NIOSH/NPPTL Public Meeting to Discuss Escape Respirator Standards Development Efforts for Respiratory Protection Against Chemical, Biological, Radiological, and Nuclear Agents (CBRN)

> April 29, 2003 Radisson Hotel Pittsburgh Green Tree Pittsburgh, Pennsylvania

TRANSCRIPT LEGEND

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1 PROCEEDINGS

- 2 ROLAND BERRY ANN: Good morning everyone. Let me start
- 3 out by saying Rich Metzler, the Director of the National Lab,
- 4 had planned and hoped to be here this morning, but
- 5 unfortunately he had to be in D.C. for meetings and was unable
- 6 to make this, but we want to thank everybody for taking time
- 7 out of their busy schedules to be here today. We're expecting
- 8 lively discussions, good exchange of information, and welcome
- 9 to Pittsburgh. Now John Szalajda will give you details
- 10 of . . . the . . . what's going to happen today. Thanks
- JOHN SZALAJDA: Well obviously I'm not Rich Metzler
- 12 either, but again, thank you for your attendance on this topic
- 13 and this continues what we're trying to do at NIOSH in terms
- 14 of using conceptual discussions to promote ideas and dialogues
- 15 for chemical, biological, radiological, and nuclear standards
- 16 to protect workers. In this case, we're addressing the
- 17 development of CBRN standards for an emergency escape hoods or
- 18 masks. We have a pretty ambitious agenda for today. What
- 19 we're going to try to do is to break down the day into a
- 20 couple of discrete areas. This morning we're going to
- 21 concentrate on the air purifying aspect of the escape
- 22 respirator. You're going to hear some discussions regarding
- 23 the overall strategy as well as some of the conceptual
- 24 requirements that we're considering at this time for the

- 25 respirator. Unfortunately, there'd be one small change,
- 26 Mr. Mattson from NIST is not here. I'm not sure if he's in
- 27 route or not. So we're going to skip over that part of the
- 28 agenda and bring him in later on if the schedule permits.
- 29 Some of the topics that we'll be covering through this
- 30 morning include the gas-life requirements for the respirator
- 31 as well as special tests that we're considering, in
- 32 particular, chemical warfare agent testing and laboratory
- 33 respiratory protection level or LRPL testing that we're also
- 34 considering. This afternoon we're going to move to another
- 35 area where we'll be looking at a self-contained escape
- 36 respirator. In addition, we're also going to be covering work
- 37 at NIOSH and SBCCOM are collaborating on in terms of
- 38 developing simulants to assist manufacturers in the design of
- 39 their equipment. And near the end of the day, Mr. Boord is
- 40 going to lead us, lead a discussion on some of the other topic
- 41 areas that NIOSH is addressing, in particular, things that
- 42 might be of interest to the manufacturing community, are R&D
- 43 program that we're conducting with SBCCOM to allow testing,
- 44 chemical warfare agent testing prior to the submittal of an
- 45 application.
- 46 In terms of the actual standards development, we've come
- 47 a long way with the program that initially NIOSH set out to
- 48 build partnerships with other Federal agencies to include the

- 49 National Institute of Standards and Technology, Soldier
- 50 Biological Chemical Command, Occupational Safety and Health
- 51 Administration, National Fire Protection Administration, and
- 52 we've defined working relationships with these agencies
- 53 through interagency agreements which allow us to cooperate,
- 54 provide some linkage and allow us to cooperate in development
- 55 of the standards.
- We've also received funding to develop the CBRN standards
- 57 from a variety of sources. One that we have received money
- 58 through the Centers for Disease Control to address CBRN as
- 59 well as initial funding and continuing funding through NIST
- 60 from the National Institute for Justice. We also have
- 61 established a good working relationship with our partners from
- 62 the Army at the SPCCOM Soldier Biological and Chemical Command
- 63 to support us and using their expertise on testing with the
- 64 chemical warfare agents as well as the laboratory protection
- 65 level testing. I talked . . . I briefly talked on the topics
- 66 that we're going to be covering this morning earlier.
- As far as some of the logistics concerned with the
- 68 meeting, there were signup sheets in the back. If you
- 69 didn't . . . If you snuck in without signing in, I encourage
- 70 you at some point this morning to go back and register that we
- 71 can record your attendance here at the meeting. Also just
- 72 wanted to remind you that we are transcribing the meeting in

73 terms of the actual discussions and comments from the 74 audience, what we'd like you to do at the point where the forum is opened up for your comments and your discussion, to 75 come to the microphone in the center of the aisle and identify 76 77 yourself and your organization as well as providing your 78 comment. Also if we have an open period at the end of the day 79 to cover any additional presentations if there's anyone in the audience that would like to address the meeting. If you could 80 81 either let me know or let the ladies in the back know who are coordinating the meeting and we'll get you billed into the 82 83 agenda. Another, a couple other administrative things that 84 came to my attention, I think when you all came in, you received this packet. In there, there's a survey which we 85 86 would like you to fill out and leave at the sign-in desk at 87 the end of the day. Also it was brought to my attention that the hotel is offering a buffet lunch at the River's restaurant 88 off the main lobby. I quess the buffet is \$9.95 so if you're 89 interested in staying within the confines of the hotel, it 90 91 sounds like it might be a good opportunity for you to sustain yourself during the course of the meeting. One other thing to 92 bring to your attention before we get into the conduct of the 93 94 meeting is that NIOSH has created a docket to receive public comment regarding the standards development efforts and in 95 this, we'd like . . . the purpose of the document or the 96

- 97 docket is to solicit information from stakeholders and
- 98 interested parties that you feel should be considered by NIOSH
- 99 and this part of the standards development effort and there's
- 100 several different ways of contacting the docket office either
- 101 by mail, e-mail, fax, or phone. Those are all provided on
- 102 this slide. Also I think probably most of you are aware that
- 103 we try to make extensive use of our web site in promoting the
- 104 concepts and ideas that we're considered for the standards
- 105 development and that's our web site right there. And with
- 106 that, right now we'll move to . . .
- 107 ROLAND BERRY ANN: Can we load Phil's?
- JOHN SALLOTTO: If you can bear with us for a minute,
- 109 Mr. Mattson is here and we'll load his presentation and . . .
- 110 PHILLIP MATTSON: And we've had the privilege of working
- 111 with NIOSH and SBCCOM for about, I quess, about 3 years now on
- 112 this project. And I'm going to talk a little bit about how we
- 113 got here, how we are managing a program that to this point has
- 114 been funded by the National Institute of Justice to develop a
- 115 suite of CBRN protective standards, and kind of where we're
- 116 going which we really don't know, but that's okay.
- 117 Again, the Office of Law Enforcement Standards at NIST,
- 118 what does the . . . why is there an organization dealing with
- 119 law enforcement at the National Institute of Standards and
- 120 Technology which was the organization formerly known as the

- 121 National Bureau of Standards? Some of you may remember 1967;
- 122 some of you may not. In 1967, it was period of great unrest
- 123 in this country. The crime rate was going up, confidence in
- 124 public security was going down at that time. A study was done
- which basically indicated that the law enforcement community
- 126 was inadequately equipped in that they had a difficult time in
- 127 order to determine what type of equipment to procure.
- 128 Basically if you were a sheriff in New Mexico or a police
- 129 chief in Chicago or something like that, you were basically
- 130 left with the sales brochures and the salesman and the vendors
- 131 coming in telling you what they could do for you without a
- 132 great assurance that even if the equipment did as they as
- 133 advertised, that it would fill your needs. And this is not a
- 134 mark against the manufacturing community and in a lot of cases
- 135 they just didn't know what the requirements were that they
- 136 needed to meet.
- Jurisdictions found themselves shelling out truckloads of
- 138 money on equipment that may or may perform their job. In
- 139 1971, the National Institute of Justice established what was
- 140 then known as the Law Enforcement Standards Laboratory at the
- 141 National Bureau of Standards. The NBS at that time was the
- 142 country's leading forensics lab and had years of experience in
- 143 developing standards and measurement technologies. So at that
- 144 time it seemed a reasonable fit. And then later on, we were

- 145 changed to . . . the name was changed to the Office of Law
- 146 Enforcement Standards.
- 147 We support the development of performance standards for
- 148 the National Institute of Justice. One of the major more
- 149 popular well-known standards that we develop is the standard
- 150 for body armor which is administered through NIJ and to this
- 151 point I believe it's approximately 2,600 law enforcement
- 152 officers' lives have been saved by wearing compliant body
- 153 armor and no officer has lost their life by wearing the
- 154 appropriate body armor. We talked a little bit about
- 155 performance standards. These are the missions of OLES to
- 156 develop or assist in the development of performance standards,
- 157 assist in compliance testing programs, develop technical
- 158 reports, and users' guides. You know, talked about minimum
- 159 performance standards, we're not talking mil specs. We're
- 160 talking about a standard that as opposed to a design standard
- 161 which says how you're specifically going to build it. We're
- 162 more concerned about performance standards which says it needs
- 163 to be able to perform in this manner under these conditions.
- 164 Now the Office of Law Enforcement Standard is a matrix
- 165 management organization. This picture was taken on one of our
- 166 better days and we're basically a group of program managers
- 167 that identify the needs of the customer, the community, and
- 168 develop teams and networks of organizations in order to

169 accomplish the mission. We're organized into six major 170 program areas which are outlined here. The CBRNE standards 171 effort is within the Critical Incident Technologies program 172 The senior program manager is Dr. Alf Ataw* and I'm his 173 assistant or backup or whatever. We focus in two main areas: developing a suite of CBRNE standards and also a series of 174 175 equipment guides which some of you may be familiar. When we talk CBRNE we're talking chemical, biological, radiological, 176 nuclear, conventional explosives and incendiaries. 177 178 people sometimes wonder what's the difference between an RDD, 179 the R and the N, the R generally refers to radiation dispersal 180 devices where you have some sort of radioactive material that 181 is then disseminated either through an explosive device or something like that. The N is the nuclear which is generally 182 associated with a mushroom cloud, and after the mushroom cloud 183 184 is gone, then you have a very large RDD to clean up. Also this year we're looking to incorporate into our 185 program communication interfaces with the first responders 186 187 which is definitely going to be of interest regarding 188 respiratory protection in order to make those interfaces work. 189 For each of the areas, the chem, the bio, the rad/nuke, we're 190 looking at the full suite of protective equipment including 191 respiratory protection, protecting ensembles, the necessary detection equipment standards, decontamination, and then the 192

- 193 supporting guides and testing programs in order to pull the
- 194 whole thing together.
- Now we didn't get there on our own. We work quite
- 196 closely with an organization called the IAB, the Interagency
- 197 Board for Equipment Standardization Interoperability. One of
- 198 the first things that the IAB did was to develop what is
- 199 referred to as a standardized equipment list or SEL which
- 200 basically outlines the equipment that is needed to outfit
- 201 various types of organizations to respond to WMD-type
- 202 incidents. One of the first things that the IAB noted after
- 203 they pulled the equipment list together was that they wasn't
- 204 really certain that . . . the IA . . . the SEL, if you had a
- 205 chance to take a look at it, is rather generic. It says
- 206 radiation detection equipment and so on. We're currently
- 207 working to make it a little more specific, but one of the
- 208 concerns is that they be interoperable that you're going to be
- 209 able to respond to a multi-jurisdictional incident and again
- 210 that the equipment is going to perform as you desire to meet
- 211 your needs.
- 212 So based on the results from the IAB and a number of
- 213 other areas, a multi-disciplinary organizational team was
- 214 formed to address the first priority of the IAB which was
- 215 standards for respiratory protection which includes obviously
- 216 self-contained breathing apparatus which was the first

- 217 standard that was developed by this group. The funding was
- 218 provided through the National Institute of Justice and two of
- 219 the main players on this group has been obviously NIOSH and
- 220 SBCCOM but with participation from a number of other
- 221 organizations as well.
- Now as you can imagine, there's a number of technical
- 223 challenges associated with this. First of all, there's a lot
- 224 of information out there on the military aspects of chemical
- 225 and biological warfare agents, but a lot of that was behind
- 226 the green door. Our partnership with SBCCOM has helped
- 227 address that, but also the fact that a lot of the military
- 228 scenarios and the military equipment don't necessarily pertain
- 229 to typical first responder incident, whereas in the military
- 230 environment chemical warfare agent is disseminated is
- 231 generally going to be outside. The military suits up and goes
- 232 around it or scoots through it. In the civilian terrorist
- 233 incident, you're not necessarily going to have that luxury.
- 234 It could very well be a dissemination of a chemical warfare
- 235 agent in an enclosed area, you know building, subway, shopping
- 236 mall, sports arena, and the responders to that don't have the
- 237 luxury of going around it or avoiding it. The first
- 238 responders are actually going to have to go into it and so
- 239 it's going to be a much higher concentration of potentially
- 240 than the typical military scenario. The civilian equipment

- 241 which has been working fine for years against toxic industrial
- 242 chemicals going against chemical warfare agents is a new
- 243 untested arena and as many of you have found out doing through
- 244 the SCBA testing that chemical warfare agents do behave
- 245 differently.
- This is next . . . a little bit . . . kind of explains
- 247 the methodology for the program. First thing that is done is
- 248 to do a hazards vulnerability assessment to identify what is
- 249 the threat, what are the conditions, the operating conditions,
- 250 and are we looking at exposure limits, protection factors
- 251 required for protective equipment? Are we looking at key
- 252 values that we need to ensure that our detection equipment
- 253 will be able to detect?
- Next is the process to develop the standard, examine
- 255 existing standards and test protocols, determine the required
- 256 performance doubles for the equipment in question, and then to
- 257 draft test methods and standards in order to evaluate the
- 258 equipment. We then procure equipment and test our test
- 259 methods to make sure that something that was put together by
- 260 committee is actually something that can be executed
- 261 reproducibly in a laboratory and modify accordingly and then
- 262 the standard is revised and issued through the appropriate
- 263 means whether it's through NIOSH or NFPA or NIJ or ASTM or
- 264 ANSI as the case may be.

- Next and very important is a compliance or certification
- 266 testing program. You have this wonderful document that says
- 267 you know what the equipment should do and how you should test
- 268 it. Then you need to test it to make sure that everything is
- 269 working. Develop a user guide, these are decision guides
- 270 which take the technical standard and convert it into a useful
- 271 English that is going to be understood by the folks in the
- 272 field that are using it or the procurement officials which
- 273 outlines the capabilities and limitations of the equipment as
- 274 a result of the standard.
- 275 And then obviously, you need to be able to maintain and
- 276 update the standard as new technologies come into play,
- 277 lessons learned through the testing program, maintain a data
- 278 base of compliant equipment, and so on, but again, this
- 279 process is not done in a vacuum either. There's procedures
- 280 built in throughout to solicit public and user comments such
- 281 as this forum right now.
- We've achieved a number of milestones in this program
- 283 which have directly as a result of the work with NIOSH and
- 284 SBCCOM to examine the threat agents and concentrations.
- 285 Modeling was done to do that. The SCBA certification is
- 286 undergoing. The APR testing or standards and applications are
- 287 being accepted now for the APR. Now we're here for escape
- 288 masks.

- 289 In other areas, we're working with NFPA and other organizations on protective ensembles and the challenge there 290 is going to be ensure that the interface between the 291 respiratory protection and your ensemble is not going to be a 292 path of entry. And we have published through the National 293 294 Institute of Justice a series of equipment guides which are basically information in one area for users, procurement 295 officials to see what kind of equipment is out there. We're 296 297 currently in the process of updating the guide for chemical and biological detection equipment. We hope to produce a 298 299 guide for radiation detection equipment, explosive detection 300 equipment, and then we will go on and revise the guides for 301 the decontamination and communications in PPE. We eventually, 302 as it stands right now, these guides basically reflect in a 303 qumball chart kind of affair the manufacturer's claims on the performance of the equipment. We hope to be eventually able 304 305 to provide actual testing results as testing programs ramp up 306 and we're going to have this migrate to a web-based report as 307 opposed to producing hard copy. Because by the time you get a 308 hard copy through all the editors and reviews and so on, it's 309 been a year and a half since we started it. It's already out 310 of date.
- Now, what's happening with the program, as I stated, we have been funded to this point from the National Institute of

313 Justice. Now with the establishment of the Department of Homeland Security, the Department of Homeland Security is 314 going to be picking up the funding for this program and 315 obviously with a new sponsor there's going to be potentially 316 some slight tweaks in priorities and so on. We're in the 317 process of sorting that out with the Department of Homeland 318 319 Security. There's two main potential sponsors: the Office for Domestic Preparedness which previously was within the 320 Justice Department that handles the training for law 321 enforcement and equipment grants for law enforcement 322 communities. They're in one directorate of Homeland Security. 323 Another organization which is responsible for developing 324 standards within DHS which is in there science and technology 325 326 directorate is another organization that we're negotiating with and it's been high adventure. 327 One of the results of all these changes and so on is the 328 Office of Law Enforcement Standards. We are changing our name 329 330 to something much more simpler, the Technology Office for 331 Public Safety and Security Standards or TOPSSS. We haven't quite . . . You know what . . . one of the things is . . . in 332 order to be a viable organization, you have to have a good 333 acronym. You have to have a good logo and you have to have a 334 budget. Okay, we'll just leave it at that. I guess we're 335 going to be the office formerly known as OLES for awhile. 336

- 337 Bottom line is standards and that's what we're all here
- 338 about. From our prospective, this is our definition.
- 339 Actually this comes from Webster's dictionary of standards,
- 340 conspicuous object such as a banner or flag carried to the top
- 341 of a pole and used to mark a rallying point especially in
- 342 battle or to serve as an emblem that is our prospective of
- 343 standards. One thing that we hope to achieve through the work
- 344 here is to avoid something like this . . . (background noise
- 345 occurs) hopefully our standards will be a little more clear
- 346 and a little more effective than this.
- And so for right now anyway, the contact information is
- 348 still the same, the phone number will still be the same, and
- 349 I'll be available I quess I don't know if we have a couple of
- 350 minutes for questions now or later. Thank you.
- 351 LES BOORD: Good morning. Phil, unfortunately, I
- 352 remember 1967. I think I remember it too well. What we'd
- 353 like to do to kick this session off is talk a little bit about
- 354 the Standards Development Program and some of you have seen
- 355 some of this before so maybe it'll be a little bit redundant
- 356 for you. I think it's worthwhile to go through the whole
- 357 picture so that we all see where we stand, but where we've
- 358 been touches a little bit with what Phil mentioned. We have a
- 359 CBRN SCBA standard which was announced in December 2001. We
- 360 have a CBRN full-faced piece air purifying respirator or gas

mask standard which was announced in March 2003. We are currently in the certification process for both the SCBA and the gas mask standard and we are in the development stages for

the CBRN escape respirator.

- To put it all in perspective I think on this timeline, you can see the SCBA, December, the gas masks last month, the escape respirators we're targeting that for October of this year for finalization of the requirements, and from there we'll move on to the powered air-purifying respirators which are currently targeted for March of next year. And then following that, we'll look at other classes and types of respirators, particularly the combination-type respirators.
 - The program that we're following, the CBRN concept development program, we do have a program management system in place where we identify milestones and timelines associated with the programs and I think as most of you can recognize in good program management, you need to do that in order to keep the programs moving and to achieve the endpoints. Part of the process includes . . . a very valuable part of the process I may add includes the stakeholders' meetings and discussions that we have including public meetings such as this. The dialogue that we can conduct with the experts in the field from all perspectives from the users, from the academia, from manufacturing are very valuable in constructing the standards.

385 The process that we use to do that is what we call concept 386 development so I think most of you being here in this room today to listen to these presentations are familiar with the 387 388 concept papers that we use to identify concept requirements. The concepts as they are matured and become refined and become 389 390 more clearly visible that input and content is reflected into 391 the concept requirements. What we try to do is address 392 performance and design requirements, okay, primarily the 393 interest is to go for performance requirements so the 394 preference is to identify performance requirements for the 395 respirator. However, I think as we all know from our experiences with respirators or standards in general, it's not 396 397 always entirely possible to achieve the endpoint that you want 398 just by a performance standard. In many cases, there are 399 requirements to specify design requirements. So I think the 400 more in a philosophical way, I think the more defined the user 401 segment becomes in the user group for the type of respirator that we're defining, the more likely there is to be design-402 403 type requirements because typically the user will have very strong interests on certain requirements. 404 So design requirements do work their way into the standards where we 405 need to ensure technical integrity of the requirements and 406 technical integrity of the product that's tested against them 407

- 408 and where we have strong user demand, but clearly the
- 409 preference is for performance-based requirements.
- 410 Following our concept program of concept development, we
- 411 try to maintain and it may not seem this to all who are
- 412 viewing it, but we try to maintain a logical and consistent
- 413 rationale following sound engineering and scientific
- 414 principles when we identify both performance and design
- 415 requirements. The consequence of this is that we certainly
- 416 find ourselves in positions where perhaps we're stretching the
- 417 technology, the technology that's traditionally or routinely
- 418 used for respirator performance and design. The result of
- 419 that is that existing respirators may not comply with the
- 420 standards that we're developing as we move forward, but with
- 421 that in mind, we always try to make sure that even when we
- 422 stretch that technology that the requirements are still within
- 423 reach of state-of-the-art available, state-of-the-art
- 424 technology for design and performance.
- With all that in mind, the topic that we're here to talk
- 426 about today is the CBRN escape respirator and as many of you
- 427 who have heard me say before I think you really need to have a
- 428 goal when you launch a project and you want to achieve an
- 429 endpoint. The goal for this particular effort is to develop a
- 430 standard for an escape-only respirator that address CBRN
- 431 inhalation hazards for use in terrorist events by the general

- working population. So you may ask well what is the general
 working population and we envision that as the people perhaps
 in this room, office workers, perhaps emergency responders to
 some degree, but basically the standard and the most important
- so beine degree, but bubleally one beambally one entry
- 436 point is the standard that we are working on and developing is
- 437 intended for the general work force.
- 438 When you look at the problems or the challenge of designing an escape respirator standard, it certainly begins 439 440 with hazard analysis and I think for escape hazard analysis is a very complex problem. And the reason is you need to have 441 442 some idea of what the intentions are for escape from where and 443 from what. Traditionally within the discussions of terrorism response and terrorism incidents and events, we talk about hot 444 445 zones where we have high concentrations, potentially high 446 concentrations, warm zones where you have perhaps the support 447 activities that may result from a terrorist event or develop 448 over a period of time. So there just inherently are a wide 449 variation in the hazards, the possible hazards, and threats 450 that an individual may need to escape from. So we have 451 multiple, in addition to that, we have multiple escape activities. Okay, we talk about hazard and threat analysis 452
- 453 and hazard and threat analysis can very much be site specific.
- 454 I think when you think about it, the hazard or threat
- 455 situation for . . . may differ from metropolitan area to

- 456 metropolitan area. The threat for perhaps Washington, D.C.,
- 457 is different than the threat that may exist in Houston, Texas,
- 458 or in Chicago or Los Angeles. So I think depending upon
- 459 proximity to industrial facilities and what the basic threat
- 460 for that area is so I think site specific is one of the
- 461 primary factors.
- I addition to that there are different escape strategies.
- 463 Most people think escape, put it on, and run till you get out
- 464 and that is, that's an escape strategy, but that may not be
- 465 the only types of activities that you need to perform in an
- 466 escape scenario. Okay, you may need to, you may intend to put
- 467 it on and run till you get out, but you may get out to that
- 468 stairwell and find out geez*, this crowd isn't going down
- 469 those steps so easily or up the steps. So you may actually
- 470 find yourself very rapidly progressing to an area and then
- 471 having to wait. In addition to that, there may be escape
- 472 strategies, appropriate escape strategies that say shelter in
- 473 place. You don't necessarily exit the area, but you go to
- 474 perhaps a designated area and stay there. So escape strategy
- 475 has a multitude of variations and possibilities associated
- 476 with it. Now the key to all of this or the significance to
- 477 all this is that I think in designing and developing a
- 478 standard for escape CBRN escape respirators the standard needs

- 479 to be able to address respirators that in turn address the
- 480 multiple variety of hazards and escape strategies.
- The escape strategy concept that we actually introduced I
- 482 think at the . . . right around September 1st last year
- 483 appeared in our first concept for this type of device defines
- 484 the overall range of escape respirators into three categories.
- 485 And the three categories are a high category, specific
- 486 category, and a low category. In a high category, we envision
- 487 a requirement for high protection. We're talking about areas
- 488 where we just have no idea what the hazard may be or we have a
- 489 really strong feeling that we're in the target area that could
- 490 experience extremely high concentrations basically hot zone
- 491 type concentrations or we have situations where we can
- 492 envision an oxygen-deficient environment that we need to
- 493 escape from. For the high category, the universal solution
- 494 for this type of protection is really a self-contained escape
- 495 respirator. From a high category, we go down to what we call,
- 496 what I want to do is skip down to the low category. And the
- 497 low category is where we're looking at a possibility for a
- 498 multi-hazard protection similar to the hazards and the
- 499 protections that we defined for our CBRN gas mask respirator
- 500 so we're talking about wide range of protections but from a
- 501 relatively low concentration point so these would be low
- 502 category type applications where you perhaps you're not in a

real high threat area or you're removed from some distance
away from what is thought to be a high threat area. So you
have the requirement for a low protection or a low level of
escape.

In between the high and the low, we envision a specific 507 category. Now the specific category is where we do envision 508 multi-hazard protection capability certainly with the chemical 509 510 warfare agent theme. Okay, one of the primary threats when we 511 talk about terrorism is certainly chemical warfare hazards, 512 but we all know that's not the only type of threat that we 513 need to be concerned about so with the specific category we see a range of respirators that are providing perhaps a higher 514 515 level of protection against the hazards because there's more refinement, more known relative to the requirements of the 516 types of hazards that need to be dealt with. And within this 517 category, there would be an opportunity to focus in on what 518 those toxic industrial protections might be as opposed to the 519 low category which gives an overall broad range of coverage. 520 So looking at the three categories and for those of you 521 who have looked at the concept paper this should be familiar 522 to you. This little table or tabulation really summarizes the 523 categories as I've just explained them. We have the high 524 category, the specific category, the low category. 525 we're looking at protections that would involve certainly CWA 526

- 527 protection, chemical warfare agent, toxic industrial material
- 528 hazards, high concentrations, oxygen deficiency, and the
- 529 respirator performance that you need if that is the hazard,
- 530 the type of hazard that you're dealing with is again a self-
- 531 contained respirator.
- At the low category and we're talking about levels that
- 533 would be more comparable to warm zone and chemical warfare and
- 534 toxic industrial material hazards relatively low
- 535 concentrations, but oxygen deficiency is not necessarily a
- 536 protection consideration and here we're talking about an air-
- 537 purifying type of an escape respirator.
- 538 Then for the specific category, again, we're looking at
- 539 chemical warfare agents, but perhaps a greater focus on toxic
- 540 industrial on certain or select toxic industrial material
- 541 hazards, perhaps higher concentrations but still adequate
- 542 oxygen. So again, we're looking at a type of air-purifying
- 543 escape respirator.
- Now with the categories defined and sort of setting that
- 545 as the framework, the objective is to develop a respirator, an
- 546 escape respirator standard and identify a concept for the
- 547 escape respirator standard that addresses both protection
- 548 needs and yet still achieves a balance between performance and
- 549 use. You might say well what do we mean by that . . .
- 550 performance and use and when we look at performance, we talked

551 about performance requirements a little bit earlier. performance, we're looking at respiratory protection from 552 hazards. We're talking about performance to meet 553 physiological demands or physiological requirements of the 554 user, performance in the way of ruggedness of the device or 555 556 its ability to withstand environmental extremes that it may be exposed to during its everyday existence, and then finally, 557 558 performance, I think focuses on materials and when we talk 559 about . . . start talking about CBRN and materials, we need to 560 talk about the hazards, the hazards that we're dealing with, 561 and the effects those hazards may have on the materials 562 because chemical warfare agents are destructive by nature, but 563 we also need to be concerned about storage and what happens to 564 the materials when they're stored. Escape respirators hopefully you never need to use them so they remain in their 565 566 package for a period of time and the materials need to be able to withstand the storage conditions and yet be operable when 567 568 you need it -- so performance issues. Use on the other hand, we're looking at the human 569 interface. When you don it, how does it don? What are the 570 steps in the procedures, the mechanical adjustments, the 571 fixtures, and the accessories that you need to function and 572 operate in order to use the unit. So the human interface 573 becomes a consideration. Donning, obviously, an escape 574

575 respirator you need to be able to open it up and get it on pretty quick. So donning is an issue. I think also with 576 escape we can't, we can't ignore the training aspects. Again, 577 578 we're talking about a piece of equipment that hopefully we never need to use. Typically we don't have the opportunity to 579 open it up every other day and try it on and practice with it. 580 So the training concept needs to be an important part of it I 581 think. And then finally, size and weight, because we're 582 583 talking about an escape respirator, an escape respirator that is likely to be stored in a desk drawer or perhaps carried on 584 a belt or carried somewhere on a person's being. Size and 585 586 weight become factors that need to be considered. 587 At the meeting today, we're going to focus our 588 discussions and our discussions on the performance and the use issues relative to the CBRN escape respirators and we're going 589 to focus on the April 15th concept. And I think for most of 590 591 you, you've probably pulled it off the internet, and if you haven't, there are copies at the back of the room. 592 593 version of the escape concept is divided into two sections. 594 Part 1 is where we addressed the CBRN air-purifying escape respirator concept requirements and Part 2 is where we address 595 the CBRN self-contained concept requirements. And within 596 those parts of the concepts and through the discussions today, 597 I think we hope to illustrate to you that the efforts are 598

really aimed at addressing the protection and the use needs 599 and to achieve a good balance between those. Okay, and at the 600 same time, we want to stretch the technology, but we want to 601 be able to be within the reach of the technology because if we 602 have a standard that nobody can . . . that is impossible to 603 meet, we haven't protected anybody. So we need to make sure 604 that we achieve that balance and we stretch it the right 605 amounts and in addition to stretching it, make sure that 606 there's room for growth within the requirements. 607 I would like to also stress that the escape respirator 608 standard is in the development process so the April 15th 609 concept paper is indeed a draft of concept requirements. 610 Those concept requirements are not necessarily at a high 611 maturity level at this point through presentations and 612 discussions and further development work. We will refine 613 those requirements to the point that they do become clearer. 614 As we do that, those concept revisions will be entered into 615 the concept paper and posted on the web site. So as clarity 616 is provided, requirements will be adjusted and concepts 617 identified in the concept paper, but we'll try to limit that 618 to, as we've had in the past for other standard developments, 619 we'll try to limit to that to twice a month so that you're not 620 forced into a position where you have to go look at it 621 everyday. So typically if there are changes that are going to 622

- 623 be entered, it will be done at the middle of the month and at
- 624 the end of the month. And with that, I'd like to turn it over
- 625 to Mr. Szalajda.
- JOHN SZALAJDA: I see that this is always dangerous when
- 627 you're out of town the day before a presentation like this and
- 628 we just never quite know what we're going to get when you put
- 629 the charts up on the system. What we'd like to do is spend
- 630 maybe about the next hour talking about some of the
- 631 requirements that we're considering for the air-purifying
- 632 respirator. We're going to focus on initially is to discuss
- 633 the gas capacity of the system and some of the results from
- 634 the benchmark testing that our Mike Monahan from NPPTL has
- 635 been managing and then also to address some of the breathing
- 636 gas control issues and requirements associated with the
- 637 respirator.
- Bear with me for a second please. Let's try that again.
- 639 There we go. Thanks for bearing with me on that. I guess
- 640 with the just kind of get everybody back on the same frame of
- 641 reference and those who've been involved with the CBRN
- 642 standards development program can probably see this as a
- 643 refresher, but for those of you who are new to the process
- 644 that you know with any effort that part of the . . . critical
- 645 part of the program is to conduct a hazards analysis as far as
- 646 what we need to design the respirator to protect against.

Back in the beginning of the CBRN program, NIOSH worked along 647 with SBCCOM, reviewed multitude of different lists that 648 presented potential chemicals which could be used as a 649 terrorist weapon. And from those various lists, we developed 650 a vulnerability assessment which identified chemicals or toxic 651 industrial materials that could present a respiratory hazard 652 653 to a responder or to an individual that would require protection. And that list covered both chemical warfare, or a 654 multitude of things that covered chemical warfare agents and 655 covered toxic industrial chemicals and also covered toxic 656 industrial materials and in trying to come up and design the 657 system, we felt that in order to have . . . establish a 658 659 manageable certification program, we felt there was a need to break down the identified hazards in a way that we pursued in 660 661 doing that was to take the chemicals and put them into what we called a test represented the families or families of similar 662 chemicals and we broke these down into different classes. 663 There was an organic vapor, hydrocarbon class, an acid gas 664 class, a base class, special families chemicals like 665 formaldehyde that didn't necessarily fit into one category or 666 667 another and also unknowns which are chemicals that we 668 identified to present a hazard but we're going to require more research on our part before we can incorporate them into the 669 standard. We also spent a great deal of time looking at what 670

- 671 would be required in terms of particulate protection and the
- 672 results of the work that we did and evaluations of existing
- 673 data indicated that for biological and radiological particles
- 674 a P100 filter media would be sufficient.
- Now the toxic industrial chemicals presented a unique
- 676 challenge in looking at the . . . trying to classify the
- 677 chemicals we decided to use after evaluating a lot of physical
- 678 property data associated with the chemicals we broke down and
- 679 classified and identified test representative agents for each
- 680 of the families based on vapor pressure considerations. In
- 681 that way we felt that this was really the single best
- 682 indicator of the ability of being able to absorb a chemical
- 683 onto the filter, the filter media and these are the . . . on
- 684 the chart identifies the materials that we are addressing as
- 685 part of the standard. I think if you are familiar with the
- 686 CBRN APR standard, I think that this list will look very
- 687 familiar in terms of the gases and other materials that we're
- 688 attempting to protect against.
- Along with that, this is a list of the biological agents
- 690 that the P100 media will provide protection for and likewise
- 691 with the particulate matter associated with radiological or
- 692 nuclear agents that particulate matter will be absorbed by the
- 693 P100 as well.

What we're going to cover here in the next few minutes 694 are . . . let's try to go over and review some of the 695 benchmark testing that we've been conducting over the last few 696 697 months where we've gone out and taken commercially available products then used to determine what the state-of-the-art is 698 in terms of respiratory protection and how well that is 699 related to the concepts that we're exploring. We're going to 700 spend a few minutes now talking about gas capacity. Live 701 702 agent testing we're going to cover a little later this morning and immediately following gas capacity, we're going to talk 703 704 about the breathing gas control. For the low category in addressing the air-purifying 705 respirator, these are the 10 representative . . . the test 706 707 representative agents are indicated on the left and the test 708 challenge is based in part on considerations of ideal age factors. We initially looked at what we had established as 709 710 part of the air-purifying fine respirator program and the consideration in trying to come up with the proper balance of 711 712 breakthrough versus concentration in looking at the use 713 scenarios for the different chemicals that you know we don't necessarily believe that the higher concentrations that were 714 identified with the APR would be necessary as a test challenge 715 for this escape-type of device. The breakthroughs also are an 716 717 interesting topic that initially in starting and using the APR 718 as a basis that primarily we had considered the permissible 719 ratio of 50 percent of the permissible exposure level of the REL level and as a result of our research, we identified and 720 we found that there are some other potential concentration 721 values that we could consider and these are called ERPG's 722 which are Emergency Response Planning Guidelines. And these 723 things were developed by the American Institute of American 724 725 Industrial Hygiene Association and they recently came out in The way the ERPG's are set up and why we found that a 726 2002. 727 tract of that in the selection of this number for the breakthrough is that it's the maximum concentration in air for 728 which an individual could be exposed to for up to 1 hour 729 730 without suffering irreversible or other serious health 731 effects. And we thought for an escape respirator with the intent of being to remove yourself from a situation that this 732 may be an appropriate value to consider and that's what's 733 734 reflected . . . the ERPG values are reflected in the concept paper, but after some additional deliberation, you'll see 735 there's some values up there that are indicated in white 736 primarily the cyanogen chloride, the phosgene, and the sulfur 737 738 dioxide where there are some questions as far as how the ERPG value was determined and what we've done is we've indicated 739 740 there what the APR value was and what we had originally considered and the concept papers as far as a potential 741

- 742 breakthrough and again you know I think the point that to keep
- 743 in mind here in trying to develop and determine the capacity
- 744 that's needed for the filters with these devices is to try to
- 745 come up with the right balance between identifying the
- 746 protections that the device can afford.
- 747 A couple of other things of note on this chart, one of
- 748 the things that we were concerned about with the, in the APR
- 749 work was potential byproducts that could be seen by -- could
- 750 be seen in the breathing gas as a result of the
- 751 chemicals . . . exposure to the chemicals in the filtration
- 752 process and the one thing of note with the nitrogen dioxide is
- 753 that in looking at the APR requirements initially that we
- 754 sampled for both nitrogen dioxide and nitrogen oxide or NO is
- 755 part of the breakthrough concentrations. And right now we're
- 756 getting the impression from looking at the toxicology
- 757 associated with NO and NO2 and the use scenarios with the
- 758 respirator that sampling for NO may not be necessary as part
- 759 of the standard that the wearer may not receive enough of a
- 760 dosage of NO to present a respiratory risk.
- 761 In moving along as Les said, had mentioned earlier we
- 762 were . . . the second category in looking at specific threats
- 763 and trying to provide a means for a manufacturer and user
- 764 community to still get the chemical warfare agent protection
- 765 as well as addressing other toxic industrial chemical threat

and to give some leeway between the user and the manufacturer, 766 the manufacturing community the capability to tailor a product 767 to meet a specific user requirement. I think one example that 768 always comes up is that you know if you live, if you live in 769 proximity of a chemical plant that you may not necessarily be 770 concerned about everything on the list but you may have a 771 particular concern about ammonia or you may have a particular 772 concern about sulfur dioxide and with the intent of 773 establishing the challenges, the challenge and the 774 breakthrough concentrations the endpoint on the specific 775 776 category was to provide the basic protection against the 777 chemical warfare agents as well as providing especially protection based on a user need or a manufacturer preference 778 779 to address a particular chemical. But what we found, we'll throw the summary chart up at 780 you first in case you can't read the detail. But what we 781 found with the benchmark testing that we've conducted to date 782 is that the commercial products perform fairly well for 8 of 783 the 10 test representative agents. The two chemicals of 784 785 concern are ammonia and nitrogen dioxide. Nitrogen dioxide in the long term may not be an issue at least as far as how the 786 787 concepts are currently being stated. Because with the benchmarking that we did originally, we're sampling for both 788 NO2 and NO and the failure . . . I shouldn't say the failures 789

- 790 but the shorter gas life's that we saw for nitrogen dioxide
- 791 we're based on the NO breakthrough, the filter. With only
- 792 sampling the NO2, that issue may dissipate.
- 793 What I'm going to do is get down on the floor so I can
- 794 use the pointer a little bit. If you can . . . Where we were
- 795 with the benchmarking is that we looked at four commercially
- 796 available escape products and in this column you see the
- 797 challenge chemicals with the original -- challenge
- 798 concentrations identified using, using the rail over two
- 799 values that we had explored with the APR. And I think you see
- 800 that, and in considering this is a 15- or 30-minute respirator
- 801 that this product performed fairly well at being considered as
- 802 a 15-minute respirator that cyclohexane, sulfur dioxide,
- 803 ammonia, and formaldehyde all had a variety of readings before
- 804 the endpoint was reached. With some of the other gases,
- 805 hydrogen sulfide, cyanogen chloride, phosphine, phosgene and
- 806 hydrogen cyanide, overall the systems performed pretty well.
- (Unidentified Speaker): (Inaudible)
- 808 JONATHAN SZALAJDA: Yeah these are . . . yeah, thanks
- 809 Rich. These are over here are minutes to the endpoint okay in
- 810 this category. At the top the 64 reflects the flow rate,
- 811 64 liters per minute at 25 percent relative humidity. This
- 812 was 64 liters per minute at 80 percent relative humidity and
- 813 then this was 100 liters per minute at 50 percent relative

- 814 humidity. Okay, this was for type A and for type B, again,
- 815 you get similar type results with varying degrees with
- 816 cyclohexane, ammonia, also nitrogen dioxide. This one
- 817 actually did slightly better than the other one. With type C,
- 818 we didn't get this part of the matrix filled in yet, but I
- 819 think you'll see that continue the same . . . the same trends
- 820 continue in addressing these four chemicals.
- Last category, I think it . . . it still reflects that
- 822 for some of the acid gases it performs fairly well. You know
- 823 ammonia continues to be a problem. Nitrogen dioxide values
- 824 are marginal, but again, that's primarily due to the NO
- 825 endpoint. And what we also did in terms of expanding our
- 826 knowledge bases, we took a look at some of the chemicals that
- 827 were more stressed as part of the testing, cyclohexane, sulfur
- 828 dioxide, and formaldehyde. And we ran these tests at a higher
- 829 concentration than what was currently established for the low
- 830 category that these were the 2600 parts per million for
- 831 cyclohexane instead of 1300 and the SO2 value was doubled and
- 832 the formaldehyde was doubled and this is roughly how they
- 833 performed. Again, they did fairly well and as for
- 834 product B . . . okay, then that's B, now let's have C . . .
- 835 and then product C. That again you know it shows that you
- 836 still . . . probably with some modifications and work that you

837 know it should be achievable to get the required service time 838 associated with the products.

And likewise with one of the considerations that we 839 840 explored in great detail as part of the APR standard development was the flow rates associated with the gas life 841 842 testing and the concern that some of the traditional numbers 843 used for certification testing may not be truly representative 844 of what actually occurs in the real world and part of the APR 845 process as we attempted to address that concern in terms of adding additional category for the gas life testing which was 846 847 to address what we call a panic demand associated with the use of the respirator or you may have a higher physiological load 848 849 on the device and a higher breathing flow rates to stress the 850 system. And the research that we conducted with the airpurifying respirator indicated that 100 liters per minute was 851 852 probably a good challenge for addressing this type of concern in addition to the considerations of the lower flow rate. 853 And has Les had mentioned earlier one of the things that 854 we're considering and my colleague, Frank Palya, will discuss 855 later in detail this morning is the environmental and other 856

later in detail this morning is the environmental and other rough handling type tests that are going to be associated with this product. And in looking at the concerns, you know granted with an escape respirator, you know, it should ideally stay in its package forever, but there are other

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- 861 considerations that we've heard in terms from the user
- 862 community . . . in terms of how long the product should last,
- 863 how it may be stored, where it may be stored, and we felt that
- 864 there is a need to conduct a certain amount of environmental
- 865 and rough handling testing to verify the integrity of the
- 866 product and again, Frank will discuss those requirements in
- 867 later detail.
- 868 I guess what I'd like to do before Les discusses the
- 869 breathing gas if anybody has any specific questions about the
- 870 breakthroughs or the endpoints, we can address those now or
- 871 else we'll let Les go one with the breathing gas control. I
- 872 think we need a lightning rod in here.
- 873 LES BOORD: Thanks John. One of the things that I would
- 874 like to comment on. I think throughout the morning anyway the
- 875 term balance you've heard it quite a few times and I think
- 876 when we look at the benchmark testing that's been performed
- 877 and we look at what we're trying to do and that is to develop
- 878 performance requirements, I think that the benchmark testing
- 879 is really significant because what it does show us is that
- 880 when we tested the commercially available product today it's
- 881 showing us that the requirements are pretty much on track for
- 882 achieving performance in a package that's relatively the size
- 883 of the commercially available products. And I think you can
- 884 all pretty much envision what those products and their sizes

are so I think that is a positive indicator coming out of the results of the benchmark study. So I think that benchmark testing for gas capacity is very important to the development process.

889 The next thing we'd like to talk about is the topic we 890 call breathing gas control and what that really means is oxygen concentrations and carbon dioxide concentrations within 891 the breathing zone or that are the result of the performance 892 of the respirator. In the concept paper, actually in the 893 894 concept since the early editions of it back in August and October of last year, we have identified a requirement, a test 895 requirement for carbon dioxide control. The requirement 896 performance wise is as illustrated on the screen there that we 897 have a carbon dioxide maximum inhalation concentration of 898 899 2½ percent and we have an oxygen minimum requirement of 900 19½ percent.

The April 15th concept paper identifies the mechanism for 901 902 establishing conformance to that requirement being performed by a machine that we call the automatic breathing metabolic 903 simulator so this device for those of you who are not familiar 904 905 with it simulates the physiology of breathing so it has 906 oxygen . . . simulates oxygen consumption and CO2 elimination at varying work rates, oxygen consumption rates which are then 907 908 tied to tidal volumes and specific breathing performance

- 909 requirements. The concept that we've identified is to
 910 actually perform that test at six different loads, six
 911 different work rates defined by the oxygen consumption rate in
 912 liters per minute and those are as illustrated there and it
 913 varies from a relatively low work load activity to a fairly
 914 demanding load which is 3.0 liter per minute oxygen
 915 consumption.
- 916 As with the breathing gas capacity and the panic demand 917 and continuing to discuss into the chemical warfare agent 918 testing, one of the key aspects in the development process is 919 to benchmark where we are with state-of-the-art. Again, we've 920 used commercially available escape sets tested against the breathing simulator requirements identified on the previous 921 922 slide. The way the benchmark testing was performed is we did multiple tests with each respirator according to the 923 924 requirements on the previous page. The results of this 925 benchmark testing from the machine tests indicated that we've 926 observed carbon dioxide levels within the breathing zone 927 greater than the 2½ percent and we've also observed oxygen 928 concentrations less than the 19% percent and this testing is continuing on as we speak. So the benchmark testing using the 929 930 simulator is continuing, but when we look at the results and I would think probably most of you who are seeing this requestor 931 932 saying well that's the breathing machine, what can we really

933 conclude from it. And at this point, we're not in the 934 position to say. We feel that those results were kind 935 of . . . non-conclusive. So what we've done in addition to 936 the breathing machine part of the study, we've identified what 937 we call a human subject testing that is also being factored 938 into our benchmark testing and evaluation for the standards development process. The testing using human test subjects is 939 in process. That testing to sort of bracket what we're 940 looking at there, we're looking at testing the escape 941 942 respirators on multiple test subjects at three different levels of activity as identified on the screen. One is a 943 standing condition, secondly walking on a treadmill at 944 2½ miles per hour, then thirdly walking on the treadmill at 945 946 3½ miles per hour. Another parameter that we're looking at in doing the human subject testing is the body weight, the size 947 of the individual. And in a broad perspective what we're 948 trying to do there is have subjects who are representative of 949 950 greater than 80 kilograms and subjects that are representative of less than 60 kilograms. That testing as I say is in 951 process. What these preliminary results or preliminary 952 indications from the benchmark testing is sort of leaning us 953 954 in the direction of for our concept requirement for breathing gas control is that we can envision and this is not currently 955 stated this way in the April 15th concept paper because our 956

957 benchmark data is developing as we go. The concept that we 958 envision is perhaps a two-part breathing gas requirement. 959 first part being using the machine, the automated breathing 960 metabolic simulator, and then secondly a human subjects test. 961 If we conceptualize about that a little bit, we would say that 962 the metabolic simulator component of that requirement would be 963 envisioned to establish the acceptable functioning and 964 operation of the respirator. We would look at conceptually 965 performing the machine test at six different work rates as 966 identified in the earlier chart ranging from oxygen 967 consumption rates of about .5 up to 3.0 liters per minute and 968 what we are conceptualizing is the carbon dioxide requirement 969 on the machine part of the test would be at some threshold 970 value that's perhaps greater than 2½ not focused exactly on what that number would be at this time. We need to continue 971 972 the development effort, but we're thinking of a screening 973 number that perhaps a little higher and that will depend on 974 how we . . . on the results that we achieve from our human 975 subjects testing. We've done the machine tests for most of 976 the respirators. It continues on some additional so we have 977 the machine component. We will be finalizing the human test 978 subject component and we'll marry the two of those together to 979 try to define what these threshold requirements would be, but 980 we would envision CO2 on the machine leg of the test to be a

- 981 little bit higher than 2½ and an oxygen requirement that would probably find a little bit of leeway or little bit of 982 relaxation on the 19½ percent. But then, when we look at the 983 984 human subjects tests, we would be looking at a requirement where we again do that human subjects test at the same types 985 of work loads that we are currently doing and performing for 986 our benchmark test which is basically the three loads of 987 988 standing and the treadmill speeds of 2½ and 3½ miles per hour. 989 At each of those activities and on the benchmark test as well, 990 I can't recall if I mentioned it, but what we would do is perform that particular level of activity for a 10-minute 991 period. So you would have the respirator in a standing mode 992 993 for 10 minutes, increase it to 2½ miles per hour for 994 10 minutes, and then 3½ miles per hour for 10 minutes. again the requirement would focus on test subjects, 995 996 categorized or defined by their weight and with the two 997 categories being greater than 80 and less than or equal to 60 kilograms. Any questions? Yes, Rich, announce who you are 998
- 1000 RICH STEIN: My name is Rich Stein from QPS. Two
 1001 questions, does this include all three categories when you
 1002 make a submittal or are you just talking about for oxygen
 1003 systems or self contained?

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and who you're with.

- 1004 LES BOORD: No, this is applicable to the air-purifying
- 1005 respirators as well as the self contained and the benchmark
- 1006 testing . . . by the way, the benchmark testing that we've
- 1007 reported on here is with the commercially available air-
- 1008 purifying type escape respirators.
- 1009 RICH STEIN: And then I think what I just heard you say
- 1010 is you went around at least conceptually 10 minutes,
- 1011 10 minutes, 10 minutes?
- 1012 LES BOORD: Correct.
- 1013 RICH STEIN: And that's even for a 15-minute unit?
- 1014 LES BOORD: That's a valid question okay that would need
- 1015 to be balanced so typically we were thinking of a 30-minute
- 1016 unit so that would be need to be factored into the requirement
- 1017 so that you have roughly 30 percent at each load. Jay?
- 1018 JAY PARKER: Jay Parker with the Bullard Company, on the
- 1019 cartridges I was just wondering if, well on the respirators,
- 1020 do you have to have inhalation and exhalation valves or will
- 1021 it be allowable to have the ability to breathe back through
- 1022 the cartridge?
- 1023 LES BOORD: That's a good question. Right now, the
- 1024 requirements for the concept, they do not specify the
- 1025 requirement to include the inhalation/exhalation valves. I
- 1026 think the experience, again, this gets to the issue or the
- 1027 sort of down the road performance versus design requirements

- 1028 so we're not specifying that you need those types of systems
 1029 in the breathing control, but here's the performance
- 1030 requirement that needs to be met.

1040

RICH STEIN: Rich Stein again from QPS, I'm not sure if 1031 this is a question or more of a comment. This is the first 1032 time I really thought about using an ABMS for simple testing 1033 and normally what happens is as the manufacturer you want to 1034 1035 set up the system to be equivalent and ABMS systems are very complicated and very expensive for what is being used for what 1036 I call a very extremely simple task and so I'd like to bring 1037 to your attention that there are other ways to do it for units 1038 1039 which are not self contained which would be easier for the

community to run the equivalent kinds of tests.

1041 LES BOORD: Yes, thank you. That's also a good comment 1042 and certainly will be taken into consideration. I think again 1043 being in the stage of developing the requirements collecting 1044 the data and then really analyzing it to focus on what those requirements will be that is a consideration. But that is one 1045 1046 of the areas where we're still in the process of developing 1047 our data base. Yes, that's also the comment that Roland just made. While the meeting is being transcribed and recorded, 1048 certainly we would like to have those comments submitted to 1049 the docket as well so we can officially address it. 1050

BODO HEINS: My name is Bodo Heins from Draeger Safety, 1051 Lubeck. Concerning your benchmark tests, the 2.5 percent of 1052 CO2 and the oxygen content which has to be more than 19.5, you 1053 should realize that these data are very important for the size 1054 and the weight of the unit that the manufacturer has to 1055 develop especially all the breathing resistances. 1056 impression is that you took most of your values from standards 1057 for working rates of a whole day, but if you only have to 1058 1059 perform a 15 minutes service than you do not need discomfort which means for the unit it is much bigger than necessary and 1060 you have to differ if the unit is stalled or . . . if a 1061 man . . . the whole day if the man has to wear a unit which is 1062 very heavy to have the comfort for 15 minutes it's perhaps 1063 1064 better to have a lightweight unit and a little more breathing resistance a little bit more CO2 content. For example, if you 1065 have 4 percent CO2 to use or not realize it if it he has more 1066 than 2.5 and you know also that in Europe for example, oxygen 1067 content is much lower than yours here in the states and it 1068 1069 works. Thank you Bodo, again if you could it is 1070 LES BOORD: being recorded, we'll have it in the minutes, but if you could 1071 submit that as a docket as well. And I would clarify that the 1072 requirements that we have specified at 2.5 percent and 1073 19.5 percent are the currently defined requirements pulled out 1074

- 1075 of as you mentioned the existing standards 42 CFR. I think
- 1076 Bodo also hit on one of the central themes that we've been
- 1077 talking about this morning and that is the ability to achieve
- 1078 that balance and that balance between performance, design,
- 1079 size, weight, and the entire system let's say which I think is
- 1080 really an important consideration in terms of an escape
- 1081 respirator. Yes.
- 1082 ZANE FRUND: Zane Frund, MSA. I guess a question, two
- 1083 questions, one on the ABMS what were you using or what do you
- 1084 plan to use as your VCO2? You outlined some criteria for CO2
- 1085 concentration, but you didn't state your VCO2.
- 1086 LES BOORD: I'm going to ask Eddie. I think the R . . .
- 1087 is Eddy available? What was the RQ?
- 1088 **EDDIE SINKULE:** (inaudible)
- 1089 LES BOORD: Did we use a factor of one or did we use a
- 1090 point -- They are identified in the concept paper. We
- 1091 tabulated the overall performance. So and I'll give you the
- 1092 two extremes at the .5 VO2, the VCO2 is .4, and at the 3 it's
- 1093 3.15. They are identified.
- 1094 ZANE FRUND: Also regarding the acceptance criteria on
- 1095 the ABMS, you said you would permit . . . you were sort of
- 1096 looking for a function so the CO2 concentration would be
- 1097 permitted to go above 2 percent, the oxygen below
- 1098 19.5 percent. What would be the acceptance criteria? You're

- 1099 looking at something like an inhalation/exhalation breathing
- 1100 resistance?
- 1101 LES BOORD: Actually the concept would be to have
- 1102 performance requirements for both CO2 and O2. When we do the
- 1103 machine component of the test, those may be different values
- 1104 than the 2½. So that would be . . .
- 1105 ZANE FRUND: They will be established values?
- 1106 LES BOORD: Yes. Yes. And that's the part of the
- 1107 program that we're in . . . trying to resolve now. Going
- 1108 through that development process in . . . so, yeah, those
- 1109 would be identified, CO2 and O2 requirements, machine and they
- 1110 would probably be different than the human version.
- 1111 ZANE FRUND: Thank you.
- 1112 LES BOORD: If I come back up a little bit too, I think
- 1113 Rich that sort of touches on the comment that you made that
- 1114 from a technical point of view using the metabolic simulator
- 1115 on a air-purifying respirator that is sort of a different
- 1116 approach. Okay, so that's why we foresee that there may be
- 1117 two levels or two, I don't want to say levels, but two
- 1118 thresholds. One based on the machine and then finally the
- 1119 real test is when you use a human test subject.
- 1120 BODO HEINS: It's Bodo Heins again from Draeger Safety.
- 1121 One important note for the breathing simulator is the way how
- 1122 you are taking out the CO2. If you allow it to let CO2 which

- 1123 goes through the respirator and it's still in the breathing
- 1124 circuit to stay in the system then you will have different
- 1125 results as if you take it completely out.
- 1126 LES BOORD: Thank you. Okay, if there are no other
- 1127 questions.
- 1128 SAM SHEARER: Sam Shearer from CSE Corporation, I believe
- 1129 the one table said that the CO2 concentration is an average.
- 1130 Do you mean average with time as in EN 401?
- 1131 LES BOORD: I would request Eddie to perhaps clarify
- 1132 that.
- 1133 EDDIE SINKULE: Can I see the slide that you're talking
- 1134 about?
- 1135 **SAM SHEARER:** Average.
- 1136 EDDIE SINKULE: Okay, that maximum average inhaled is the
- 1137 low adjusted inhaled, average inhaled CO2, and we're not quite
- 1138 sure if we're still satisfied with the 2.5 percent.
- 1139 (Inaudible.) Oh I'm sorry. It's the average over the breath.
- 1140 There's the (inaudible) average between (inaudible).
- 1141 SAM SHEARER: Basically any instance of time then you're
- 1142 saying? That's awfully tight.
- 1143 EDDIE SINKULE: Well there's two ways of looking at it.
- 1144 One way is to look at the maximum or excuse me that should
- 1145 read in fact that should read minimum average inhaled CO2 and
- 1146 maximum inhaled concentration of 19.5(inaudible). We're also

- 1147 looking at just minimum inhaled CO2 in comparison for
- 1148 (inaudible). Well the maximum O2, I guess what I'm trying to
- 1149 say is the oxygen would be a low high and the CO2 would be a
- 1150 high low. That's where metabolic simulator machine has
- 1151 (inaudible) for thinking of having only minimal inhaled CO2 is
- 1152 also averaged inhaled CO2. Average inhaled would be a flow
- 1153 adjusted CO2 during inhalation.
- 1154 SAM SHEARER: I'm not sure I'm with you, but if you're
- 1155 saying that the CO2 concentration has to be the 2.5 percent
- 1156 and you're not averaging it with time. Remember when you have
- 1157 people wearing this thing, they breathe differently and . . .
- 1158 **EDDIE SINKULE:** (inaudible)
- 1159 SAM SHEARER: Alright we'll think about that one.
- 1160 LES BOORD: Again, I think that is a good comment and I
- 1161 think that's the type of information we really need to have
- 1162 and to let's say focus on and bring light to in these types of
- 1163 presentations and discussions because as we refine the
- 1164 requirement, then that needs to be clear. Thank you.
- 1165 MICHAEL KAY: Mike Kay from Ocenco, I'd just like to
- 1166 clarify the 2.5 percent on the ABMS. Eddie Sinkule is
- 1167 correct. That is a flow-weighted average over that inspired
- 1168 wave form so it's integrating underneath the curve in that
- 1169 it's not looking at a peak. It's looking at that average
- 1170 maximum over that expired breath.

- 1171 **EDDIE SINKULE:** One single breath?
- 1172 MICHAEL KAY: Correct. It's doing it . . . It's a
- 1173 breath-by-breath analysis. Correct.
- 1174 EDDIE SINKULE: Okay. That's putting a lot of burden
- 1175 (inaudible). I can see (inaudible).
- 1176 LES BOORD: Okay, yeah, if we can . . .
- 1177 BODO HEINS: Bodo Heins again from Draeger Safety. If
- 1178 it's only for one breath, you will need a very fast measuring
- 1179 equipment and as this measuring equipment is very important
- 1180 thing, you have to fix it every time to come every time to the
- 1181 same results. And for one breath, it is very difficult to
- 1182 measure the CO2 or O2 concentration in that short time.
- 1183 LES BOORD: Thank you.
- 1184 SAM PITTS: Good morning Les. Sam Pitts, United States
- 1185 Marine Core, Chem Bio Incidence Response Force. Les, I see
- 1186 ambulatory escapees well represented. Are we going to
- 1187 consider unconscious non-ambulatory escapees at all?
- 1188 LES BOORD: Perhaps clarify the question a little bit.
- 1189 Are we going to include . . .
- (inaudible)
- 1191 SAM PITTS: We've noticed that . . . Like several escape
- 1192 mask manufacturers like some might have a bite valve to orally
- 1193 respirate and that's great if you're conscious, but for some
- 1194 unconscious people we may want to go with a nose cup type

- 1195 affair so that they can either orally or nasally respirate.
- 1196 Are you going to look at the unconscious non-ambulatory?
- 1197 LES BOORD: At this point in time, the concept does not
- 1198 focus on that. Basically, we're looking at the ability to be
- 1199 to don the respirator and use it, so not to put it on someone
- 1200 else. So that's not a part of the concept at this time.
- 1201 Thank you. Any other questions? I think we're about
- 1202 10 minutes into our break and we had a 45 minute break or a
- 1203 15 minute break scheduled so why don't we resume at 5 till 11,
- 1204 10:55. Thank you.
- 1205 (BREAK)
- 1206 JONATHAN SZALAJDA: Yeah. The requirements for air-
- 1207 purifying escape respirator. At this time what we're going to
- 1208 do is cover some of the special tests associated with the
- 1209 project chemical warfare agent testing, the LRPL test, and
- 1210 then the environmental and rough handling and human factors
- 1211 type evaluation. The next presenter is going to be
- 1212 Mr. Wayne Davis who used to be my boss in a previous life and
- 1213 at one time he was the Director of Respiratory Protection for
- 1214 SBCCOM and with the reorganizations that they're undergoing I
- 1215 don't know if that's his current title but I still know he's
- 1216 Wayne Davis so.
- 1217 **WAYNE DAVIS:** Thanks John. Can everybody hear me okay?
- 1218 I don't know what my current job is either but I'm here

representing SBCCOM and I want to go over some of the testing 1219 that we've done on commercially available hood type systems 1220 just to show you what the baseline looks like. We've been in 1221 the hood business for quite some time at ECBC or SBCCOM. 1222 started hood testing basically back in the 1985 timeframe 1223 1224 where we made some hoods for some special application purposes. We've also been working with the technical support 1225 working group who has some hood requirements that they 1226 developed for the State Department. We done hood testing 1227 there. We also have an Army program that you see there, the 1228 joint service chemical environment survivability mask which is 1229 an ongoing program looking for a hood system generally for 1230 escape purposes for military applications. 1231 What I'm going to talk about today is a NIOSH baseline 1232 testing that we've accomplished with some of the commercially 1233 available hoods. Now the way we do the chemical warfare agent 1234 testing is we use what's called the SMARTMAN system and 1235 looking around the room I imagine almost everybody knows what 1236 that is. Basically it's a head form with a breathing pump or 1237 you can put an agent concentration around the system and 1238 monitor the penetration and the permeation through the 1239 materials that go into the breathing zones. I want to point 1240 out also that with the SMARTMAN we're not looking for the fit 1241 of the respirator on the head form. We're looking for the 1242

- 1243 functionality of the system; therefore, we try to get a
- 1244 perfect fit before we go into any type of agent testing.
- 1245 The SMARTMAN equipment is shown here. Basically we have
- 1246 syringe pumps and air controllers and mixing chambers so that
- 1247 we can get the proper concentration going into the test
- 1248 chamber. We also have a breather pump which uses a sinusoidal
- 1249 wave form and we have various detectors to detect the chemical
- 1250 agents. The chemical agents we use normally are sarin or GB,
- 1251 mustard which is HD, and we also cyanogen chloride on
- 1252 occasion.
- 1253 This shows the setup. This is one of the older pictures
- 1254 when we had equipment all over the place. Our labs have
- 1255 cleaned up and simplified to some extent, but you can see that
- 1256 it's a fairly complicated test. We have the detection
- 1257 devices, the Dynatherm's gas chromatographs and what not
- 1258 located near the hood assembly. The SMARTMAN system, itself,
- 1259 the head form's in the chamber along with some of the detector
- 1260 equipment. If you need details on any of this equipment,
- 1261 Ray Lins from our laboratory is here and he can go into
- 1262 excruciating detail on every component associated with it.
- 1263 Here's another picture where we've cleaned it up a little
- 1264 bit. Show the TDA99 in the front of the hood assembly. Every
- 1265 respirator is tested with a TDA99, which is an aerosol leak
- 1266 detector before we can go into the agent test. What we found

if we can't pass the TDA99 test, normally the hood system or 1267 respirator system doesn't do well in the agent testing. So 1268 1269 that's a preliminary test to make sure that we have a good fit 1270 when we start a test. And the test method has been developed. It's been validated. It's been approved for the SCBA and APR 1271 respirators under the NIOSH certification standard. We've 1272 1273 been using it for about 5 years now in the Center. We're very 1274 comfortable with the test. There is one difference in the escape hood portion of the test from other testing that we've 1275 1276 done. Basically because we have a bladder system that seals around most of the APR systems to form a perfect fit around 1277 1278 the face piece. We don't have that same type system around the neck of the SMARTMAN head form so what we do is we tape 1279 the neck seal to the head form to get a good seal. 1280 showing gray on gray there so I'm not sure you can see it from 1281 the back of the room, but that is tape along the neck seal of 1282 1283 that particular hood system. We also do the TDA99 on the actual agent head form with 1284 the escape hoods and the reason for that is we . . . since 1285 escape hoods are generally one-time use products, we only want 1286 to put it on the head form once before we test it and because 1287 of that we test in the agent chamber itself. With APRs we do 1288 it in a separate chamber before we go into the agent chamber 1289 because once it goes into the agent chamber, the item is 1290

- 1291 toast. We're not going to re-use it. It's not going to come
- 1292 out from the contaminated waste stockpile.
- 1293 When we started the baseline testing, we were trying to
- 1294 figure out what to test to. We decided to test to the SCBA
- 1295 standard which is the most rigorous standard that we test to
- 1296 essentially. That calls for a GB challenge of 2000 milligrams
- 1297 per cubic meter for 30 minutes, a very high challenge rate.
- 1298 We have various break points for that. We have a . . . it
- 1299 cannot exceed 2.1 ct or the dosage cannot exceed 2.1 milligram
- 1300 minutes per cubic meter and also no instantaneous
- 1301 concentration can exceed .087 milligrams per liter. For the
- 1302 mustard, we challenged at 300 milligrams per cubic meter for
- 1303 30 minutes. Now we put on, look good on at the same time as
- 1304 we do the mustard test to roughly 10 grams per square meter or
- 1305 .86 milliliters of agent is what it turns out to be. We have
- 1306 a break point there of 6 ct for the dosage and the break point
- 1307 of .6 as an instantaneous challenge concentration that we
- 1308 don't want to exceed. That's the same as in the SCBA
- 1309 standard. Breather flow rate is 40 liters per minute and we
- 1310 consider this a worse case scenario as I mentioned.
- Now I'm going to put up some eye charts. Can people read
- 1312 that from the back of the room? Is that a yes? Okay. All my
- 1313 charts are set up the same way. Essentially the chart on the
- 1314 top left is the cumulative dose or ct in milligram minutes per

cubic meters with time and the bottom chart shows the 1315 concentration versus time in milligrams per cubic meter. 1316 shows one hood system that we tested. You can see essentially 1317 that it went about 28 minutes and continued to climb. 1318 probably turned off the test then so we wouldn't saturate our 1319 detectors, but we also exceeded the concentration in about 1320 1321 24 minutes also in that particular test. I'm going to run through these fast and I don't want to 1322 dwell on some of these. Here's another hood system. You can 1323 see that this went the full 2 hours. It didn't exceed our 1324 criteria of 2.1 ct and also the concentration stayed below our 1325 1326 cutoff concentration. So this test was considered a good test. Here's another set of data. We do tests with both the 1327 oral and nasal area and the eye area in some cases just to see 1328 where the differences lie, but you can see here this had very 1329 little penetration into the system during the entire test and 1330 we had two samples that just stayed at baseline. So you can 1331 see the hood technology seems to indicate we can very high 1332 protection with the basic systems themselves in terms of their 1333 functionality. This shows some HD data. You can see in this 1334 HD is normally a difficult test to pass largely because of the 1335 liquid challenge concentration. We find when we apply the 1336 liquid, we apply it to the most critical parts of the system 1337 that it can cause significant problems in terms of passing 1338

- 1339 this test in terms of permeation as well as also damage to
- 1340 components. The test here shows that it lasted about
- 1341 54 minutes, but it was up way high at the 20 ct level.
- 1342 Remember our cutoff is 6 so it really passed that point at
- 1343 about 24 minutes. You can also see that we exceeded our
- 1344 cutoff point of . . . well it ran up to the cutoff point of
- 1345 .6 milligrams per cubic meter.
- Here's another set of data. Again this one ran the full
- 1347 2 hours. It stayed below the ct criteria and it also stayed
- 1348 below our instantaneous concentration criteria. You can see
- 1349 that we put on the agent for at 30 minutes so it looks like
- 1350 this probably has some permeation based on residual
- 1351 contamination on the system that comes through with time.
- 1352 And we had three samples that showed baseline
- 1353 concentrations. So you can see the data indicates that there
- 1354 are hood systems that do provide excellent protection. Some
- 1355 of the lessons we learned not from this particular testing but
- 1356 over the years in terms of testing, these samples I gave you
- 1357 hadn't gone through high-temperature storage. They hadn't
- 1358 gone through package vibration as some of the other testing
- 1359 that we normally do prior to the agent testing. These two
- 1360 areas have been shown to be problems with other mask systems
- 1361 that we tested so in the design process, the contractor should
- 1362 look hard at these two areas. The high-temperature storage

- 1363 tends to cause the seams to disbond, causes the material to
- 1364 blot so it tears when you open it, and things like that. The
- 1365 rough handling if it's not packaged adequately, it tends to
- 1366 break things. The materials of construction are also a
- 1367 concern. Mustard, we've tested some systems and actually
- 1368 pieces have fallen apart when you put the mustard on it. You
- 1369 have to make sure that the materials are compatibility with
- 1370 the chemical agents and are durable.
- 1371 A real brief summary of results, I think escape hoods are
- 1372 capable of very high levels of CWA protection certainly in
- 1373 concert with what's been presented today. Are there any
- 1374 questions?
- 1375 BODO HEINS: It's Bodo Heins from Draeger Safety. Is it
- 1376 right that your SMARTMAN was being constructed to test a full
- 1377 face mask? Because I could see that you have only a rubber
- 1378 part which was sealed as the outside of a full face mask but
- 1379 for hoods which are using for example a half mask or a nose
- 1380 cap there's no possibility to seal this area which increases
- 1381 the fit factor for a good portion.
- 1382 WAYNE DAVIS: That's true. It wasn't designed
- 1383 specifically for nose cup sealing or neck sealing. It is
- 1384 a . . . physiologically it does match the human face fairly
- 1385 well but there is a chance that you could have some bypass in
- 1386 those areas in the nose cup or in the neck seal. Since we do

seal it, I think we have a very good seal in that area. One thing that we have found is that the quality of the neck seal can influence it. There's some neck seals we consider good quality and others that are not so good quality and that's shown in the PF testing later on also.

1392 (inaudible)

1393 Correct, right, Roland pointed out we are looking not the
1394 fit test for this but just for permeation, but I think your
1395 point is still that permeation or penetration can be impacted
1396 by the way it fits the test head itself. Are there any other
1397 questions? Thank you.

1398 The point has just been made about JONATHAN SZALAJDA: this being . . . geared to be a penetration and permeation 1399 effect or a test and not necessarily a fit test. I did want 1400 1401 to bring up at least for a minute some of the methodology that went into the development of the test criteria that is part of 1402 1403 the SCBA program and then is part of the APR program. build on modeling that Phil Mattson had discussed this morning 1404 that was developed in concert between SBCCOM and NIOSH to come 1405 up with credible events that we try to envision where a 1406 terrorist could deploy a CWA agent and various scenarios were 1407 1408 identified and evaluated and challenge concentrations were set 1409 up based upon on those scenarios and what we did as part of 1410 the interim process was in looking at the SCBA evaluation

criteria that we selected at the time we called the most 1411 credible event which we thought would be a probable situation 1412 1413 or responder would go into an event and this would probably be the challenge concentration that he would see. With the APR 1414 we're looking at a completely different scenario with as far 1415 as an operational requirement that the challenge is known and 1416 quantified and if you're in a less than ideal H scenario which 1417 I believe most hygienists call the warm zone and along with 1418 building on that knowledge that we established with the air-1419 purifying respirator with the gas mask we looked at 1420 transitioning those warm zone requirements from the gas mask 1421 1422 to the air-purifying escape respirator and, therefore, we came up with these values for the chemical warfare agent testing. 1423 As far as the vapor challenge of 210 milligrams per meter 1424 cubed or for GB which is reflective of what we tested with the 1425 or testing for the air-purifying respirator for the gas mask. 1426 As far as the test time we're anticipating doing is that for 1427 if you have a 15-minute device for example that we would 1428 expose the respirator to this concentration of sarin for 1429 15 minutes and then there would be a 15-minute decay period 1430 where the agent challenge would be shut off and we would 1431 continue to monitor for penetration or permeation through the 1432 1433 respirator.

And likewise for HD for sulfur mustard, the result or the challenges are reflective of what was developed as part of the gas mask program and again the same parameters for exposure and total test time are based on the time that the manufacturer identifies for his respirator whether its 15, 30, 45, or 60 minutes.

The other part of the special test that we're conducting 1440 with SBCCOM and I guess the one point that we would like to 1441 make as part of this discussion is that for NIOSH this is an 1442 evolutionary step in our organization as far as using another 1443 agency such as SBCCOM as our test agent and as Wayne had 1444 stated in his presentation that you know we have gone through 1445 a rigorous process and ensuring that the criteria are met and 1446 repeated for all the testing. But the second part of Wayne's 1447 presentation is going to be discussing the other aspects of 1448 the special test for which SBCCOM is our test agent and that's 1449 the laboratory respiratory protection level or the LRPL 1450 testing and again Wayne will discuss how SBCCOM does the 1451 testing in their approach and what they seen with testing the 1452 escape hooded devices and Les will discuss the requirements as 1453 1454 we currently envision them for the testing.

1455 **WAYNE DAVIS:** John said we'll talk about the laboratory
1456 respirator protection level testing. The purpose of the LRPL
1457 is shown here basically to evaluate the respirator protective

1458 equipment for military and civilian applications requiring protection against NBC warfare agents. We have various test 1459 1460 standards. We've been doing this test since 1992. developed a test method with Los Alamos. It's been approved 1461 for the joint services. It's been approved also with NIOSH 1462 for the SCBA testing as well as for the APR testing that we're 1463 1464 doing so it has quite a history behind it. This shows our 1465 LRPL test chamber. It's about 10 by 10 by 30 feet roughly. We have enough room in there for 16 subjects at a time, but 1466 1467 normally test no more than 12 at a time. We use a real light scattering photometers to detect the aerosol and we can 1468 measure protection factors up to about 100,000 using this 1469 1470 instrumentation and it's a real time measurement. This shows actually what a test looks like. Essentially we have our test 1471 chamber. We fill it up with corn oil aerosol, monitor the 1472 people inside. We have test monitors that watch the test 1473 subjects to make sure that they're performing the tasks as 1474 they've been taught to do. Also to notice . . . any problems 1475 associated with conducting the test itself. 1476 The aerosol challenge is corn oil. The concentration you 1477 can see there. The particle size is about .4 to .6 microns 1478 1479 measured regularly to make sure we maintain that kind of standard. The temperature control inside the chamber is 1480 actually 70 to 90 $^{\circ}F$. Humidity we keep it around 20 to 1481

1482 25 percent. A lot of people ask why do you test at this particle size you test at and the reason is the threat size 1483 for generally biologicals runs into the 1 or 7 to 8 micron 1484 1485 range. There's various reasons for that. That's the best 1486 lung retention. That's what generally you would find among the various countries in the world. Viruses run smaller than 1487 1488 that, but generally it's very difficult to disperse a virus as 1489 a single particle in the size range as shown. Also if you 1490 remember how HEPA paper works, the most penetrating size 1491 particle is somewhere between .1 and .2 microns. Efficiency increases both above and below that point so you're getting 1492 about 99.97 percent efficiency at about .3 microns. That's a 1493 1494 very conservative test we feel and does demonstrate that you get adequate biological and particulate protection. 1495 The protection level itself is an expression of the 1496 outside concentration over the inside concentration. 1497 a . . . as you can see in the example, you have 1,000 ppm 1498 outside and 1 ppm inside, you would have a protection level of 1499 1500 1,000. When I report the data, we'll be going over some of 1501 that. For the exercise routine, it varies depending on the agency that comes in and asks for the testing. Basically 1502 these are the normal type exercises that are done inside the 1503 We've also done lots of different type exercises to 1504 chamber. simulate specific military conditions or civilian conditions. 1505

1506 Generally we would run these exercises for 1 minute duration. Well we also have done different tests such as sweat testing 1507 we call it where we actually run some fairly hard exercises 1508 over a duration of about 30 minutes just to see what happens 1509 under different conditions, but we found that generally just 1510 1511 going through the standard head motions shows the same type of information that we get by going through some other rigorous 1512 1513 type physical activities. Now I'm going to go into some actual data that we 1514 generated on some of the commercially available hoods. 1515 charts are all basically the same although the format looks a 1516 little bit different. On the left, you'll see the protection 1517 factor in terms of specific bands that we try to report it in. 1518 The frequency just tells how many people out of the total 1519 number of subjects fell into what band. The cumulative 1520 percent that shows a percentage of people that were in that 1521 particular band and the past percent shows a percentage that 1522 were higher than that particular band. Generally we look for 1523 a 95 percent point. That's what we'd like to see for a 1524 protection level requirement. You can see in the one test 1525 500 pf was roughly what 95 percent of the people received. 1526 might point out that all the data that I'm going to show you 1527 here is for a hood with a one-size-fits-all type neck dam. 1528

The other test on the right-hand side you can see I've

1529

- 1530 highlighted a 93 percent so somewhere between 500 and 1,000 is
- 1531 what the pf would be on that particular hood system. You can
- 1532 see the total number of people. The first one had
- 1533 48 subjects; the second one had 96 subjects. That often
- 1534 depends on how much somebody is willing to pay to do the test
- 1535 and how many subjects we have.
- 1536 Here's some other; here's two other samples. This
- 1537 particular one shows that the one on the left anyway we didn't
- 1538 have very good protection factors. You can see that only
- 1539 83 percent of the people got above a pf of 10. Nobody got
- 1540 above a pf of 1,000. On the one on the right-hand side, you
- 1541 can see that 95 percent got a pf greater than 2,000 and this
- 1542 all has to do with the design basically of the neck dam in
- 1543 most cases but there also can be other leakage points within
- 1544 the system that we found during testing.
- 1545 We also test. This is one mask shown with a hood sample
- 1546 as well as an oral and nasal sample. Generally there are some
- 1547 small differences between the two. You can see with the hood
- 1548 sample on this particular one 93 percent of the people got
- 1549 over 5,000 and on the oral and nasal sample, 97 percent of the
- 1550 people got over 5,000. So this shows an example of one hood
- 1551 system that provides a very high LRPL sample.
- 1552 Summary results though are basically escape hoods are
- 1553 capable of fairly high LRPL levels values of 500 that look

like they're readily met and greater utilizing the one-sizefits-all neck dam. So I think the baseline data shows that we're in the ballpark in terms of what kind of protection

1557 factor we can expect with hood systems. Are there any

1558 questions? Okay, thank you.

1559 JONATHAN SZALAJDA: Again, you know we're translating and 1560 building the requirements and building on the experiences that 1561 we gained as part of the other programs and I think that this chart basically covers the topics that Wayne addressed in 1562 terms of actual aerosol and the particle size. In addressing 1563 the escape respirator, it's a unique concept in terms of how 1564 we ensure a proper fit for between the respirator and the 1565 individual wearing it and in looking at the population and 1566 1567 trying to consider the audience the user community that would be using this to try and come up with a mechanism to ensure 1568 that we can fit the population that would potentially require 1569 the use of a respirator and to that end, we fall back on 1570 1571 addressing anthropometrics. And with a traditional gas mask type of approach, there's a lot of data, Los Alamos data that 1572 1573 approach that we've addressed to try to come up with different cells and anthropometrics and fit of the respirator to the 1574 face. But with the concerns as far as having an untrained 1575 population trying to use this type of device whether or not 1576 you know trying to design the parameters for the system around 1577

the traditional methodology there, we had some concerns about
how to accomplish that and in looking at a hood type of device
and the physical parameters between the head, the neck, and
the face length seem to pretty well identify and break down
along the traditional small, medium, and large sizes that
could potentially be used to fit an individual to a
respirator.

1585 And to that extent, we fell back and found a fairly 1586 amount of good data that was used by the Air Force in terms of developing a data base for the anthropometrics associated with 1587 1588 the hooded type of device. And we built a test matrix based 1589 upon those requirements that were identified in that 1590 anthropometric data base to encompass small, medium, and large 1591 sizes with really the critical dimension being the neck circumference and with a lot of the issues associated with 1592 1593 wearing a hood and providing a good seal between the wearer 1594 and the respirator that there may be some potential benefit to having a size a tariff-type matrix to address the potential 1595 1596 needs of the user community. Again in terms of actually 1597 conducting the tests, we conceptually view or envision right now is to conduct samples at least five samples per each cell 1598 and use that as the basis for the conduct of the test. 1599 1600 anybody have any questions?

1601 JAY PARKER: Jay Parker with the Bullard Company, I have 1602 a question getting back to the requirements of the test. I see that in Wayne's paper he was using the 5th percentile what 1603 I normally call the 5th percentile or the 95th percentile; 1604 1605 however, the draft does not state that it just states the 1606 measure LRPL shall be 2,000. And that also brings another 1607 question to mind and that is that Wayne's paper stated that 1608 the hoods are capable of 500, but these standards requiring 2,000 so I was wondering why NIOSH has gone with 2,000 whereas 1609 the baseline data indicated lower results. 1610 LES BOORD: Concerning the 2,000, we'll do it in reverse 1611 order. I think some of it and this is one of the areas that 1612 we need to stress that we still are developing and refining 1613 1614 the requirement. Some of the data that Wayne had mentioned did show values I think as high as 5,000 so while the 1615 predominance of the data on a one-size-fits-all would indicate 1616 1617 the 500. There is data that supports a higher level as well. So that sort of goes down the line in the direction of 2,000. 1618 The other area and the other aspect that we're still under 1619 review and considering is the concept of the one-size-fits-1620 1621 all, right now the concept is noncommittal in that regard. So there may be actually some advantages that can be realized by 1622 not employing a one-size-fits-all type of a hooded respirator 1623

- 1624 so that's relative to the order of magnitude. And what was
- 1625 the second question?
- 1626 **JAY PARKER:** About the 5th percentile versus the average
- 1627 or --
- 1628 LES BOORD: Again, this is part of the development
- 1629 process, okay. As we investigate this area more, we will
- 1630 define what that percentile is. Any others?
- 1631 IRA GURVITCH: Ira Gurvitch from I.B.N. Protection
- 1632 Products. Why does the standard have to be a hood if you have
- 1633 a one-size-fits-all mask?
- 1634 LES BOORD: One of the requirements and I think that
- 1635 stated in the concept or one of the concept principles is that
- 1636 it needs to be a head covering so that you are providing both
- 1637 eye protection and head covering from the chemical warfare
- 1638 agents.
- 1639 IRA GURVITCH: Why the head covering? I mean, I've heard
- 1640 that the layer of the skin on the head is thinner than on
- 1641 different parts of the body, but right now you have the
- 1642 general gas mask, you don't have a head covering?
- 1643 LES BOORD: Yes, the concept is we are talking about an
- 1644 escape respirator that you're putting it on. The person
- 1645 really doesn't have any other personal protective equipment to
- 1646 use in this type of environment. The escape respirator is the
- 1647 unit that's carrying him out or carrying him to the safe zone.

- 1648 So it's the feeling conceptually that the need for a head
- 1649 covering is there for head protection.
- 1650 IRA GURVITCH: But I'll go back to the APR's, there's no
- 1651 head covering there and today policemen are walking around
- 1652 with gas masks on their side and they put it on. They don't
- 1653 have an MBC suit or something to cover their head.
- 1654 LES BOORD: Again, good comment, but again, people who
- 1655 are working with an APR in a work environment, they're
- 1656 typically . . . they have the ability to use additional
- 1657 personal protective equipment at the time so it's . . .
- 1658 IRA GURVITCH: Policemen out in the street or civilian in
- 1659 an office . . .?
- 1660 LES BOORD: Good point. I would suggest that you can
- 1661 document these and send it into the docket because it may be
- 1662 something we need to consider.
- 1663 IRA GURVITCH: Thank you. I have.
- 1664 (Unidentified Speaker): If you're talking about the CBRN
- 1665 APR, one of the conditions of use, excuse me.
- 1666 IRA GURVITCH: What are those initials? I am not
- 1667 familiar with those.
- 1668 (Unidentified Speaker): Are you talking about a regular
- 1669 gas mask?

- 1670 IRA GURVITCH: I'm just . . . I'm comparing it to that.
- 1671 Why does it have to be more stringent here than it does for a
- 1672 conventional gas mask for a head covering?
- 1673 (Unidentified Speaker): Our standard is addressing the
- 1674 chemical warfare agents, blistering agents, and you know we're
- 1675 doing the permeation and penetration so on the CBRN air-
- 1676 purifying respirator gas mask, there's a condition of use
- 1677 which says use appropriate dermal protection before entering
- 1678 the area. With the escape mask . . .
- 1679 IRA GURVITCH: But that's not the real world, what's
- 1680 going on. I mean take a look at the New York City police.
- 1681 They're walking around with a gas mask on their side and they
- 1682 have no head covering and the same thing, forgive me, but Les,
- 1683 you're original concept was for inhalation hazards. I
- 1684 remember your original concept on there. So I'm saying what
- 1685 does that have to do with the head and if you're talking about
- 1686 a low concentration for 15 or 30 minutes and you have a one-
- 1687 size-fits-all mask, to me that's a lot more . . .
- 1688 LES BOORD: Again, the concept is and the concept
- 1689 requirement is to provide the protection to the eyes and to
- 1690 the head. That is the concept requirement. I think your
- 1691 point is a good point and I think, I mean we can't really
- 1692 debate it in this forum.

- 1693 IRA GURVITCH: I understand. I'm just trying to bring it
- 1694 up so I was . . .
- 1695 LES BOORD: That's good. I think what I would suggest
- 1696 is, as with everybody else, the comments that are being made
- 1697 here are being transcribed and recorded, but I would encourage
- 1698 you to submit that to the docket as well so it can be part of
- 1699 the decision process in constructing our final requirements.
- 1700 IRA GURVITCH: Okay, because also within a mask versus a
- 1701 hood, at least I know with my mask, it's a lot easier to put
- 1702 on than a hood and a lot quicker and a lot smaller and a lot
- 1703 lighter in weight. I'm just saying those are all important
- 1704 factors that have to be weighed in this type of thing.
- 1705 LES BOORD: Sure, sure. Thank you.
- 1706 RANDY SAKOWITZ: My name is Randy Sakowitz. I'm from
- 1707 TeleScience International. When you talk about one-size-fits-
- 1708 all, is that in terms of adult or is that children or is that
- 1709 both?
- 1710 LES BOORD: Primarily we're talking about escape
- 1711 respirators that are for the general working population so I
- 1712 think by that definition, you would be looking at an adult
- 1713 population.
- 1714 RANDY SAKOWITZ: So these standards aren't in regards to
- 1715 children.

- 1716 LES BOORD: No. Again, it's for the general working
- 1717 population.
- 1718 RANDY SAKOWITZ: Okay, thank you.
- 1719 LES BOORD: Any other questions? I think we are running
- 1720 a little behind, but would really like to try and finish the
- 1721 morning segment of the presentation. So . . .
- JONATHAN SZALAJDA: Okay, to that extent, we're going to
- 1723 move ahead and discuss some of the human factors and the
- 1724 environmental conditioning aspects as well as some of the
- 1725 engineering design parameters that we're considering for this
- 1726 type of device. The next presenter is going to be Frank Palya
- 1727 from Policy and Standards Group within NPPTL.
- 1728 FRANK PALYA: Thank you John and good morning, barely. I
- 1729 am going to present the concept for the human factor
- 1730 requirements for the escape respirator. As you can see, it's
- 1731 the field of view, fogging, and communications.
- 1732 The first one that I'm going to discuss is the field of
- 1733 view requirement. In order for the escape respirator to pass
- 1734 the field of view requirement, it must obtain a visual field
- 1735 score of greater than or equal to 70. An apertometer that
- 1736 meets the requirements of the EN 136 or equivalent will be
- 1737 used to perform the field of view test. And the respirator
- 1738 size that anatomically best fits the head form will be used.
- 1739 Again, we're talking about the concept of one-size-fits-all

and that will be the official visual field score will be the 1740 average of three different fittings too. This 70 points was 1741 derived from the AMA guidelines, the functional impact which 1742 basically translates to a mild visual impact when you obtain a 1743 score of 70 which basically means they require scanning for 1744 some of the obstacles. This is the same test that we use to 1745 test a full face piece gas mask respirator. It was set at 75. 1746 1747 This one is set at 70. On the left part of the slide illustrates is an 1748 illustration of the apertometer that will be used for the 1749 field of view test. On the right side is the field of vision 1750 plotting chart. Both of these, if you look at it, has the 1751 same skill and the grid on the right here assigns a 110 points 1752 to a field of view within the radius of 70. 50 points are 1753 assigned to this same area up to 10 degrees fixation. 1754 There are 36 meridians . . . this thing has a hair 1755 trigger . . . I was trying to point on there but it wasn't 1756 working . . . place at the top. If you look at the different 1757 meridians, there's 36 of them basically at the 10-, 20-, 30-, 1758 40-degree mark and so on around the entire circle there and 1759 the radius's are, again as I said, at the 70-degree mark 1760 radius and the 10-degree mark at the . . . there are 50 points 1761

assigned to the central area and basically what this does is

that it assigns a high priority to the center area as opposed

1762

1763

- to the outer periphery. As you can see on the hemisphere 1764 there, the apertometer hemisphere, it's a dome shape and 1765 again, the center has a higher priority and the points are 1766 assigned there at 25, 55, 120 as you can see all around. 1767 how this works is when you put the respirator on the head form 1768 and you illuminate the lights, the lights will shine through 1769 1770 the lenses of the respirator and it will illuminate around the It'll create a lighted area and then what you basically 1771 do is count the points inside the lit area and that'll be your 1772 score. Go ahead Les. This is an example of such. As you can 1773 see in the upper right quadrant, this area has a value of 1774 22 points. The left upper 22 again, lower left is 27, and 1775 lower right 25. This particular fit, this is fit 1 of 1776
- This slide illustrates the field of view scores for some of the escape respirators. As you can see, there's different fits and then to average at the end and that will be the official field of view score.

respirator 1, you got a score of 96.

1777

The next human factor requirement that I'm going to

1783 discuss is the fogging resistance. The fogging resistance

1784 will be tested in two environmental conditions. The low
1785 temperature one will be at 13 °F. It was based on the normal

1786 daily mean temperature of Minneapolis, Minnesota, in January.

1787 January was selected because it was the coldest month of the

- 1788 year on record for the past 30 years. The data was obtained
- 1789 from the National Oceanic and Atmosphere Administration
- 1790 (NOAA). The next environmental condition is the hot humid
- 1791 condition. It will be set at 90 °F at a 60-percent relative
- 1792 humidity. Miami, Florida, was used as the base city because
- 1793 it's one of the hottest and most humid cities in the United
- 1794 States. The data was also obtained from NOAA and the month of
- 1795 July was used.
- 1796 There will be three visual acuity tests administered.
- 1797 The human subject will don the mask in atmospheric conditions.
- 1798 A visual acuity test will be administered and will then be
- 1799 administered as soon as they enter into one of the
- 1800 environmental chambers whether it be the hot or be the cold.
- 1801 The Snellen chart will be used to test for visual acuity.
- 1802 Then there'll be a 5-minute exercise period and then during a
- 1803 2-minute rest period another visual acuity test will be
- 1804 administered. The procedures . . . you're probably wondering
- 1805 why well geez* why are they going and donning an ambient and
- 1806 then going into an environmental chamber? And what this is
- 1807 suppose to replicate is if an office worker or somebody
- 1808 indoors in ambient condition dons the respirator and runs out
- 1809 into the outdoor conditions, we want to make sure that this
- 1810 doesn't . . . they'll fog up when they go from ambient to
- 1811 extreme cold or ambient to very hot humid conditions. I think

- 1812 that would create another hazard if they would go ahead there
- 1813 inside the mat, respirator where they cannot remove it and
- 1814 then it would create a physical hazard by not being able to
- 1815 see.
- 1816 There will be two different human subjects tested for an
- 1817 environmental condition; however, the same human subject will
- 1818 be used for hot and then also for cold. For each individual,
- 1819 an average of visual acuity score chamber will be calculated
- 1820 and that's basically the first reading plus the second reading
- 1821 divided by two. And then to get the performance rating, what
- 1822 you basically do is to take the average visual acuity in the
- 1823 chamber and divide it by the ambient and multiply it by 100.
- 1824 In order for the escape respirator to pass the fogging
- 1825 requirement, all four performance ratings must be greater than
- 1826 or equal to 70.
- 1827 This slide illustrates some of the models that were
- 1828 tested for fogging. As you can see -- I'm sorry this one
- 1829 right here is for the cold chamber. The average ambient
- 1830 temperature test was 75.8 degrees. It was a little bit higher
- 1831 than what we wanted, but it successfully passed. All the
- 1832 models passed the requirement for the cold chamber. Next was
- 1833 the hot humid. As you can see, model P did not pass for this
- 1834 particular test. If you look at the ambient, again it was in
- 1835 the afternoon when we started testing and we didn't have

- 1836 the . . . the air conditioner wasn't functioning so it got a
- 1837 little bit higher. The data may have been worse, it may have
- 1838 been worse, if it was a little closer to 72 degrees.
- 1839 The final human factor requirement that I'm going to
- 1840 discuss is the communications requirement. The communications
- 1841 speech and intelligence capability of an escape respirator is
- 1842 an optional feature. We look at it as a market-driven
- 1843 feature. The communications conveyance is not a mandatory
- 1844 requirement like I said so it'll be up to the manufacturers.
- 1845 The manufacturer wants the respirator to be NIOSH qualified
- 1846 for communication. They'll request NIOSH to do the testing
- 1847 for it and they'll be denoted on the NIOSH approval if it
- 1848 passes the requirement. Again, the requirement should be
- 1849 greater than or equal to 70 percent.
- The test method that will be used to test the
- 1851 communication performance requirement of the escape respirator
- 1852 will be the Modified Rhyme Test. This is the same test and
- 1853 test requirement as the CBRN gas mask. The background will be
- 1854 set at 60 decibels consisting of a broadband pink noise with a
- 1855 frequency range of 20 hertz to 50 kilohertz. The distance
- 1856 between the speaker and the listener will be 10 feet. There
- 1857 shall be 10 MRT's trials conducted yielding 15 MRT scores per
- 1858 listener with respirator and without respirator, 15 without.
- 1859 Enclosed are some of the MRT test results of the three

- 1860 respirators that NIOSH obtained. As you can see, none
- 1861 successfully passed the requirement. And also I may note that
- 1862 none of the respirators has any voice conveyance mechanism
- 1863 incorporated into the design.
- In summary, enclosed are the requirements for NIOSH
- 1865 escape respirator requirement for the human factors. At this
- 1866 time, I'll answer any questions.
- 1867 If not, I'd like to move on to the environmental
- 1868 durability challenge test. I'd like to go . . . briefly go
- 1869 over the overview. I want to discuss the purpose of the test,
- 1870 the goal, the general assumptions, type of durability tests,
- 1871 assumptions for the test, and the rationale. The purpose of
- 1872 the test is to ensure that integrity is integral to design and
- 1873 packaging of the escape respirator. Basically because it's
- 1874 almost a one-time use situation that's in a self-contained
- 1875 packaging, the packaging would be inspected but think about
- 1876 it, the respirator really can't go through its inspection such
- 1877 as a full-face air-purifying respirator. The goal is to
- 1878 ensure that the escape respirators provide adequate
- 1879 respiratory protection after being subject to potential
- 1880 environmental and normal transportation storage conditions
- 1881 induced by the user. Again we're not testing the
- 1882 manufacturers' over pack or trying to replicate any kind of
- 1883 shipping, but this is from the point of issue.

General assumption is that again it's from the point of 1884 issue by the user. The CBRN escape respirator will be 1885 subjected to the durability test and the ready-to-use 1886 configuration to individual unit pack. The assumption is that 1887 it will remain sealed. And also it's for a non-industrial use 1888 scenario for CBRN emergency use only. First the escape 1889 respirator will be subjected to high temperature at 71 °C 1890 constant temperature in accordance with MIL-STD-810F. 1891 1892 duration will be for 5 weeks. The reason for this testing is to simulate solar loading conditions representative of 1893 climates in the southwest U.S. Again, the rationale is that 1894 1895 we went ahead and looked at the meteorology data from Phoenix, Arizona, from the Arizona State University and from NOAA. 1896 also factored in an inducement factor from MIL-STD-810F. 1897 also takes into account induced temperature and aging testing 1898 of the respirator. After the high-temperature test, the 1899 respirator will be subject to the low temperature of -31 °C. 1900 Again, this will be constant in accordance with MIL-STD-810F. 1901 The duration will be for 3 days. It simulates the outdoor 1902 storage temperature in the basic cold regions. The 3 days was 1903 chosen because it's representative of minimum temperature in 1904 the U.S. intermediate zones and also the duration is what 1905 1906 MIL-STD-810 recommends.

1907 The third and last environmental test condition is the humidity storage test. The escape respirator will be subject 1908 to a natural diurnal humidity cycle which varies from 31 °C to 1909 41 °C. Also the relative humidity is 88 percent to 59 percent 1910 and that's also in accordance with MIL-STD-810F. It's for a 1911 5-day quick look and it's representative of again humid 1912 regions, also, again, such as Miami, Florida, and also again 1913 the rationale for the 5-day quick look is what MIL-STD-810 1914 1915 recommends.

The next test for durability is the transportation shock 1916 1917 test which consists of vibrating the escape respirator in accordance with MIL-STD-810F. Again, this is similar to the 1918 CBRN gas mask, full-face gas mask. The respirator will be 1919 vibrated on three axes for 12 hours per axis. This vibration 1920 test is the same, again, it's the same vibration test as the 1921 gas mask. This replicates conditions over the U.S. highways 1922 in a vehicle and we're doing this test to determine if there's 1923 any initial life-cycle failures. This chart illustrates the 1924 three axes of vibration. 1925

1926 And the last durability test is the drop test. The
1927 intent is to drop the escape respirator from a height of
1928 3 feet onto each of the three different axes. There'll be one
1929 drop per axis totaling three drops. One impact surface per
1930 axis and this is to replicate several falls from a table or an

- 1931 automobile over the life time of the respirator. Again, this
- 1932 is incorporated into the requirement as to ensure that there's
- 1933 integrity built into design factoring of the respirator. This
- 1934 is the axis of the drop, again, I'm just emphasizing that it's
- 1935 just only one . . . it will be dropped on one surface of the
- 1936 axes totaling three.
- 1937 In summary, this is all the durability test requirements
- 1938 for the escape respirator. The very first one will be hot,
- 1939 cold, humidity, and on down to drop. At this time, I'll
- 1940 answer any of your questions.
- 1941 JOE DUNLAP: Joe Dunlap with ILC Dover, what is going to
- 1942 be the acceptance criteria after these conditioning tests are
- 1943 run? Are you going to use the laboratory respiratory
- 1944 protection level as your acceptance criteria? Are you going
- 1945 to be using SMARTMAN or some other standard?
- 1946 FRANK PALYA: Well, as it was with the CBRN APR, we went
- 1947 ahead there and . . . I mean . . . We would look at the
- 1948 packaging and it would be denoted in the test report but then
- 1949 it would go through a series of gas life testing, pressure
- 1950 drop testing, all the usual tests that NIOSH conducts,
- 1951 filtration testing. For the LRPL test, I believe that
- 1952 probably would be a different batch of respirators for that
- 1953 similar to the CBRN APR gas masks. There's a flow chart on
- 1954 the web site. Now that's just for the gas mask, illustrates

the flow of the respirator that is brought in and what 1955 1956 respirators are used for what testing. I would imagine this 1957 escape-type respirator will be pretty similar. Thank you. 1958 JONATHAN SZALAJDA: In an effort to get us pretty much on 1959 schedule or close to schedule, Les is going to wrap up this morning's session with some of the other design parameters 1960 that we're considering as far as concepts for the requirement. 1961 1962 LES BOORD: Okay, this last section will be a little bit of a hodgepodge because we're in . . . run through the 1963 requirements for donning, flammability, the definition of the 1964 1965 hood device, and breathing resistance. In the first slide is 1966 the requirement . . . flammability requirement or concept and again this is principally for the respirators and the hoods 1967 that would be used let's say in a fire-type environment so 1968 1969 what we did was we actually looked to an existing standard, a 1970 draft standard which is the ANSI ICA air-purifying protective 1971 smoke escape hood device and also EN 136 test equipment where 1972 the respirator is exposed to an array of burners. requirement there is that after the flame exposure, there is 1973 no after flame after 5 seconds and that no drip, melt, or 1974 other damage is visible to the respirator and primarily the 1975 1976 hood. And again, understanding that again, this is in the concept stage and how we actually fit this requirement into 1977 the overall requirement still needs to be determined whether 1978

1979 it is applicable to 100 percent of the devices or whether it's 1980 applicable to only those that achieve certain protections. So

1981 that's still an area that would need to be further developed.

1982 The next requirement and as it's defined in the concept 1983 paper we're looking at a donning time requirement and the donning time of 30 seconds which I think is again consistent 1984 with some of the other escape masks, escape respirators 1985 1986 standards that are in existence or being worked on. And the donning time of 30 seconds from a ready-to-use configuration 1987 where ready-to-use is considered to be the operational 1988 package, the package that the user would be confronted with if 1989 he needs to employ the respirator. Again, as stated in the 1990 concept, the requirements would be for escape respirators 1991 rated at 15, 30, 45, or 60 minutes depending on how the 1992 manufacturers specifies it and again rated according to the 1993 gas capacity for the particular respirator so the gas life at 1994 1995 the appropriate interval of time.

And then, finally, to touch back on the head covering
again that the concept currently is that the escape respirator
is for a head covering shall be designed as a hooded device
and the hood shall include an area for field of vision and
compatible with wearing glasses. And again, I would encourage
any comments relative to other alternatives to be provided to
the docket so that they can be reviewed.

- Then the final requirement that I'd just like to mention
- 2004 is the breathing resistance which is again borrowed directly
- 2005 42 CFR and that requirement is stated at 85 liters per minute
- 2006 the inhalation resistance is less than 70, 70 mm of water and
- 2007 exhalation resistance is less than 20. And with that if
- 2008 there's any questions, any questions relative to those? So we
- 2009 managed --
- 2010 LARS RONNER: Lars Ronner from Sundstrom Safety coming
- 2011 back to flammability, did we talk about six-burner test or
- 2012 one-burner test?
- 2013 LES BOORD: I believe it's the six-burner test. That's
- 2014 the array of burners.
- 2015 LARS RONNER: Of course talking about 800 °C according to
- 2016 EN 136, then it's a one-flame burner test.
- 2017 LES BOORD: Okay, thank you.
- 2018 ERIK JOHNSON: Erik Johnson, 3M, you're comment that the
- 2019 flammability was definitely in the concept phase it might be
- 2020 only applied to some of the submissions. Was that for the
- 2021 submissions that would have the CO approval?
- 2022 LES BOORD: That would be the possibility, yes.
- 2023 **ERIK JOHNSON:** Okay.
- 2024 LES BOORD: So it may be you could actually segment these
- 2025 types of escape respirators by their protection.
- 2026 ERIK JOHNSON: Thank you.

JAY PARKER: Jay Parker with Bullard, I would just add to 2028 this last statement here that it should also be compatible with beards as well as glasses.

LES BOORD: Good point. Yeah, I think that's a very good 2030 point. When we think about a hooded respirator, a lot of 2031 times we sort of think that that bypasses some of the normal 2032 considerations that we need to address when using a face piece 2033 and that's not necessarily the case facial hair, glasses, and 2034 so forth still enter that equation. Any other questions or 2035 comments? Notice how quick that was. So with that, I think 2036 we'd like to adjourn for lunch. We have allowed 1 hour and I 2037 think we can stick to that. So . . . 2038

2039 (BREAK)

JONATHAN SZALAJDA: The chemical warfare agent simulant 2040 project as well as introducing concepts for the self-contained 2041 escape respirator and then we have some additional CBRN 2042 standards development topics which will be covered at the end 2043 of the day plus also any comments or information that you 2044 2045 would like to share either with the standards development team or with the community as a whole. With the standards of 2046 development program, one of the things that we heard in 2047 responding to our stakeholders and the whole development 2048 process was a need for tools for the manufacturing community 2049 to allow pre-certification testing of their equipment against 2050

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the chemical warfare agents that . . . You know, there aren't
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      that many facilities available for evaluation of materials
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     that could be used in the development and construction of the
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      respirator to be tested against the penetration and permeation
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      effects of the chemical warfare agents. So following the
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      request from the manufacturers for us to look into the
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      identification of potential simulants, NIOSH and SBCCOM sent
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      out in collaboration to conduct a project to identify
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      simulants for use by the manufacturing community and others to
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      evaluate the materials for effects of penetration and
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     permeation from different agents and what we're going to cover
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     here for the next half hour or so is the current status of
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      that work. Frank Palya is the NIOSH project officer who is
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      managing the work. Dr. Rivin from SBCCOM at Natick or at
2064
      least for today is the principal investigator who's conducting
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      this effort. And what I would encourage you to do if you have
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      some specific technical questions regarding the work if it's
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      going to be getting to too much of a technical detail that
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      Dr. Rivin will be making himself available to your questions
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      and I would suggest if it's not something of a general nature,
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      but if you wanted to get into more specific technical type
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      discussion if you could catch him during the break or
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      following the presentations at the end of the day. So with
2073
      that Frank Palya will introduce the project.
2074
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FRANK PALYA: Thank you John. As John had mentioned 2075 before that I am the project coordinator for the chemical 2076 warfare agent's simulant project and Dr. Rivin is the 2077 principal investigator. I'm going to discuss the need for the 2078 project and some of the administrative details. This project 2079 was funded by NIOSH and SBCCOM conducted the research and 2080 experiments at the Natick, Massachusetts, locations and at the 2081 Edgewood, Maryland, locations. For this project I want to 2082 make it clear to everyone that when we're talking about 2083 simulants we're talking about chemical compounds that have the 2084 same permeation and penetration effect on personal protection 2085 equipment varying materials as chemical warfare agents namely 2086 sarin GB and sulfur mustard HD. 2087 I would like to emphasize that actual chemical warfare 2088 agents will also be used during the testing for NIOSH 2089 certification of respirators. This project is to provide 2090 personal protection equipment manufacturers with information 2091 so they can select simulants to perform development at work or 2092 2093 for doing some of the pre-testing before submitting their applications to NIOSH. For the overview, we'll present some 2094 background, the purpose and the objective, the permeation of 2095 the chemical warfare agent simulants, the goal or approach. 2096 Dr. Rivin will be talking about the technical details,

2097

2098 potential benefits, accomplishments and current status of our 2099 research, and the summary and conclusions.

The purpose is to identify through research and testing 2100 chemical compounds to simulate the permeation and penetration 2101 effects of GB and HD through barrier materials. The objective 2102 is to identify simulants and laboratory procedures that can be 2103 used by manufacturers for estimating breakthrough or 2104 permeation breakthrough times of the actual chemical warfare 2105 agents through materials used by the manufacturers for their 2106 personal protection equipment. In general, the breakthrough 2107 time is the time for a chemical to seep through the surface of 2108 a barrier material of the personal protective equipment such 2109 as in respirators or protective suits that are worn by the 2110 2111 first-responder community.

Our goal was to develop a low-cost, rapid simulant 2112 screening method for determining agent permeation through 2113 2114 barrier materials. Again, the approach was to develop an inexpensive permeation test that can deploy a new test cell 2115 design that can accommodate both hard and soft barrier 2116 materials up to at least 1-cm thick. The manufacturers can 2117 use at their own convenience in their own research labs making 2118 it a lot available . . . availability to them would certainly 2119 reduce the cost. Selects relatively non-toxic simulants for 2120 GB and HD based on solubility of the standard polymers. Tests 2121

- 2122 the performance of certain barrier materials by comparing
- 2123 their breakthrough times when exposed to the actual chemical
- 2124 warfare agents in other words just compare the agents
- 2125 for . . . the permeation times of the actual chemical warfare
- 2126 agents versus simulants.
- 2127 At this point, I'd like to call upon Dr. Rivin to discuss
- 2128 the technical details.
- 2129 DONALD RIVIN: Thank you Frank. Before I start, let me
- 2130 just add that as Frank mentioned, this work was done both in
- 2131 Natick and Edgewood and there were co-investigators at
- 2132 Edgewood, Wendel Shuely and Bob Lindsy, and Wendel is here in
- 2133 the audience and sure you'll be willing to talk to everyone
- 2134 afterwards also.
- 2135 On this, we see the basic permeation system. I'll go
- 2136 into more detail of the cells shortly, but it's quite a simple
- 2137 system. The basic detector we've been using is a flame
- 2138 ionization detector. We tried other detectors too and any
- 2139 detector that is sensitive enough for the vapor concentrations
- 2140 that we experienced would be okay. And we're dealing with
- 2141 high vapor concentrations and the reason for that is that we
- 2142 have chosen to use a fully wetted specimen rather than drops.
- 2143 There are theoretical reasons to do this. There is a direct
- 2144 relationship between how the materials perform with the drop
- 2145 challenge and a fully wetted surface challenge, but you get

much higher permeation rates. It's much faster permeation. 2146 It's much simpler test when you run it with the fully wetted 2147 surface. I won't go into more detail about the system. 2148 can ask questions later. It's as I say relatively simple. 2149 The cell is composed of two major parts: the bottom 2150 section which has the gas flow below the specimen. 2151 specimen sits on a little platform in that specimen . . . in 2152 There is where the air fluent is swept into the 2153 that cell. detector. The top part is the section which screws into the 2154 bottom section and it creates the liquid well. We can see 2155 that much better in the next slide. Here are two views of the 2156 The first are the two major components, the top and 2157 bottom of the cell. Upper left-hand corner is the top of the 2158 cell and we have a quick connect gas connection on there; 2159 that's on the left-hand side. Relatively simple, it has 2160 grooved sides and the top section which is directly below it 2161 has a screw on it and it just screws in. However, you first 2162 put the specimen in. The specimen is a 1%-inch diameter disk. 2163 The actual size is not critical. It has to be large enough to 2164 cover that hole and this is about three-quarters of the 2165 available surface at the bottom of the base of the cell. You 2166 put the specimen in and the Teflon O-ring or gasket which is 2167 shown on the right sits on top of that specimen. 2168 is there so that when one screws in the top part, there's no 2169

movement of the sample which is underneath. And on the right-2170 hand side, you see the arrangement that's the bottom of the 2171 cell with the specimen in there, the Teflon O-ring, and the 2172 top part screws in. Sitting on top of this is a loose fitting 2173 cap that's just to limit the evaporation of the liquid. 2174 don't want it to be very tight because you don't want to 2175 create a vacuum up there as liquid permeates through. We find 2176 2177 that there is very little evaporation of liquid through the 2178 top of the cell. Now, using the cell, we now have to find what are the 2179 best simulants to use with the agents. And to do that we 2180 first selected test materials and we decided to use 2181 representatives of a series of well-characterized elastomer 2182 samples which covered a range of barrier properties. 2183 initially emergent testing with these samples to determine 2184 relative rates of uptake and solubilities and from this we 2185 selected four samples, four rubbers. Three of them we did 2186 permeation testing with both agents and simulants as well as 2187 emergent testing. One of them which is nitrile rubber we did 2188 simulant work and emergent testing. We had not yet done agent 2189 testing on that. So when I show you the results later, most 2190 of what you will see would be these three elastomers with 2191 different agents and simulants and there'll be some results 2192 with the nitrile also. As far as the simulant, before we get 2193

to that, the question, what we're really after is how good of 2194 a barrier material do we have so this is a permeability 2195 question. Permeability is the product of the diffusion 2196 coefficient or diffusivity, the solubility and it's inversely 2197 proportional to the thickness. Diffusion coefficient is 2198 mainly a function of the molecular cross section or volume so 2199 a molecule which is much larger than another molecule will 2200 diffuse more slowly. Solubility, however, is controlled by 2201 factors which are much more complex than just the size of the 2202 molecule. They have to do with the specific chemical 2203 2204 interaction which shows up in the solubility. So here you want to be able to pick a simulant which has similar chemical 2205 interaction to the agents in a variety of different materials. 2206 If you don't do that, you end up showing an excellent 2207 correlation in one particular barrier material and a 2208 completely different relationship in another. So that's why 2209 we did our preliminary evaluation doing emergent testing which 2210 allowed us to both get a measure of the diffusion coefficient 2211 2212 and also the solubility. I don't want to leave thickness out because that's 2213 critical. If you are using permeation, let's say the steady-2214 state permeation as a criterion, then your permeation is 2215 inversely proportional to thickness. If you're using break 2216 time or other time characteristics which I will talk about a 2217

- 2218 little more in the future and later on, then it's proportional
- 2219 to the square inverse square of the thickness. So thickness
- 2220 is a very, very important parameter here and you have to
- 2221 correct for that in order to compare materials.
- Now we looked at a relatively large number of simulant
- 2223 candidates, actually more than I have on this table here, but
- 2224 we did the most work with the ones that you see here. And
- 2225 those four which have an asterisk are the ones that we decided
- 2226 to go ahead with the more intensive permeation studies with.
- 2227 So what you will see from this point on are data with these
- 2228 four simulants. I have them broken down here as HD simulants
- 2229 and GB simulants because everyone always talks about simulants
- 2230 particular agents. When I go farther on, you're going to see
- 2231 that there's a fallacy here. Now this is a permeation curves.
- 2232 One of the things we did was we chose the thickness of the
- 2233 elastomer to compensate the differences in barrier properties.
- 2234 We didn't want to do these experiments with one elastomer,
- 2235 let's say silicon rubber, which is a relatively poor barrier
- 2236 so that we would get an experiment which took place in 2 hours
- 2237 with the particular thickness and then ran with butyl rubber
- 2238 and got it, took place in 4 days. So what we did was knowing
- 2239 what the properties of these materials were, based on the
- 2240 emergent results, we could select thicknesses of these
- 2241 polymers so that we would get results within let's say a

- factor of two or three in terms of overall time of the
 experiment. This doesn't in anyway affect the overall result.

 It just makes it a more convenient experiment. So here we
- 2245 have results with three different polymers and three different
- 2246 simulants. You get an idea of what the curve shape looks
- 2247 like. Now we use these curve shapes to determine
- 2248 characteristic parameters and that's as we see here. Now
- 2249 there are three of these characteristic parameters that really
- 2250 define the permeation curve.
- 2251 First is this T_b which is the time at initial break. Now
- 2252 you will often see break time of values and very often what's
- 2253 meant by that is the time at which people first detect some
- 2254 air fluent coming through. This is of course very sensitive
- 2255 to the method of detection. The $T_{\rm b}$ value here is one based
- 2256 more closely to theoretical . . . on theoretical grounds and
- 2257 it's the intercept of the linear portion of the curve. If you
- 2258 notice this "S" shaped curve the lower portion of it is
- 2259 linear. And you take the intercept on the background time
- 2260 axis and see there's a slight positive background in this you
- 2261 take that intercept that's $T_{\rm b}$. For the agent work we measured
- 2262 both the first detection of penetration and $T_{
 m b}$ and, in fact
- 2263 for most of the cases, they were the same or within few
- 2264 percent. In the case of silicone there was some detection of
- 2265 small amounts of material before you came to T_{b} , but it did

not affect the overall results. T 1/2 is the time at which 2266 you reach one-half of a total permeation. This again is 2267 related on theoretical grounds with the fusion coefficient. 2268 So both T_b and T 1/2 you can calculate the fusion coefficient 2269 from these which are completely independent of solubility of 2270 the chemical interaction. That's very important because in 2271 order to check the validity of our results it's nice to have 2272 some independent methods of comparison. And what we did was 2273 we compared the diffusion coefficients that we obtained from 2274 T_b and T 1/2. Which again, are independent of solubility, or 2275 any of these factors, to the diffusion coefficient that we 2276 obtained at the third characteristic parameter, that is the 2277 steady-state permeation value. And that requires, as you saw 2278 from the equation previously, knowledge of solubility, as well 2279 as the thickness. So if one can obtain a diffusion 2280 coefficient at steady-state, which is not too different from 2281 what you obtain at T 1/2 and T_b then you have an internal 2282 check that you have meaningful data here. We also included a 2283 diffusion coefficient obtained from the emergent work, which 2284 again is a completely different experiment. That checked out 2285 pretty well with these results. I have one other parameter 2286 here the $T_{\rm s}$, this has no theoretical significance, and it's 2287 simply there, as an indication of how long the experiment is. 2288 We now have a final report on this. We list $T_{\rm s}\mbox{ data}$ so one 2289

2290 has an idea of how long it takes to reach a steady-state. 2291 you have some idea what the total experiment time is. T_b and 2292 T 1/2 are fundamental and what I'm showing on this graph is 2293 the normalized T_b and T 1/2. Mentioned earlier that you can 2294 calculate diffusion coefficient but the diffusion coefficient 2295 is related to these times and the square -- inverse square of 2296 the thickness. What this is is we've taken these times, Tb and T $\frac{1}{2}$, and divided by the square of the specimen thickness. 2297 2298 What we see on the bottom, I hope you can see it all, are 2299 three polymers, starting with Silicon, we show the 2 agents, 2300 HD and GB and the four simulants. The left-hand block is T_b 2301 and next to it is T 1/2. First thing I'd like you to see is 2302 the general fingerprint that you get. There are some 2303 differences in these polymers and they are not terribly 2304 different. The biggest change we have, the biggest range we 2305 have is in the case of butyl, which is the middle set of the 2306 graph and that has about a factor of 8 between the highest and 2307 lowest normalized diffusion parameter, characteristic time. 2308 In the case of Silicon and EPDM it's much smaller. Also notice, the relationship of HD and GB, they're not very 2309 2310 In the most extreme case is about a factor of 2 different. 2311 difference, in many cases they're much closer than that. Also 2312 as I inferred before the question of what is a HD simulant or 2313 a GB simulant. Well the first two simulants, DCH and CEPS are

presumably HD simulants and the next two are DIMP and DEMP are 2314 2315 GB simulants or D agent simulants and you can see that there isn't much of a difference. So bottom line here is that you 2316 could chose any of these simulants and get a pretty good value 2317 2318 for the data for most of the -- particularly in Silicon and In the case of butyl, you can bracket the data you get 2319 2320 with the agents with DCH and CEPS or DCH and DIMP. Again, 2321 within a factor of 2, you can do better if you develop a more extensive data base, you can do much better than that but it's 2322 not very hard to get that kind of agreement. Now there are 2323 other ways we can take this data and other criteria we could 2324 use for looking at the barrier properties. So this is one 2325 this is actually measured break time or half-time, let's limit 2326 it for simplicity to break time. Another method that's been 2327 used is the permeability. Permeability is simply the 2328 permeation divided by the thickness. As I mentioned earlier 2329 since thickness comes into it you can compare a 50 mil 2330 material with a 2 mil material and you don't know what their 2331 real characteristics are unless you correct for thickness. 2332 I've just said that, but I will go into the next exhibit and I 2333 will negate that. Right now looking at this, what we see on 2334 the left-hand side are the four polymers and the simulants and 2335 the agents. And you can see that silicone is such a . . . is 2336 such a poor barrier relative to the others that you can't tell 2337

very much about the other polymers if you put them on this 2338 scale because silicone dominates. But looking at the silicone 2339 results, what you see is that no matter what we're using as 2340 the permeable we're getting results which are pretty close. 2341 Again, this goes along with those kinetic parameters T_b and 2342 T 1/2. Permeability, of course, takes in both, the kinetic, 2343 the diffusion coefficient as well as, I believe, not much 2344 difference in the case of silicone. Now on the right-hand 2345 side I've eliminated silicone the same data that we see on the 2346 left with the scale now is expanded we've left out the 2347 silicone. Here you begin to see more of a difference between 2348 these polymers. On the right-hand side of that is the HD and 2349 GB and you can see again that you can pretty well bracket the 2350 HD and GB results with CEPS and DCH. As I mentioned earlier 2351 we have not run nitrile with the agents so I don't have a 2352 nitrile curve there. So you'll have to limit the comparison 2353 to EPDM and butyl on the right-hand side. Again, you can 2354 easily bracket them with these agents, or if you have again, a 2355 data base and in our report we have the data for these 2356 materials but if one has a more extensive data base one can 2357 easily develop pretty good correlations there. Finally, I 2358 said I'd negate my comments about thickness. Let's say you 2359 have an unknown material of whatever thickness and you wanted 2360 to say, well how does this compare as a barrier material to 2361

something else that we're using which we know is a good 2362 barrier. Now we know for example the butyl rubber is a good 2363 barrier, 12 mil butyl will pass the drop test, easily enough. 2364 And we could simply say let's take . . . this is our standard 2365 material and we run it with a particular simulant, let's say 2366 we ran it with dichlorohexane, DCH, which is the top line. If 2367 our unknown material, of whatever thickness gives us a 2368 permeation curve which is equal to or below this then that's 2369 as good a barrier as butyl, based on this kind of criteria. 2370 If we took DCH as the value, that's the line right near the 2371 bottom, the dark -- I'm colorblind I think that's blue -- line 2372 near the bottom. Then you would then relate that, if you had 2373 an unknown material that was much greater then it would not be 2374 as good a barrier. If it were equal to or less than this then 2375 you have a good barrier material. So this would be a way of 2376 using the test method and a simulant with an unknown material 2377 2378 if you want to relate it to a standard material. described three methods, I have not said use one or the other 2379 of these because I think there are considerations for both. 2380 There is a fourth method that could be used. You could say 2381 well we want to get a certain amount of permeation now in the 2382 drop methods they listed a certain permeation level which 2383 would be a pass or fail. You could do the same thing with 2384 this test. So again, the question of how to use it and what 2385

will be the easiest and most effective for you is something which you can be thinking about and we can talk about

2388

afterwards also.

Just to summarize this, where we are now we have 2389 developed a permeation test method that we feel is quite 2390 reproducible and reliable. And as I mentioned it uses a fully 2391 flooded permeation cell, which gives you a maximum air fluent, 2392 which is again relatable to the smaller permeation you get 2393 with the drop loadings but allows you to use a variety of 2394 different kinds of detection equipment. I mentioned the flame 2395 ionization detector, in fact, we used a few of these, one of 2396 them was actually a gas chromatograph. We just bypassed the 2397 columns and just used the detector in the cell. I've given 2398 you a few different ways that you could use this data and 2399 we've shown some simulants, which we feel are pretty good ways 2400 of predicting how these materials will respond to an agent. 2401 2402 We've written a paper on this and a test method, and this has been submitted to NIOSH. I'll leave it up to them to decide 2403 how they want to discuss that aspect of it. Now this is a 2404 method which was developed for correlating relatively nontoxic 2405 chemicals with agents, but as you can see the cell doesn't 2406 care and the detectors don't care what the toxicity of the 2407 material is. So this method is just as useful for TIM's and 2408 TIC's and whatever other chemicals you want. The only 2409

requirements that you would have on this is that the simulant 2410 you use doesn't dissolve the material. The test doesn't work, 2411 if it dissolves, and it doesn't attack the cell. The cell 2412 is . . . materials we used were stainless steel and aluminum 2413 alloy which we knew were stable and useable with agents and 2414 we've had no problem with them. How one uses this well as 2415 Frank mentioned it can be used as a preliminary test this is 2416 not part of a specification. This is not the final test you 2417 use but you can, I think, really characterize materials and 2418 determine whether something is likely to pass the agent 2419 testing by running a test like this. I've basically, 2420 summarized most of what we have here. At this stage we have, 2421 I think, a good method and we have statistical data over a 2422 range of materials which indicates the reliability of the 2423 method. There are additional things that we feel should be 2424 done; for example, we only have a limited range of polymers. 2425 2426 Two of them are basically hydrocarbon polymers they were carbon black filled butyl and EPDM. One of them was a 2427 peroxide cured silicone which is more polymer -- more polar, 2428 excuse me, but we would like to extend this to a few more 2429 polymers to make sure that the relationships that we're seeing 2430 are durable. The test procedures are described in the draft 2431 we have given to NIOSH and the disclaimer is I guess you've 2432 seen that before. Thank you, that's it if there are any 2433

- 2434 questions I'd be glad to answer them. Oh yes, if any of you
- 2435 would like to go into greater detail about specific aspects of
- 2436 this, more technical aspects and what have you Wendell and I
- 2437 are available to meet with you this afternoon.
- 2438 BODO HIENS: You said that these tests could be easily
- 2439 done by the manufacturer but we can't buy these warfare
- 2440 agents.
- 2441 DONALD RIVIN: Well that's the whole point. You don't
- 2442 have to use the warfare agents. What this is showing you is
- 2443 that you can use a nontoxic or relatively nontoxic liquid,
- 2444 some other simulant and get results which will predict what
- 2445 you should be getting with the warfare agent, within
- 2446 relatively close they're not exact but they are pretty close.
- 2447 Depending on how good a data base you've developed, you can
- 2448 get closer. If you want to run a range of liquids and compare
- 2449 it to a known material which has good properties with the
- 2450 warfare agent, you can actually get a very close correlation.
- 2451 (inaudible) Oh yes they're all, I got them from normal
- 2452 laboratory supply houses.
- 2453 ZANE FRUND: Zane Frund, MSA. Have you identified the
- 2454 fundamental -- you've showed empirical, you've shown data,
- 2455 fundamental reason why silicone is so much poorer than the
- 2456 butyl? Is it something related to solubility cross-linked
- 2457 density or glass transition temperature?

- 2458 **DONALD RIVIN:** Vaguely to the third it is due to the
- 2459 so-called free volume in the polymer.
- 2460 ZANE FRUND: Molecular free-volume, Okay.
- 2461 DONALD RIVIN: The packing in silicone it's pretty wide-
- 2462 packing and butyl is very tight.
- 2463 ZANE FRUND: Okay, thank you.
- 2464 LES BOORD: Okay what we'd like to do now is focus our
- 2465 attention on the self-contained escape respirator concept.
- 2466 I'll talk a little bit about the strategy for what the concept
- 2467 requirement is and then John will elaborate a little more on
- 2468 some of those . . . the details of some of those concept
- 2469 requirements. Basically, for the self-contained escape
- 2470 respirator we envision a requirement or a concept that's very
- 2471 similar to the concept that we use for our self-contained
- 2472 breathing apparatus, which basically is a three-tier
- 2473 requirement. The first tier being 42 CFR Part 84 approval.
- 2474 So recognizing that there are requirements for this type of
- 2475 device in place 42 CFR does identify those. Then the second
- 2476 tier being enhanced performance requirements and then finally
- 2477 the requirements or the concept requirements that we see for
- 2478 the CBRN applications. To talk a little further about the
- 2479 first tier of that requirement 42 CFR Part 84 approval the
- 2480 rated duration or the rated service of the time for the escape
- 2481 respirator as defined by 42 CFR would be 15, 30, 45 or

60 minutes. And then another requirement that one of the 2482 enhanced requirements that we'll see as John does his 2483 discussion, and we talked about it a little earlier this 2484 morning, was the requirement for a fogging performance or a 2485 fogging test. In that test we actually have a low temperature 2486 requirement of 10.5 °C. So for the self-contained escape 2487 respirator it needs to be operable and approved at at least 2488 that low temperature requirement. So concept one for the 2489 escape respirator is 42 CFR Part 84 approval, service time 15, 2490 30, 45, or 60 minutes as determined by 42 CFR and then a low 2491 temperature use approved for at least 10.5 °C. With that I'd 2492 like to turn it over to John, who will talk about tiers --2493 2494 tier 2 and tier 3. JONATHAN SZALDJDA: I think, and if nothing else I think 2495 we're trying to be consistent with the approach that we've 2496 taken with CBRN standards as far as having the tiers of 2497 requirements. To go along with that, we've identified these 2498 areas as potential requirements that we would like to explore 2499 as part of the concept. I think a couple things and 2500 we've . . . I guess basically you've heard this morning as 2501 part of the discussion the technical details as explained by 2502 Frank Palya as far as the actual conduct of the test. I did 2503 want to make one point that just to clear up I guess any 2504 confusion as a result of one of the questions from this 2505

morning was that what we envision on doing along like what 2506 we've done with the gas mask standard is to do the 2507 environmental . . . environmental conditioning of the product 2508 prior and to proceeding into the last tier of testing. 2509 think from this morning with the gas life testing in 2510 particular with the, I believe one of the questions came up as 2511 far as the equipment and how the equipment would be tested 2512 against those requirements. And they were going to try and 2513 maintain that consistency throughout the effort. Again, we 2514 are looking at the self-contained device being a hooded type 2515 system. At least conceptually that's what we envision right 2516 I think we heard several good comments this morning with 2517 regard to considerations of facial hair, the potential for 2518 wearing glasses, people that have long hair that this could be 2519 a concern as well, but again these are all factors that will 2520 be considered as part of the evaluation criteria. 2521 Donning time again, donning we envision being an 2522 important characteristic as far as going from the packaging to 2523 on the user and ready to be used within 30 seconds. Likewise 2524 the types of environmental conditioning we're envisioning are 2525 pretty consistent with what we explored in detail this morning 2526 with regard to the temperature and humidity challenges as well 2527 as the transportation parameters. Again, in looking at the 2528 type of environment with this type of system, we are 2529

anticipating having the flammability concept, we will do some 2530 additional explorations, as far as whether it's the one burner 2531 versus six burner type test but the parameters of the 2532 evaluation will stay pretty consistent. With the human 2533 factors type testing, again we're looking at field a view, 2534 fogging and communications, with the communications being an 2535 optional type of requirement with the actual numerical values 2536 fairly consistent with what we discussed this morning. I 2537 think we've heard that no fogging given the potential use of 2538 this system and the donning and ambient condition in moving 2539 into a potentially different temperature environment will be 2540 very important. Breathing gas is less explained we're looking 2541 this morning with the air-purifying respirator; we're looking 2542 at using the metabolic simulator as the tool for the self-2543 contained system. Again, these are all conceptual but we're 2544 trying to base along the lines of what's currently captured in 2545 existing standards. The third tier after . . . in line with 2546 our standard is the special CBRN requirements, and in this 2547 case obviously with a self-contained system there isn't going 2548 to be a filtration requirement so we will just be solely 2549 addressing the LRPL testing and the chemical warfare agent 2550 testing. With the LRPL again, the parameters of the test are 2551 the same. Conceptually we are looking at the same fit factor 2552 requirement that was identified with the air-purifying escape 2553

2554	respirator. Understand that this is a concept at this point
2555	and as we move further along with the definition of
2556	requirement that you may see some variability with the LRPL
2557	value. Again, going back to looking with the hood system
2558	tying into the anthropometrics associated with the data base
2559	that we identified from the air force and measurements of head
2560	circumference, neck circumference and face length. Again
2561	going into filling these cells in terms of conducting the
2562	actual certification test, I think one of the sidebar
2563	discussions that we addressed earlier is that even with this
2564	type of matrix it doesn't preclude a one-size-fits-all
2565	characteristic but just that conceptually as far as conducting
2566	the certification testing that we would be filling a panel
2567	with each of those associated cells and evaluating the
2568	respirator as appropriate. Along with the other special test,
2569	or the other CBRN unique test is the chemical warfare agent
2570	challenge. In looking at the requirement for the self-
2571	contained unit in comparison to our earlier work that we
2572	anticipate that the self-contained unit would be used in areas
2573	of unknown and unquantified types of concentrations and as
2574	such we're looking back at the parameters that we establish
2575	for the SCBA program where a responder would be going into a
2576	unquantified, unknown environment. And we're using the CWA
2577	parameters that were established as part of a hot zone type

operation for the SCBA. Again the test time would be 2578 dependant on the manufacturers indicated service life as part 2579 of the application whether it's a 15-minute device would mean 2580 a 15-minute exposure and then a total test time of 30 minutes 2581 for any penetration or permeation through the respirator would 2582 be required. Likewise, we're following the same methodology 2583 for the sulfur mustard test with the application of not just 2584 the vapor challenge but also the liquid challenge to the 2585 respirator system. And with that these are I guess the 2586 general . . . the general concepts that we've anticipated for 2587 the self-contained unit but it seemed originally with our 2588 concept development process we weren't planning on addressing 2589 the self-contained aspect initially but as we got into the 2590 identification of the requirements and the evaluation of 2591 potential concepts for the air-purifying respirator it just 2592 seemed it was a convenient and naturally evolving process to 2593 take the information that we've accumulated and then roll it 2594 into the self-contained concept as well. I think you'll see 2595 over the next several months the evolution of our thinking 2596 with the self-contained concept. Any questions? 2597 STEVEN BERNING: My name is Steven Berning, I'm with 2598 Ocenco Incorporated. I'd like to make three recommendations 2599 related to duration. First, there's hundreds of thousands of 2600 NIOSH approved devices in use in the United States for escape 2601

- 2602 less than 15 minutes. So my recommendation is that you
- 2603 include the durations that are in Part 84, that is the 3, 5,
- 2604 and 10minute ratings. In fact, you are not showing the full
- 2605 range of durations from Part 84. My second point is small
- 2606 changes in self-contained devices have dramatic changes in the
- 2607 size of the self-contained device and for that reason Part 84
- 2608 also includes a clause that says that intermediate durations
- 2609 are acceptable. I recommend that you also adopt that
- 2610 approach.
- 2611 My third recommendation is that you, consistent with Part
- 2612 84, you look at the possibility of long duration, self-
- 2613 contained CBRN devices and let the market determine if 60
- 2614 minutes is long enough and Part 84 would have 2 hours,
- 2615 3 hours, 4 hours ratings.
- 2616 JONATHAN SZALAJDA: Thank you very much, appreciate it.
- 2617 JAY PARKER: Yes Jay Parker with Bullard. I was struck
- 2618 by having the same laboratory respirator protection level
- 2619 requirement for a negative pressure device and a positive
- 2620 pressure device; I think that's somewhat questionable. You
- 2621 know, in other words a positive pressure device should be
- 2622 capable of providing a higher fit factor or protection factor
- 2623 so you may want to look into that a little bit. The other
- 2624 comment I have is on the flammability test you're referencing
- 2625 EN 136 which is full-face masks as something you looked at for

- 2626 quidance but how about EN 270, which is airline hoods, which
- 2627 does have a flammability test also with a single burner. So
- 2628 you might want to look at that flammability test because
- 2629 that's hoods rather than full-face masks.
- 2630 JONATHAN SZALAJDA: Thank you for that comment. I guess
- 2631 on the one comment on the LRPL value, I think that one of the
- 2632 things that we're considering while we acknowledge the
- 2633 difference between the positive and the negative pressure that
- 2634 in the event that the positive pressure aspect of the
- 2635 respirator fails, for whatever reason, then you can still have
- 2636 a degree of protection from wearing the respirator in a
- 2637 negative pressure mode and as Rowland said, that's the way
- 2638 it's tested.
- 2639 WILLIAM NEWCOMB: Bill Newcomb with North Safety. As I
- 2640 read the concept paper originally it sounded as if this was
- 2641 going to be full body and take into consideration all sorts of
- 2642 dermal protection. Was I wrong in reading it that way or is
- 2643 it changed?
- 2644 LES BOORD: One of the concepts that is mentioned in
- 2645 there is the possibility of additional dermal protection.
- 2646 Again, it's a concept I think, the evolution or development of
- 2647 that concept we need to mature further. At this point, it's
- 2648 identified as a concept, dermal protection will be required.

- 2649 WILLIAM NEWCOMB: One other issue that comes from this
- 2650 morning's discussion. In the concept paper it indicated that
- 2651 the liquid mustard was going to be 60 minutes, rather than
- 2652 being the same as the vapor and the gas and your overhead
- 2653 showed them being the same. I wanted to just confirm that the
- 2654 concept paper is not correct in that aspect.
- 2655 LES BOORD: The intention for the liquid application
- 2656 would be the same as the vapor.
- 2657 **WILLIAM NEWCOMB:** Thank you.
- 2658 LES BOORD: That's correct. Another comment that I
- 2659 would . . . thanks . . . another comment that I would like to
- 2660 make is the . . . we talked about bench testing quite a bit
- 2661 for the air-purifying type respirators for the self-contained
- 2662 respirators, we do intend to do bench testing as well,
- 2663 particularly in the agent environment. So we do plan to
- 2664 continue our bench testing program to evaluate self-contained
- 2665 equipment on the SMARTMAN. Additionally, there was a element
- 2666 of bench testing reported this morning, which I think is
- 2667 applicable and that is some of the CWA testing that Wayne
- 2668 spoke about. Where we tested hoods from some of the
- 2669 commercially available escape respirators, air-purifying
- 2670 respirators but we tested those systems at the high challenge
- 2671 rates. We tested them at basically the GB, HD challenges that
- 2672 we're mentioning for the self-contained unit. We saw very

- 2673 positive results in that area. So in that respect, that bench
- 2674 testing tells us that the hood technology is certainly there
- 2675 to meet the types of requirements that we're looking at for
- 2676 the self-contained. So as we go forward, further bench-
- 2677 testing will be done on the self-contained systems on the
- 2678 SMARTMAN configuration. Any other questions?
- I think what we'll do is, we're . . . miraculously, we're
- 2680 a little bit ahead of schedule. I think what we'll do is
- 2681 we'll take a break now and let's convene at 2:30 and then
- 2682 resume with the last segment of the program.
- 2683 (BREAK)
- 2684 **JONATHAN SZALDJDA:** A couple . . . before we have the
- 2685 last presentation and the open period of the program for
- 2686 additional public comments, there are a couple . . . couple
- 2687 things I just wanted to re-bring into everybody's attention.
- 2688 The yellow . . . yellow form that was in the pamphlet that you
- 2689 received, if you can fill that out and give that to the
- 2690 receptionist at the end of the day, we'd appreciate that. The
- 2691 other thing, is that the attendees list is for who is at the
- 2692 meeting today is available and it's on the back table with the
- 2693 other standards as well as some of the other concept papers
- 2694 and letters to manufacturers and interested parties that we've
- 2695 released in the last few months. To conclude, or at least as
- 2696 far as our formal presentations today, there is some general

topics of interest that we would like to cover related to the
CBRN program, as well as some other programs that the National
Personal Protective Lab is conducting that may be of interest
to both the stakeholders, as well as potential users of these
products, so with that let's talk about some of the CBRN
related topics.

Actually, we're going to jump ahead a little bit and I 2703 wanted to at least spend a couple minutes talking about an 2704 effort that I'm the project officer on for the NPPTL. As a 2705 result of the events of September 11 and the collapse of the 2706 World Trade Center, NIOSH has undertaken a program to develop 2707 health and safety quidelines for emergency workers, who may be 2708 working in a post-structural collapse hazard. And the intent 2709 of the quidelines is to address the first 24 to 48 hours of an 2710 event where responders would come on site and what they would 2711 need to do to protect themselves against hazards that would be 2712 2713 present in the environment just solely from the aspect of the building itself collapsing. We're working this project in 2714 conjunction with . . . under an interagency agreement with the 2715 2716 National Science Foundation and the RAND Science and Technology Policy Institute. What we're doing in terms of 2717 this project is using a three-part approach to develop these 2718 quidelines. The first part was to characterize the response 2719 mission and the hazard associated with the emergency responder 2720

going to a collapse site. Simply put we broke it down into 2721 physical, chemical, and biological type hazards that a 2722 responder may be faced with in moving into one of these types 2723 of environments. Along with that we spent a good deal of time 2724 researching the hazards associated with the collapse, 2725 primarily based on looking at the timeframe . . . looking at 2726 tall buildings around the country that were using, primarily, 2727 a 20-meter type building as the baseline. Developing, looking 2728 at the data and construction trends based on the last century 2729 of building within the United States to try to identify and 2730 develop as a tool, a model of what a responder may expect to 2731 see in the event of responding to one of these types of 2732 I guess for example, just to go on a tangent for a 2733 minute, when you look at the building trends in the country 2734 especially for developing tall structures, there are some 2735 distinct periods which pretty well track along the times of 2736 good economic prosperity, where tall structures were built 2737 across the country and along with . . . following those trends 2738 there are also distinct trends in the types of building 2739 materials that went into . . . went into the structures. 2740 Earlier parts of the century was very concrete based, latter 2741 parts of the century, a lot more steel, a lot more glass. 2742 part of what we're . . . what the effort was, was to identify 2743 in the event of a building collapse knowing the construction 2744

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     parameters of the buildings. How to take that and translate
      that into the hazards that a responder may see in the first 24
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      to 48 hours of being on site and to that extent we've gone
      ahead and identified the . . . conducted a hazards . . .
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      identified the hazards, conducted a hazards analysis and we're
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      at the point where we've identified traditional industrial
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     hygiene practices that in a real . . . in a perfect world that
      could be applied or should be applied for the responder and
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      working in one of these types of environment. I think the
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      interesting aspect of this program is that for us we're trying
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      to take a step beyond the traditional industrial hygiene
      quidance. The traditional things that you may look up in a
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      manual or HAZWOPER training or whatever but to provide
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      guidance to the responder based on questions that he may have
     with regard to the hazards and his equipment. Really Rich
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     Metzler likes to say that this program began about 2:00 in the
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      morning on September 12, when he got the first call from New
      York City about what type of respirator do I need to wear for
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      asbestos. Not knowing anything about concentration levels or
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      the amount of hazard, the duration of hazard, you know, it's
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      flying by the seat of your pants type of industrial hygiene.
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      The intent of this effort that in the event we have another
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      incident whether it's caused by a terrorist incident or caused
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      by natural disaster (earthquake, flood, or whatever) but to
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- 2769 develop the guidelines associated to answer questions that the 2770 responder may have regarding the hazards that he could be 2771 facing as well as questions regarding his personal protective 2772 equipment. Where we are in this project, we're planning on 2773 having a final document available by the end of the summer and 2774 we're doing coordination between different federal agencies, 2775 with OSHA, with FEMA, with the Environmental Protection 2776 Agency, as well as working with the ISEA with the 2777 International Safety Equipment Association and responders and 2778 trying to develop these guidelines. What I would encourage 2779 you to do, if you're interested in more information or 2780 potentially would like to be part of this effort, you can see me after the meeting or give me a call or send me an e-mail 2781 2782 over the upcoming weeks and I can give you some more 2783 information regarding the project and the potential for your 2784 involvement. And with that I'm going to stop talking and let 2785 Les finish with the other R&D -- or the other CBRN related 2786 topics. LES BOORD: What we'd like to do now is go over a few 2787 topic areas and programs or projects that we've identified 2788 that are pertinent to the CBRN standards development 2789 2790 activities and some additional ideas and visions that we see
- 2792 certification costs and fees and so forth.

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for the program and perhaps some of the impact on

2793 The first one I'd like to talk about is what we are labeling as our inhalation flow investigation. This has been 2794 initiated due to information provided to the docket concerning 2795 high physiological demand or high work rates, high breathing 2796 rates and respirator use at those high rates. Some of the 2797 data provided or submitted to the docket indicates that peak 2798 inhalation flows can range from 700 to 900 liters per minute. 2799 Other more recently submitted data would tend to suggest that 2800 2801 that flow rate . . . peak flow rates are more in-line with 400 to 500 liters per minute. In addition to the high flow rates 2802 2803 the data also suggests that there are increases in the peak 2804 inhalation flow that are the result of speaking type exercises. I think if you look at the data that's been 2805 2806 submitted that would suggest that you can have perhaps a 10-percent increase in what the peak inhalation flow rate is. 2807 2808 And then finally, the submitted data suggests that the result 2809 of such high flows may indeed affect the overall performance of the respirator. In addition to all that, I think there is 2810 independent data available that would sort of indicate and 2811 support the flow rates in the range of 400-500 liters, may 2812 indeed be the high end of what the human response is. So to 2813 address the information that has been provided to the docket 2814 NIOSH is conducting an investigation to address the concerns 2815 of the high physiological demand. The investigation basically 2816

has three parts or three components to it. The first is what 2817 we've labeled as a literature search or a research into what's 2818 been published. Secondly, is the testing respirator testing 2819 and data analysis to . . . that may be required, and then 2820 finally is a protection analysis. With the literature 2821 research we intend to look at what's been published and 2822 perhaps look at some ongoing research to actually zero in on 2823 what the maximum ventilation rates that we should expect to 2824 experience when using a respirator. In addition to that, we'd 2825 like to see what the research says relative to the wave shape 2826 or the shape of that breathing response as we increase the 2827 work flow . . . or the work rate. And then finally to see 2828 what research says relative to influencing factors, speech, 2829 and so forth. The first part of the investigation is the 2830 literature search or literature research, then secondly, the 2831 respirator testing and data analysis, we look at the . . . 2832 what we're looking at there is perhaps filling in some of the 2833 gaps that we identify in looking through the research. We 2834 anticipate that there is testing that will be required on 2835 different types of respirators, self-contained, particulate, 2836 gas and vapor respirators. We also can envision that the 2837 second part of the program will not necessarily be totally in 2838 series with the first. We may actually . . . I think there 2839 are some suspect areas now where testing can actually parallel 2840

the research investigation. The testing and data analysis is 2841 the second part. Then finally I think once we focus and have 2842 data and information in these areas, I think we need to 2843 finally then put the whole picture together and see what is 2844 the impact -- what we're calling the protection analysis. Ιf 2845 we do experience the effects of the high, extremely high 2846 inhalation flows and the different types of respirators, and 2847 what is the real impact on that respirator system and the 2848 protection it is intended to provide. The final phase then is 2849 the protection analysis and any resulting impact that may come 2850 from that. With this investigation we hope to be able to 2851 address some of the information that has been submitted to the 2852 docket as part of our standards development process. 2853 The next program I'd like to talk a little bit about and 2854 this is probably very apropos to the discussions we've had 2855 today. That is a program that we refer to as our CBRN R&D 2856 program and this program was announced in a letter to all 2857 manufacturers on March 4. Basically, what it does is outline 2858 a program where we . . . where a applicant (the manufacturer) 2859 can do CBRN agent testing on the SMARTMAN test apparatus 2860 through NIOSH. It provides an access to applicants and 2861 manufacturers to actually do chemical agent testing on 2862 respirator designs that they have . . . that they want to 2863 evaluate. There is a qualification on it in that we limit the 2864

participation in the R&D program to applicants or 2865 manufacturers that have a quality control plan evaluated as 2866 acceptable by NIOSH. Basically, it comes down to as part of a 2867 certification program you have a quality control plan that 2868 basically needs to be in place in order to participate in this 2869 R&D . . . CBRN R&D effort. The part of the program is that it 2870 will provide three days of testing to the applicant. 2871 days of agent testing at the SBCCOM Chem. Lab. The vehicle 2872 that the manufacturer would use to initiate this testing is a 2873 letter application to NIOSH. The form and the format of that 2874 letter application is provided as an attachment to the March 4 2875 letter. So it's a pretty simple format that's used by means 2876 of the letter then and that is an attachment to the March 4 2877 2878 letter. A qualification and information that's I think very 2879 important to it is that one of the restrictions is that the 2880 R&D testing, any of the testing cannot and should not be 2881 counted as certification testing eventually. Basically, the 2882 testing is independent from certification. The applicant 2883 certainly can be in the laboratories to witness the test. I 2884 think there are criteria and guidelines relative to who can 2885 access into the Chem. Lab. I think it's a maximum of three 2886 individuals and with also requirement relative to citizenship 2887 and so forth and that still needs to be adhered to. And then

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finally the data, any data that's generated by means of the 2889 R&D program belongs to the applicant or the manufacturer. 2890 Basically, what this does it gives an opportunity to do what I 2891 like to refer to as trial and error testing. Trial and error 2892 testing on respirator designs that the applicant the 2893 manufacturer then can make decisions relative to the 2894 performance of their equipment. Within the constraints of 2895 that program then there are a maximum of four . . . within a 2896 three day period there are a maximum of four live agent tests 2897 that can be performed. That would be two sarin tests and two 2898 mustard tests. In addition to that within the three day 2899 turnaround time there's up to 10 agents, material swatch test 2900 that can be performed. These tests with the March 4 letter, 2901 there is a menu that identifies the testing fees as well as 2902 the test possibilities. You can see that the SMARTMAN sarin 2903 test is \$4,500 per test, the HD test is \$4,500 and then 2904 material swatch tests are \$50 per swatch. Just working out a 2905 little example, you don't have to do all of the tests. 2906 other words, in the letter of application to perform the R&D 2907 testing you may only want to do two GB tests or you may want 2908 to do two HD or one HD, two GB. That's up to the individual; 2909 you use the test menu fees then to determine what the cost 2910 would be. So for the example that we've illustrated there if 2911 you did two GB tests, 1 HD test and then 10 material swatch 2912

- 2913 tests the total fee would be \$14,000. Again, that's in a 3-
- 2914 day turnaround time. The only restriction relative to access
- 2915 to it is that the applicant needs to have a NIOSH acceptable
- 2916 quality control plan. Before I go off that any questions on
- 2917 that . . . On the R&D program?
- 2918 BODO HEINS: Bodo Heins, Draeger Safety. When you're
- 2919 speaking of the turnaround time, then you mean once the test
- 2920 is starting but what about the time until the test will start?
- 2921 Second question is, are we allowed to take the data from this
- 2922 testing here as pre-submission data?
- 2923 LES BOORD: That start time to testing once you make the
- 2924 application depends purely on the backlog for testing at that
- 2925 particular time. The R&D testing does take a second priority
- 2926 to certification testing. So if we have certification testing
- 2927 in queue . . . okay . . . that is being performed then that
- 2928 has a priority over the R&D. I think what typically happens
- 2929 is that there are sort of gaps in the certification testing
- 2930 where the R&D testing can be inserted. That's the first part,
- 2931 the second part is can . . . yeah the pre-approval test data
- 2932 or data that's generated during the R&D program can be
- 2933 provided as pre-approval test data but it can not count as
- 2934 certification data.
- 2935 WILLIAM NEWCOMB: Bill Newcomb from North. Has NIOSH
- 2936 considered having an R&D program for the metabolic simulator?

LES BOORD: As of about 2 seconds ago, that's a good 2937 concept, good idea. And as the requirements for the breathing 2938 gas control continue to develop further that may indeed be a 2939 direction that we need to go. Again, the whole motivation 2940 behind identifying a CBRN R&D program is as I'm sure everybody 2941 recognizes there is extreme or there is limited access to 2942 using chemical warfare agents. With this program, we see a 2943 way to actually facilitate the ability to do research and 2944 development type testing. 2945 Concerning the estimate of certification fees for an 2946 escape . . . CBRN escape respirator we would, at this point in 2947 time, just using a gross gauge we would say that it's probably 2948 going to be in the \$90,000 area. I think those of you who 2949 have been following the program, and involved in the program, 2950 pretty much know where that number comes from because it's 2951 very . . . it's comparable to the certification fees that we 2952 2953 have for our CBRN gas mask. The scope of the testing is relatively the same so I think that is a good gauging number 2954 at this point. Now as the program develops as requirements 2955 become more defined there will be more definition behind that 2956 Then the processing time, the 120-days, again is 2957 patterned after and estimated after the CBRN gas mask, where 2958 we know that we have 80 days of pure test time involved. 2959 120-days would seem to be a reasonable number there. And 2960

- 2961 again, both based on the CBRN air purifying respirator. Very 2962 rough numbers at this point.
- Finally, what I'd like to do is the development process 2963 for the escape respirator obviously will continue. At the 2964 beginning of the program we announced that our timeline for 2965 completion of the standard in our overall CBRN program calls 2966 for the escape respirator to be completed in October of this 2967 year, so October 2003. But as I'm sure everybody in this room 2968 realizes the escape respirator is a topic of intense interest. 2969 So while that is our goal and our timeline, we're not sure 2970 2971 what the pressures . . . how outside pressures or other pressures may affect that. Right now our defined time is 2972 October of this year. In anticipation of continued 2973 development efforts we are scheduling another public meeting 2974 that we'll discuss the CBRN escape respirators the end of 2975 That target is actually is being even more focused, 2976 it's like June 25 is the date we're trying to nail down. 2977 we will need to make that official or finalize that June 25th 2978 is the target. The target would be, again in Pittsburgh 2979 probably at one of the Pittsburgh locations, perhaps where we 2980 had our October 2002 meeting in Cannonsburg but it will be 2981 local in Pittsburgh. With that I would like to ask if there's 2982

2983

any questions?

- JAY PARKER: Jan Parker with Bullard. I would just like 2984 to say that I think NIOSH should consider a similar program 2985 for this standard as they did in the gas mask standard in 2986 which the live agent testing would be performed up front on 2987 two samples to sort of weed out any . . . or to prevent the 2988 wasting of resources both money and time on respirators that 2989 aren't going to pass the test. You know, I think that would 2990 be the smart thing to do. 2991
- 2992 LES BOORD: Thank you, I think that's an excellent 2993 suggestion. Any other comments?
- SAM SHEARER: Sam Shearer, CSE Corporation. I have a 2994 couple of comments I'd like to make in general . . . part of 2995 the program . . . future thoughts. Have you considered 2996 2997 different applications, permit different standards for the apparatus? For example, people working in offices should not 2998 require an apparatus that can withstand abuse you may find in 2999 the industrial market. What I'm saying is, if somebody has a 3000 unit in an office, it's not going to be exposed to all the 3001 atmospheric conditions that it would be in a commercial 3002 industrial plant. Training, has there been any thought 3003 regarding training potential users of these types of 3004 3005 apparatus? Can we expect users to put on apparatus in 30 seconds? If their unit is stored in their desk does it 3006 need to pass the long duration temperature test and etc.? 3007

3008 LES BOORD: Thank you, both of those I think are 3009 certainly good comments. To answer the first question, at this point I need to say that we hadn't considered a . . . 3010 3011 let's say a tiered type of a performance requirement where you 3012 may have light use units versus heavy duty use units. So we 3013 hadn't considered that but that is a good idea. The second 3014 thing, concerning training, I think, again, a very good point, 3015 I think when we talk about escape respirator the training element can not be over emphasized. When you . . . for those 3016 of us who are familiar with respirators and using respirators, 3017 I think it's quite evident that you can't expect a person to 3018 have an escape respirator, train them on it in July of 2002 3019 and expect them to be able to use it in February 2003 without 3020 ever having looked at it again and without a proper type of a 3021 3022 training program. I think that the training aspect is certainly something that needs to be factored in to our CBRN 3023 standard. I do envision that the concept will address that, 3024 3025 the training, and the training module for these types of units. I think it is an important aspect. Any other 3026 3027 comments, questions? ERIK JOHNSON: Erik Johnson, 3M. I must say, I don't 3028 3029 envy having to rationalize all these enduring comments. You made quite a distinction between the full-face standard, where 3030 you're required to wear other types of PPE on their body. 3031

This one scope is for office workers who are clothed as we are 3032 today. I quess the question would be why are we even testing 3033 them for liquid agent resistants, possibly flammability, if 3034 our scope really is office workers who do not have this extra 3035 type of PPE to protect the rest of their body? 3036 LES BOORD: First, the question relative to the 3037 flammability, we do see that the requirement for flammability, 3038 may in fact, be something that can be directed towards only 3039 escape respirators providing certain types of protection, CO 3040 protection and so forth where you may have the high heat or 3041 the flame hazard. So I think that's a possibility as we 3042 develop that requirement. Secondly, concerning the liquid 3043 agent I don't know, and I don't think that we've seen or 3044 perhaps rationalized our way through to the point where we can 3045 say that there would never be a liquid agent potential. I 3046 think even in an escape scenario, if we're talking about 3047 escape from CBRN type environments, then you always have that 3048 potential that you could have a liquid present. So I think it 3049 is . . . I don't think we can preclude it from being one of 3050 the hazards. I think also when you take that aspect and you 3051 marry it to the benchmark testing that we've done that 3052 demonstrates the ability to provide liquid agent protection is 3053 within state-of-the-art technology. I think that also 3054

- 3055 supports the idea that it shouldn't . . . shouldn't just 3056 eliminate it, that we shouldn't preclude it.
- IRA GURVITCH: Ira Gurvitch, I.B.N. One of the areas 3057 3058 that we didn't go over that much has to do with the size and 3059 the weight. Is it possible as previously mentioned, there 3060 could be a two-tier structure where let's say the smaller it is, let's say from the low level, the 15, 30 minutes versus 3061 3062 the specific area where you're talking 45, 60 minutes? Generally speaking the smaller, naturally is not going to last 3063 3064 as long but it's important for people that are taking subways 3065 or around a bus or a train.
- 3066 LES BOORD: Correct. I think relative to the size and 3067 the weight right now the concept is silent relative to those. 3068 We don't come out and specify a particular size requirement or a weight requirement. In fact, I think we've sort of taken a 3069 3070 different approach and the approach we're trying to develop through the concept is, again, coming back to the idea of 3071 3072 balance. Balance between what the performance requirements 3073 are, what the user requirements are, and the technology. let those minimize the packages that result. I think our 3074 3075 benchmark testing is very useful in helping us to do that. So 3076 when we talk about size and weight, I think that becomes one 3077 of the areas where we sort of verge on the line between performance requirements and design requirements. Right now, 3078

so far, our approach has been to try and build it through the 3079 performance requirements. But there will be . . . we do 3080 expect there's a distinct difference between the short 3081 duration unit and the longer duration unit. Okay, if there 3082 are no other comments, I think we can rap up today's program. 3083 Again, the next meeting is targeted for June 25^{th} in the 3084 Pittsburgh area. Look for a federal register notice to that 3085 affect and a letter to manufacturers as well. Thank you for 3086 your participation, the input has been valuable to us and 3087 don't forget comments supplied to us, both verbally and 3088 written, to the docket, I think, are very meaningful. Thank 3089 3090 you.

(END)