5  
**summarize** 120:3,9  
131:19  
**summary** 12:7 58:6  
132:2  
**summer** 110:22  
**summers** 103:8  
**superimposed** 63:8  
**supervision** 161:5  
**supplied** 23:2  
**support** 32:18 36:17  
56:6 87:13 132:7,14  
134:1  
**supposed** 111:19  
151:21  
**sure** 2:4 17:21 57:11  
69:1,6 71:5 76:9  
77:21 84:14 92:22  
94:7 109:14,14  
110:16 111:3 129:4  
151:12  
**surface** 54:16 148:12  
**surprised** 141:15  
**surrogate** 19:19  
**surrounding** 6:4  
**survey** 4:15,17 47:18  
51:4 52:4 53:21 54:9  
54:12 55:17 57:12  
58:15 60:1 75:22  
77:17 158:15  
**sustainable** 148:17  
**sustains** 148:16  
**sweating** 103:21  
**Sweden** 71:20  
**Swedish** 72:5  
**system** 14:21 42:18  
67:5  
**systematic** 61:5

## T

- table** 2:8 22:2 58:6,13  
69:17 131:17  
**take** 10:17 43:3 77:1  
78:20 88:2,6 99:8  
103:17 107:6 112:8  
112:11,12 113:19  
135:15 150:6 152:13  
156:20 158:16,20  
**taken** 43:6 57:6 71:12  
88:11 111:9,21 112:3  
118:22 149:10 161:4  
161:9  
**taking** 77:4 103:10  
142:3  
**talk** 9:15 44:15 46:3,4,8  
46:9 50:5 73:13 96:2  
119:14 137:9 147:6  
157:22  
**talked** 91:15 110:14  
150:15  
**talking** 13:19 40:10  
42:16 44:12,21 47:8  
71:9,16 79:11 116:15  
120:5 147:10 149:18  
150:14  
**task** 99:5  
**tasks** 98:8 99:7  
**taxes** 118:6  
**teacher** 109:7  
**team** 24:2 143:3,4,8  
145:12  
**tech** 88:19  
**technical** 9:16 11:1,2  
24:1,5 119:20  
**Technologies** 22:5  
**technology** 1:2 2:16,21  
9:8 10:8 15:16 27:2  
36:19,22 45:15 64:9  
**tell** 107:18 112:9  
113:14 154:2,12  
**telling** 103:2  
**temperature** 121:8,14  
121:17 122:7,9,12  
123:4 126:9,12 127:6  
127:15,22 128:1  
142:6  
**temperatures** 96:8  
121:3  
**ten** 49:11,11 61:14,15  
67:11,11,12,14 80:1  
98:19 113:10 120:21  
124:3 125:18,20  
126:2 127:2 130:14  
139:11  
**tends** 139:8



**ten-minute** 88:2,6  
**term** 39:17 149:18  
**terminology** 134:5  
**terms** 11:5 93:3 138:18  
**test** 5:8,9 7:13 8:2,11  
     8:17 10:4,5,11 12:13  
     14:11,22 15:3,8,9,11  
     18:21 20:3 23:22  
     24:5,6,7,8 26:20 27:5  
     27:7 28:5,14,15,20  
     29:6,10 30:15,20 32:9  
     32:13 34:4 35:1  
     37:11,14 44:13 46:1,4  
     46:18 47:2,7 53:5  
     56:14 60:4 63:21  
     64:3 79:13,14 81:1,2  
     82:20 83:3,7,20 84:7  
     84:9 85:9,20 86:21  
     87:11 90:17 91:3,12  
     95:13 97:15 109:18  
     114:21 115:5 120:18  
     120:18,19 121:7,20  
     122:3,13,16 123:3,8  
     123:20 124:4,6,7,13  
     124:13 125:2,10  
     126:1,20,21 127:1,2,2  
     127:3,7,8,8,11,22  
     128:2,7,12,16,17,19  
     130:1,11,14 131:2  
     133:2,2,10,16 136:2  
     137:1,19,20 138:17  
     141:18 143:5,13,21  
     148:21 149:5 151:6  
     154:9,14 155:15  
     156:6,8  
**tested** 19:18 34:12  
     105:11 107:18 108:9  
     109:11 120:21  
**testing** 7:14 9:5,7,11  
     15:18 16:18 20:10,16  
     21:4,6,21 24:8,12,17  
     24:19 26:2,18 27:2,11  
     27:18 28:1 30:3,4,16  
     31:1 33:21 34:12  
     35:11,18 37:1,4 38:7  
     40:18 41:19 42:18  
     45:5 48:21 49:16  
     61:12 63:12 74:2  
     80:16 81:5 82:16,19  
     82:22 86:1,4,14,14  
     104:2 109:9,19 110:7  
     110:17 111:5 117:6  
     119:9,11,13,16,18,21  
     120:6,12,16,22 121:1  
     121:22 122:6,17,18  
     122:21 124:2 128:10  
     133:7 142:5 143:14  
     144:12 145:5 150:15  
     151:3,21 152:13  
     156:20  
**tests** 14:12 18:8 20:5,21  
     21:16 26:6 36:1,9  
     53:4 64:7 84:6 86:6  
     87:17 97:7 104:5  
     107:19 109:18 110:12  
     119:8 120:1 123:10  
     123:12 126:16,16  
     137:8 138:8 156:20  
**Texas** 57:13  
**thank** 16:20 17:4,16  
     31:11 36:12 41:21  
     43:5 45:20 65:15  
     87:21 94:5,6,10,14  
     101:9,10 109:5  
     115:10,11,20 117:21  
     118:12 119:3 127:12  
     129:6 131:9,10  
     157:18 159:2,9,15,22  
     160:1,3  
**thanks** 79:8 147:3  
     152:7 159:8  
**their** 4:22 18:13 22:21  
     32:1 33:3,14 36:3  
     43:12 44:1 46:17  
     47:2 48:2 53:1,3,12  
     53:16,19 54:1 55:4,8  
     64:14,16,22 66:5 76:1  
     78:7 81:19 99:15  
     104:14 107:20 108:7  
     112:12,17,20 113:21  
     114:1,4,5,7,8,8,19  
     116:11 127:17 135:6  
     146:2 150:7 154:7  
**themselves** 39:21 41:10  
**thereon** 22:3  
**thereto** 161:12  
**thing** 25:1 26:12 29:14  
     42:15 44:10 58:17  
     105:7 110:16 117:7  
     117:22 121:17 148:1  
     149:8  
**things** 17:6 40:22 41:3  
     82:4 104:21 111:9  
     129:16 131:21 132:6  
     133:17 142:15 151:8  
     153:15 157:7,22  
**think** 4:21 8:8 9:21  
     10:22 11:7 13:7 14:2  
     14:16,19 36:6 39:9,10  
     40:21 42:2,14 43:14  
     45:3 54:14 57:7  
     69:17,21 72:7,21  
     77:18 80:13 89:6  
     90:11,15 91:3,8,9,11  
     91:14,16,18 92:7,10  
     92:14,18 93:2,17  
     94:16,17 95:15,17,19  
     95:20 96:4,16,19  
     97:14,16,21 98:3,5,5  
     98:9,12,16,18,20  
     99:13,22 100:1,2,6,16  
     100:19,20,22 101:6  
     102:13,15 106:3,3,14  
     107:9,11 109:3  
     115:16,18 116:7  
     118:10,13 119:12,19  
     120:10 129:14 130:19  
     132:5,11,13,16,22  
     133:8,12,17 134:1,3,4  
     134:15 135:2 136:14  
     136:17 138:14,21  
     139:13,18,19 140:1  
     140:15,20 141:1,9  
     142:13 144:5 146:9  
     149:17 150:9,19  
     151:1 154:17,18  
     155:5,7,7 156:18  
     157:16,20 158:3,10  
**thinking** 84:2 141:20  
     149:21 158:9  
**third** 5:7 9:2 101:7  
     132:22  
**thirdly** 134:12  
**thirty** 45:12  
**though** 44:22 81:2  
     82:21 97:9 105:8  
     106:4 109:5  
**thought** 29:10 38:9  
     42:7 74:17 87:7  
     102:10,18 107:10  
     113:6 128:20 129:18  
     142:10 149:6  
**thoughts** 13:2 134:17  
**three** 5:13 18:10 23:15  
     23:18 26:22 53:7  
     56:20 57:2,5,6 58:9  
     60:16 67:15,16 68:2  
     72:3,9 74:5 79:15,21  
     83:16 85:19,20  
     119:15 121:3 148:15  
     148:18  
**three-inch** 108:12  
**three-size** 64:2  
**through** 21:5 30:11,16  
     40:12 43:17 44:8  
     45:6 63:21 65:9  
     71:21 73:10 77:21  
     100:19 102:2 114:18  
**throughout** 16:5 17:2  
**ties** 81:16  
**tight** 19:10 20:11 22:13  
     22:14  
**TILIS** 119:8  
**TILS** 35:8  
**Tim** 8:20  
**time** 20:9,19 44:17 45:2  
     45:17 47:22 48:9  
     50:6,6,13 54:8 71:14  
     72:6,7,17 73:9 86:2  
     87:2 94:18,19 99:6  
     101:11 108:6 114:13  
     115:10 120:15,16  
     125:8 126:6 127:10  
     131:5,7 136:2 140:16  
     141:18 148:22 149:17  
     149:22 150:4,6  
     154:15 158:13,16  
**timeline** 46:12 64:10  
**times** 38:17 81:17 96:5  
     160:2  
**timing** 86:10 149:16  
**tip** 78:21  
**tissue** 76:15 77:5 79:1  
**title** 45:22  
**today** 2:7 3:6 4:12,21  
     5:22 8:20 9:10 10:12  
     10:18 11:8 12:8  
     13:11,18 14:21 16:21  
     32:7 44:12 46:3 47:8  
     50:5 55:18 56:6  
     93:22 103:13 104:9  
     105:1 106:1 115:1  
     116:3 117:5 130:12  
     131:21,21 136:4  
     146:22 147:21 151:3  
     155:6 159:13  
**today's** 12:7 13:22  
     131:13  
**together** 73:5,8 82:5  
     87:2 115:6 146:13  
**told** 105:10 108:15,18  
     108:20 109:8,11  
**tolerance** 78:2  
**tool** 16:11 45:9 58:5  
**tools** 47:12 57:20  
**top** 59:14 63:8 112:10  
     112:12,13 148:14  
**topic** 6:9 136:11  
**topics** 4:9 5:21  
**total** 2:3 5:4 6:8,10 7:3  
     7:11 8:16,22 10:20  
     12:14,21 13:17 18:3,4  
     22:12,13,15 23:5,10  
     25:2,22 27:18 29:3  
     33:10 41:1,5 42:16,18  
     47:7 49:12 56:7  
     58:11 59:6 63:3,14,22  
     64:4 95:13 96:11  
     98:14 116:16 117:2,5  
     117:8 119:8,22 121:5  
     122:19 126:6 135:17  
     144:6,10 150:20  
**tough** 75:7  
**toxins** 19:8  
**toyed** 78:12  
**toying** 79:5  
**track** 136:22  
**traction** 139:5  
**Trades** 95:1 101:4  
**traditional** 55:9  
**traditionally** 55:3  
**train** 108:16 142:10  
**trainer** 101:20 107:17  
**training** 53:6 77:7,8,19  
     77:21 100:9 102:1  
     106:11 108:12  
**transcribed** 4:12  
**transcript** 161:3,6  
**trap** 103:4  
**treadmill** 130:18,20  
**treadmills** 130:8  
**treat** 77:5  
**trend** 59:16,17,18  
**trial** 115:4  
**trials** 14:12 126:15  
**tried** 38:16 77:20 157:9  
**trigger** 76:9  
**tripling** 74:1  
**true** 41:9 70:12 109:13  
     161:6  
**try** 38:19 39:11 42:9  
     62:1 68:15 88:12,16  
     128:6 130:16 138:1  
     154:20  
**trying** 19:21 41:1 79:3  
     81:13 84:14 86:3  
     87:1 150:5  
**TSI** 150:12  
**turn** 38:16 95:16 101:1  
     141:7  
**twice** 63:17  
**two** 6:15 9:13,22 12:2  
     16:21 22:18 30:1  
     35:6 48:22 49:4,6,14  
     49:14,15 50:18 51:13  
     60:13,16,19 61:16  
     62:1,18,19,21 63:16  
     63:18,19 66:10,11  
     67:14,16 68:2,11  
     70:15,16,21 76:21  
     79:21 82:4,13 84:6  
     101:13 115:6 116:8  
     121:4 122:14 125:16  
     126:15 137:14 148:18  
     149:10,12 150:13  
     157:7  
**two-stage** 138:21 139:7  
     139:17 140:3  
**two-step** 125:13 136:18  
     136:21

**type** 7:9 13:18 40:8  
45:5 66:20 71:16  
75:10,16 85:12 143:5  
156:2  
**types** 4:19 6:18 8:3  
11:9 23:13 31:7  
35:14 41:3 102:5  
110:2 111:3 119:15  
144:22  
**typewriting** 161:5  
**typical** 78:13  
**typically** 17:7 135:14  
156:3

---

**U**

**ultimately** 41:13,15  
92:12 138:6  
**uncontrolled** 142:3,11  
**under** 18:7,17 27:12  
62:6 90:5 99:11  
113:22 126:9 127:1  
128:18 129:9 134:11  
161:5  
**undergoing** 56:2 86:2  
**underline** 141:12  
**underscore** 13:21  
16:17  
**understand** 5:13 83:14  
85:16 107:21 149:13  
**understanding** 3:19  
54:7 64:8 136:6  
138:19,19  
**understands** 107:19  
**underway** 34:17  
**unfold** 11:8  
**Unfortunately** 21:12  
**uniform** 15:3 47:14  
52:9 127:20  
**unintelligible** 71:15  
**Union** 101:19 108:2  
**unions** 95:2  
**United** 140:19 147:19  
**University** 73:1  
**unknown** 135:15  
**unless** 155:3  
**until** 19:3 101:2  
**updated** 34:21  
**upper** 49:3,8 62:13  
82:10  
**upside** 17:6  
**upstream** 40:16  
**urge** 142:8  
**Usage** 21:13  
**use** 11:20 19:8 22:2  
27:6 28:21 33:2,12  
35:7 40:11 42:4  
43:21 44:20 46:5  
49:17 50:8,10,14 54:9

55:5 56:19 57:20,22  
58:5 63:11,13 67:5  
68:10 70:4 92:6 93:5  
96:7 98:21 100:17  
107:22 114:4 124:9  
124:19 125:7 130:14  
132:20 134:22 137:16  
145:9,20,22 148:4  
152:21 154:8 155:22  
**used** 9:7 15:19 16:11  
27:2,18 28:7 40:9  
42:8 44:3 45:13  
46:17 47:10,10 50:1  
53:8 54:13,19 55:11  
66:14 77:16 79:18  
98:11 116:20 117:14  
127:3 128:6 138:5  
144:21  
**useful** 138:2,15  
**user** 6:13 7:3 25:4 33:2  
81:12 82:5 93:14,15  
93:20 127:17 154:7  
**users** 24:2 31:6 32:22  
33:11,15,21 55:18  
56:12 116:17 117:16  
117:18 118:2  
**user's** 10:19 27:16,19  
93:8 117:7,11  
**using** 18:8 36:9 39:17  
39:18 49:4 55:5  
56:18 81:6 87:13,15  
119:22 122:22 125:11  
126:10 130:8 133:13  
134:9  
**usually** 107:16  
**utilizes** 156:8  
**U.S** 46:2 47:17 48:6,14  
48:18 50:20 51:7,10  
54:18,20 60:3 68:20  
101:8 133:22  
**U.S.A** 52:22

---

**V**

**vague** 106:18  
**validated** 91:5  
**validating** 136:16  
**validation** 21:4 24:19  
31:1  
**validity** 138:20  
**valuable** 158:17 160:3  
**value** 25:9 26:16 46:22  
**valve** 41:3 99:18  
110:18,18,21 113:19  
**valves** 98:22,22 114:1  
**vapor** 19:13,14,17  
103:18 107:9 109:1  
**variable** 42:12 48:9  
76:7

**variables** 101:2 120:10  
120:10 151:2  
**variance** 76:15 78:15  
**variation** 15:7 40:7  
48:3 54:7 67:13,18  
68:3 70:6 122:2  
125:2  
**variations** 41:13  
130:15  
**varied** 54:2 58:13  
142:22  
**variety** 149:14 156:13  
**various** 15:1 36:21 38:7  
47:11 56:18 57:16  
65:8 149:13  
**vary** 38:15 81:6,8  
**varying** 77:5  
**verified** 125:5  
**versus** 68:20 69:8  
136:3  
**very** 3:16 5:16 13:7  
41:13 42:22 44:12  
47:11 57:8,19 59:16  
63:10 64:7 69:18,22  
70:18 71:10 72:2,13  
75:7 89:19 90:13  
91:16 93:11,13,14  
94:5 96:8,11,16 97:11  
97:12 99:5,6,7 106:18  
110:19 121:19,20  
122:2,7,15 123:1  
136:20 137:4 138:7  
139:15 146:4 147:17  
147:19 148:1 149:17  
149:22  
**Veterans** 31:20  
**view** 8:13 10:6 56:3  
117:7,12 136:10  
139:21  
**views** 56:4  
**vigorous** 89:19  
**vincent** 85:14,14 86:9  
86:22  
**Virginia** 1:22 57:14  
**virtually** 19:22  
**visualizing** 148:20

---

**W**

155:2,6 156:5,7,16  
158:22 159:9  
**wanted** 74:18 95:12  
152:19 153:8  
**wants** 135:3 153:18,19  
**warfare** 87:16  
**warn** 103:16  
**Warren** 146:17,18  
**wasn't** 19:3 150:17  
**watch** 158:12  
**water** 110:22 113:5  
114:5,6  
**watts** 148:11  
**way** 39:9 40:15 60:18  
68:15 72:1 75:3  
84:12 90:9 100:4,10  
110:10 112:16 129:15  
129:19,19 130:18  
141:2 149:2  
**ways** 138:16 141:4  
**wayside** 83:10  
**wear** 106:11,14 110:13  
112:7 113:9 116:6  
117:18 118:8 120:22  
124:7,8,9 156:3  
**wearer** 7:1 26:6 93:8  
93:20  
**wearers** 14:17 19:11  
26:2 90:15,21 93:1  
**wearer's** 90:10  
**wearing** 14:8 20:11  
91:14 104:12 106:12  
111:2,15 115:13  
116:9 156:10  
**website** 6:3 8:9 34:21  
89:22 158:10  
**Wednesday** 1:7  
**weed** 150:12,12 152:8  
**weeds** 90:19  
**week** 77:7  
**weeks** 71:7 140:18,18  
**weigh** 97:4  
**welcome** 2:2 3:13 5:3  
17:18 26:10 29:16  
44:20 65:13 158:6  
**well** 8:1 19:20 35:8,13  
40:21 41:3,6,8 43:2  
63:10 69:3 73:18  
77:3 83:22 84:8 86:8  
86:12 87:12 88:17,22  
94:19 95:11 98:4,14  
99:2 110:4 117:20  
127:4 132:19 136:1  
137:6,17,17,21 144:7  
146:13 147:12 153:21  
154:9  
**went** 56:12 57:12 65:4  
71:20 74:8,12 89:22

105:20 106:2  
**were** 4:9 18:8,14,17,20  
20:5,6 21:16 23:13  
27:21 28:6 29:9 32:4  
36:5 46:20 47:16  
49:18 53:13 55:15  
60:9,18,20,20 61:2  
62:4 66:7 79:16  
80:15 90:4,4 94:9  
95:7 102:18,19 105:7  
108:6 109:3,11 111:2  
111:16,16 112:4  
144:10 145:2 160:5  
161:9  
**wet** 111:4  
**whatsoever** 74:3  
**while** 38:6 53:5 55:6  
133:7  
**white** 51:6,8,11,15,16  
53:22 54:7 57:1 69:8  
69:12,20  
**whole** 54:21 85:6,13  
89:10 95:22 100:19  
100:20 129:5 149:21  
153:7  
**wide** 108:13  
**wide-mouth** 78:13  
**width** 48:22 49:1,18  
53:9 54:3,22 55:11  
58:5 59:8,10 61:1,11  
62:4,8,11 63:7 66:1,7  
66:13 70:3 72:9,14  
73:15  
**wind** 40:15  
**winter** 103:19 107:10  
110:19 113:18  
**winters** 103:8  
**wise** 154:20  
**wiser** 103:1  
**woman** 47:18  
**women** 110:3  
**wonder** 106:1  
**wonderful** 32:18  
**wondering** 69:9  
**woodhall** 32:16,16  
**words** 17:17 83:2 130:8  
135:16  
**wore** 107:13  
**work** 8:1 18:11 24:10  
45:10 64:11 71:6  
73:8,20 82:4 97:1  
98:8 104:12,17 105:5  
106:4 107:15 109:12  
111:1,7,8,12 112:7,21  
112:22 113:20 114:3  
114:12 117:2 123:9  
127:7 130:16 132:10  
132:21 133:22 134:2

134:7,21 135:8,12,13  
 136:15 137:1,19  
 138:13 139:2 141:2  
 148:8,19,21 149:1,12  
 154:22  
**worked** 37:6 101:19,21  
 102:13 112:1 114:9  
**worker** 13:6 21:1 92:11  
 100:3 104:20 124:9  
 124:12 132:19 139:20  
**workers** 14:7 21:5,7  
 53:21 55:21 58:19  
 60:3 80:16 93:15  
 95:3 97:18 99:15,17  
 100:11,17 101:17  
 104:10 105:17 129:11  
 130:17 140:19 141:1  
**worker's** 65:17 94:13  
 94:21 101:5 105:3  
**workforce** 46:2 50:18  
 51:22 93:5  
**working** 2:10,12,16 6:6  
 18:2 94:18 95:4,10  
 100:16 101:5 111:12  
 114:13,15 118:9  
 145:12  
**workload** 111:6 123:21  
 130:10,21  
**workplace** 16:12,13  
 20:8,22 29:13,14  
 116:21 119:9,11,18  
 119:21 120:6,8,12,15  
 122:14,16,17 126:13  
 129:10 130:17 138:5  
 138:9,12 151:21  
 152:13  
**works** 130:5  
**world** 115:15 147:22  
**worn** 103:13 105:5  
 106:5,8 112:4 113:17  
**worry** 152:3,8  
**worst** 122:21 123:2  
 127:18  
**worth** 94:19  
**worthwhile** 149:6  
**wouldn't** 80:17 111:2  
**WPF** 127:4  
**write** 85:4 116:10  
**writing** 20:6 23:9 94:8  
**wrong** 26:11 110:10  
 112:5 145:19

**Y**

**yeah** 37:21 38:4,20,21  
 39:12 45:22 46:13  
 47:2,13,15 52:2,5,11  
 53:9 55:22 56:20  
 57:4,11 58:6,12,15,21

59:2,3 60:5,6 61:13  
 62:15,19 63:3,18 64:6  
 64:10 66:11 72:20  
 77:6 78:17 81:7  
 82:13 88:22 89:2  
 129:4 130:3,18 146:9  
 159:7  
**year** 12:4 30:4 65:11  
 93:11 119:6,22  
 149:21 151:4  
**years** 17:10 18:1 45:6  
 45:12 50:21 71:20  
 95:5,9 98:19 101:20  
 105:19 108:19 113:10  
 139:11 149:10,13,18  
 159:12  
**yesterday** 90:1,3  
**York** 57:14  
**young** 52:11 102:17,21  
 103:2

**Z**

**Z** 85:22  
**zero** 40:17 121:3  
**zhuang** 1:16 2:14,15,15  
 5:10 25:19 37:21  
 38:20 39:9 44:15  
 45:10,15,20 66:4  
 68:22 69:5,16 72:20  
 74:10,16,19,22 75:3  
 75:20 76:7,13,19 77:6  
 78:6,17 79:7,17 80:8  
 80:20 81:4 87:21  
 96:14,21 150:17  
**ziquing** 1:16 2:15  
**zone** 7:1  
**Z's** 31:12  
**Z88.2** 22:16

**0**

**04** 30:11,11,16  
**05** 30:17

**1**

**1** 23:19 30:9,14 63:14  
 63:21 64:3 68:13  
**1,454** 58:12  
**1,467** 52:20  
**1.2** 70:11  
**1:30** 118:21  
**10** 43:4 51:11 53:11  
 63:14,22 64:4 89:17  
**10.3** 53:12  
**100** 40:11 126:14  
 135:18  
**11** 51:16 69:20  
**117.5** 49:1  
**12** 51:18 69:21

**12-month** 23:16  
**12.6** 53:16  
**120** 62:11  
**134** 22:1  
**139** 62:10  
**14** 58:12  
**15** 95:2,5 113:10 121:4  
 124:15 139:11 148:18  
**15,000** 38:14  
**15-minute** 43:3  
**15.3** 59:20  
**153** 49:2  
**16** 38:14 55:14,19  
 64:17  
**160** 62:11  
**166** 70:13  
**18** 52:6 57:2 60:14  
 71:14 101:20  
**18.3** 59:4  
**19** 63:2 131:3  
**1910** 22:1  
**1934** 18:8  
**1959** 18:18  
**196** 90:4  
**1965** 18:18  
**1967** 47:17 60:1  
**1967-1968** 51:4  
**1968** 47:17  
**1972** 19:3  
**1975** 52:20  
**1991** 119:20 120:4  
**1995** 20:2  
**1996** 73:22

**2**

**2** 24:7 30:15 38:13  
 124:18 143:20  
**2,000** 38:13  
**2,543** 58:11  
**2:37** 160:5  
**20** 60:14 125:3  
**200** 48:1 135:18  
**2000** 51:5,14 52:5  
**2001** 21:14  
**2002** 65:1  
**2003** 21:14 65:3,4  
**2004** 1:7  
**21** 18:7 121:4,11  
**21A** 18:17  
**21B** 18:18  
**21C** 19:8  
**24** 58:22  
**25** 1:7 49:12,20 61:15  
 63:2,15 79:18,21 86:3  
 108:3  
**25-member** 48:20  
**275** 148:11  
**28** 60:10

**29** 52:6 57:2  
**29CFR** 22:1  
**2900** 121:11  


---

**3**  
**3** 24:17 31:1 49:15 95:2  
**3,000** 38:13  
**3,997** 57:4  
**3-D** 55:4,5  
**3.3** 55:18,19  
**30** 18:8,12 50:20 52:6  
 52:14 57:3  
**32** 121:4,12  
**33** 60:10,17  
**350** 97:4

**4**

**4** 51:19 62:20 63:21  
 64:3 124:16  
**40** 17:10 18:1 70:17,22  
**40-hour** 99:9  
**44** 52:7,14 54:20 57:3  
**45** 52:7,15 57:3 113:15  
**48** 53:21

**5**

**5** 51:19 59:1 62:20 64:3  
 68:13 70:10 148:19  
**50** 64:1 70:9 97:7  
 121:19  
**50,000** 125:9  
**500** 126:9,11  
**500,000** 55:20  
**53** 21:15

**6**

**6** 63:21 64:4 69:21  
 124:16  
**6.2** 63:1  
**6.8** 63:1  
**60s** 52:1  
**65** 126:6 148:11  
**66** 52:7,15 57:3  
**67** 52:2,4  
**68** 52:2,4 60:1

**7**

**7** 64:3 72:6  
**70** 51:15 69:20  
**70s** 66:21  
**75** 59:18 64:5 85:19,19

**8**

**80** 67:17 121:12  
**80s** 120:14  
**80,000** 95:3  
**84** 20:2,6,15 21:20 90:5  
 131:3,3

**84.7** 59:6,21  
**85** 121:5,12  
**87** 119:17  
**88** 76:1 77:17  


---

**9**  
**9:02** 1:21  
**90** 48:18 51:10 67:17  
 68:14  
**93** 70:12  
**95** 40:11 48:18 68:10  
 68:11,16 70:8  
**96** 63:3  
**98** 51:8  
**99** 51:8 62:9