

NIOSH Personal Protective Technology Program

Plan to Implement the National Academies Evaluation Recommendations

DRAFT

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56 **Introduction**

57
58 In fiscal year (FY) 2001, the U.S. Congress allocated funds to the National Institute for
59 Occupational Safety and Health (NIOSH) to develop standards and technologies for protecting
60 the health and safety of America’s workers who rely on personal protective equipment (PPE),
61 such as respirators, clothing, gloves, hard hats, eye and hearing protective devices with an
62 emphasis on emergency responders. NIOSH established the National Personal Protective
63 Technology Laboratory (NPPTL) in Pittsburgh, Pennsylvania to provide national and world
64 leadership for improved personal protective technologies (PPT). Creation of NPPTL
65 consolidated NIOSH’s existing respirator approval program with respiratory protection research
66 and standards development activities and launched an initiative to align all PPT activities within
67 NIOSH. This initiative was emphasized and further developed when the NIOSH PPT Cross
68 Sector Program was formally established in 2005. The PPT Cross Sector Program is also
69 relevant to all industry sectors and complements the NIOSH Hearing Loss Program, the
70 Emergency Response Program, and the Traumatic Injury (TI) Program.

71 72 **Mission Statement**

73
74 The Mission of the PPT Cross Sector Program within NIOSH is to prevent work-related injury,
75 illness, and death by advancing the state of knowledge and application of personal protective
76 technologies.

77 78 **Vision Statement**

79
80 The vision of the Program is to be the leading provider of quality, relevant, and timely PPT
81 research, training, and evaluation. PPT in this context is defined as the technical methods,
82 processes, techniques, tools, and materials that support the development and use of personal
83 protective equipment worn by individuals to reduce the effects of their exposure to a hazard.

84 85 **Definition and scope of the Program Area**

86
87 Proper use of PPE and technologies substantially reduces injuries, illnesses, and fatalities among
88 our nation’s workers. An estimated 20 million workers use PPE on a regular basis to protect
89 them from job hazards. PPE protects workers from death and disabling injuries and illnesses
90 resulting from exposures to hazardous airborne particles, harmful chemicals, and excessive
91 noise; falls; physical trauma; and fires. Improvements in personal protective technology are
92 realized through research and development of better standards and regulations and subsequent
93 availability of PPE complying with the new standards and regulations, worker training programs,
94 and guidance on selection, use, maintenance and effective use of PPE.

95 96 **PPT Program Goal Structure**

97
98 The PPT Cross-Sector is structured around Strategic Goals and Activity/Output Goals. Further,
99 the Program is in the process of identifying Intermediate Goals and Performance Measures in
100 support of its efforts to accomplish these goals.

- 101
102 Four PPT Cross-Sector Strategic Goals have been established:
103 • Strategic Goal 1: Reduce Exposure to Inhalation Hazards.
104 • Strategic Goal 2: Reduce Exposure to Dermal Hazards.
105 • Strategic Goal 3: Reduce Exposure to Injury Hazards.
106 • Strategic Goal 4: Broad-Based PPT Issues.

107
108 These strategic goals are consistent with goals or activities of the Program’s partners and
109 stakeholders, e.g. National Fire Protection Association (NFPA), International Association of Fire
110 Fighters (IAFF), American Society for Testing and Materials International (ASTM), American
111 National Standards Institute (ANSI), International Organization for Standardization (ISO), and
112 the International Safety Equipment Association (ISEA) to name several.

114 **PPT Program Tactics for Achieving Goals**

115
116 The approach used to achieve the PPT Program Goals includes five tactics. These are:
117

- 118 • **Conduct research on PPT**
119 A comprehensive research program can reduce inhalation, dermal, and injury hazard
120 knowledge gaps (e.g., understand performance of PPE against emerging hazards) and
121 improve existing technologies to reduce exposure to the hazards.

- 122 • **Develop standards for PPT**
123 The development of PPT standards and test methods can improve the quality, protection, and
124 performance of PPT throughout PPE life stages. The PPT Program actively participates in
125 standards development activities through rulemaking and with the ISO, ANSI, NFPA,
126 ASTM, and the ISEA in the areas of respiratory protection, hearing protection, eye and face
127 protection, fall protection, industrial head protection, and protective clothing. These standard
128 writing activities address not only PPT performance, but also use and maintenance.

- 129 • **Certify respirators and evaluate PPT**
130 PPT evaluation services, resultant recommendations and respirator certification services can
131 help ensure effective PPT.

- 132 • **Conduct outreach programs for optimal use and acceptance of PPT by workers**
133 This tactic includes the development and use of effective communication tools and outreach
134 techniques that encourage inputs to all PPT Program activities and facilitate transfer of
135 outputs (products and services) and outcomes (results) to all stakeholders.

- 136 • **Evaluate and assess programs and activities**
137 Evaluation and assessment activities are essential components of the Program’s tactic to
138 “build in” quality. It is incumbent on the PPT Program to ensure a robust portfolio of
139 evaluation and assessment activities to ensure program research protocols, proposals, and
140 outputs are based on quality science. Evaluation activities will extend to third party
141 evaluation of the PPT Program by a recognized organization such as the National Academies
142 (NA).

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Background on National Academies Review

In conjunction with a series of planned reviews of NIOSH research programs, the Institute of Medicine (IOM) and the National Research Council (NRC) convened a committee of experts to review the NIOSH Personal Protective Technology Program (PPT Program).

NIOSH contracted with the NA to conduct an evaluation of the PPT Program including its research activities and the associated respirator certification program. Specifically, the NA was tasked to evaluate the *relevance* of its work to improvements in occupational safety and health and the *impact* of its work in reducing workplace injuries and illnesses; the evaluation process required the assignment of a numerical score for each to represent its overall assessment. Finally, the NA was tasked to examine future issues and provide recommendations on areas for consideration of future research.

The PPT Program prepared an "evidence package" to document its activities, outputs, stakeholders, partners and its associated impact and relevance since the inception of NPPTL in 2001. Both printed and electronic copies were provided to the NA. The printed version is 231 pages and is available for inspection at NPPTL or the IOM; the electronic version can be found at <http://www.cdc.gov/niosh/nas/ppt/>. An overview of the Program facilities can be viewed at <http://www.cdc.gov/niosh/programs/ppt/projects.html>.

After completing its review, the NA Evaluation Committee presented its findings to NIOSH on June 25, 2008 and subsequently published the report *The Personal Protective Technology Program at NIOSH*. The NA assigned the PPT Program a score of 4 (out of a possible 5) for both relevance and impact. The NA found that the PPT Program is “working in priority areas and is engaged in transferring its research to improved products and processes,” and that “the program has made probable contributions to end outcomes in addition to well-accepted intermediate outcomes.”

The NA provided the following recommendations to the PPT Program:

- [1] *“Implement and Sustain a Comprehensive National Personal Protective Technology Program*
- [2] *Establish PPT Research Centers of Excellence and increase Extramural PPT Research*
- [3] *Enhance the Respirator Certification Process*
- [4] *Increase Research on the Use and Usability of PPT*
- [5] *Assess PPT Use and Effectiveness in the Workplace Using a Life-Cycle Approach”*

PPT Program staff reviewed the NA’s draft report and developed a Draft Implementation Plan. The Program also will disseminate the report to intramural and extramural staff, managers, and stakeholders through distribution at conferences, public meetings, and stakeholder meetings.

Purpose of Implementation Plan

The purpose of this Implementation Plan is to summarize the actions that are planned or those that are underway in response to the NA recommendations to the PPT Program. The PPT

189 Program will seek scientific input from NIOSH’s Board of Scientific Counselors at its Spring
190 2009 meeting and stakeholder feedback through a public comment period. The PPT Program
191 Implementation Plan strives to achieve an effective balance between program enhancement and
192 expansion over a five year timeframe, depending on resource availability. The plan also supports
193 the PPT Program Goals identified above. The intent is to integrate the activities described into
194 the PPT Program Strategic Plan as part of the annual strategic planning process.
195

196 **Implementation Plan Development Process**

197
198 The PPT Program initially realized that the NA report provided it with broad and
199 transformational recommendations. These could only be assessed effectively in the context of
200 other major analyses and drivers of the Program. Consequently, Program leadership directed
201 that these other studies and reports be considered during the development of the response to the
202 NA Report. These included information contained in the PPT Program Evidence Package (e.g.
203 outputs from National Occupational Research Agenda (NORA) Town hall meetings, standards
204 development committee updates), the Mine Improvement and New Emergency Response
205 (MINER) Act of 2006, the Homeland Security Council’s Domestic Chemical Defense
206 Implementation Plan, and the outputs from two previous reviews of PPT Program evaluation
207 activities, namely the NA’s *Assessment of the NIOSH Head-and-Face Anthropometric Survey of*
208 *U.S. Respirator Users (2007)* (<http://www.cdc.gov/niosh/review/public/111/>) and the NA’s
209 *Measuring Respirator Use in the Workplace (2007)* (<http://www.iom.edu/CMS/3740/29908/40062.aspx>). The PPT Program response to the *IOM*
211 *Committee on Personal Protective Equipment (PPE) Preparing for an Influenza Pandemic:*
212 *PPE for Healthcare Worker Report (2007)* (<http://www.cdc.gov/niosh/review/public/129/>) also
213 was considered.
214

215 The PPT Program Customer Satisfaction Survey (CSS) results from 2005 and 2008
216 (<http://www.cdc.gov/niosh/npptl/default.html>) were an additional input. These surveys were
217 conducted through an Interagency Agreement with the U.S. Office of Personnel Management
218 (OPM). The Assessment and Training Assistance Services Group (ATAS) of the Center for
219 Talent Services (CTS), Division for Human Resources Products & Services, OPM developed a
220 standardized *Customer Satisfaction Survey* (CSS) to assess the quality of services provided by
221 public-sector organizations.
222

223 PPT Program preplanning included NIOSH-wide brainstorming sessions conducted to identify
224 potential activities and strategies for addressing the NA recommendations. Subsequently, the
225 PPT Program partnered with OPM/CTS to help define and prioritize the information gathered as
226 inputs to the Program. The Assessment Services Branch of OPM/CTS was selected because they
227 have a staff of personnel research psychologists who specialize in survey research,
228 organizational assessment, outcome measurement, organizational development, and change
229 management. This staff has a unique perspective on the challenges faced by agencies across the
230 Federal government.
231

232 Finally, PPT Program personnel meet regularly with stakeholders to obtain their most current
233 views of the Program and its various activities.
234

235 **Dynamic Nature of the Environment Supporting this Implementation Plan**

236

237 The PPT Program continuously identifies issues of national interest which may impact the
238 Program and, in turn, this Implementation Plan. These are of particular importance because of
239 the direct and immediate interaction between the outputs of the PPT Program and its
240 stakeholders.

241

242 In most cases, issues of national interest are external factors over which the PPT Program has
243 little, if any, influence or control. Resulting Program outputs may vary from modified guidance
244 documents to new equipment requirements that can only be assessed on a “per issue” basis.
245 These external factors contribute to a dynamic environment in which the PPT Program must
246 define its initiatives and perform its functions. Current examples are:

247

248 1. **Pandemic Influenza Preparedness** has been a focus of the PPT Program for several years.
249 The threat of pandemic influenza has resulted in an increased emphasis on preparedness and the
250 personal protective technologies necessary to sustain operations in the event of an outbreak.

251

252 2. The **threat of terrorism** has resulted in an increased emphasis on incorporating chemical,
253 biological, radiological, and nuclear (**CBRN**) protection requirements into the NIOSH respirator
254 approval process and national protective clothing standards.

255

256 3. The rapid growth of **nanotechnology** has increased the amount of engineered nanomaterial in
257 the industrial workplace. As a result, the PPT Program includes assessing the effectiveness of
258 personal protective technologies against nanoparticles as a program emphasis.

259

260 4. **Recent mine disasters** demonstrated the importance of effective emergency PPT for all mine
261 workers. **The Mine Improvement and New Emergency Response Act of 2006**, also known as
262 the **MINER Act**, June 15, 2006 was instituted in response to the mine disasters at Sago, Alma,
263 and Darby mines in 2006. The Refuge Alternatives Rule describes requirements for refuge
264 alternatives in underground coal mines to enhance miner safety and implement Section 13 of the
265 MINER Act. The PPT Program is leading the development of the protocols and will lead the
266 associated refuge chamber study to support the final rule.

267

268 5. The **Homeland Security Council's Domestic Chemical Defense Implementation Plan**
269 requires the Department of Homeland Security (DHS) to develop risk assessments for chemical
270 threats. Specific PPT objectives are associated with various paragraphs of the plan. The PPT
271 Program is involved in supporting the PPT requirements of this plan.

272

273 6. **The US Food and Drug Administration (FDA)** exercising its authority to regulate PPE that
274 is intended for use in disease prevention is a device under section 201(h) of the Federal Food,
275 Drug, and Cosmetic Act, 21 U.S.C. 321(h). This includes NIOSH-certified respiratory protective
276 equipment, as well as other PPE, when intended for preparedness for pandemic flu and other
277 scenarios of possible exposure to airborne pathogens.

278

279 7. **NIJ Law Enforcement Standard:** The National Institute for Justice (NIJ) established a
280 Special Technical Committee tasked with the development of the "NIJ CBRN Protective

281 Ensemble Standard for Law Enforcement" - NIJ Standard 0116.0. The proposed standard has
282 obtained public review and comment with a planned release in early 2009. This NIJ law
283 enforcement CBRN ensemble standard requires that the ensemble certified shall be tested as
284 used with NIOSH approved CBRN respirators.

285

286 **Implementation Plan Scope**

287

288 The PPT Program developed this Implementation Plan to address the needs for the next five
289 years. Full-scale implementation of the Plan will require additional resources and a clear
290 commitment to ensuring U.S. leadership in research, policy and standards development, and
291 certification of personal protective technologies for the workforce.

292

293 **Recommendation 1: Implement and Sustain a Comprehensive**
294 **National Personnel Protective Technology Program**

295
296 The initial recommendation of the NA Report addresses the need for a more vigorous and
297 comprehensive PPT Program. It states:

298
299 *The National Personal Protective Technology Program should:*

- 300
- 301 • *Oversee, coordinate, and where appropriate, conduct research across all types of occupational PPT and*
302 *across all relevant occupations and workplaces;*
- 303 • *Participate in policy development and standards setting across all types of occupational PPT;*
- 304 • *Oversee all PPT certification in order to ensure a minimum uniform standard of protection and*
305 *wearability. The National Program should collaborate with other relevant government agencies, private-*
306 *sector organizations, and not-for-profit organizations to conduct an assessment of the certification*
307 *mechanisms needed to ensure the efficacy of all types of PPT; and*
- 308 • *Promote the development, standards setting, and certification of effectively integrated PPT components*
309 *and ensembles in which multiple types of PPT (e.g., eye protection, hearing protection, and respirators)*
310 *can be effectively and seamlessly worn together.*

311
312 The PPT Program defined five issues that it must aggressively address in order to translate the
313 recommendation into practice as it conducts its operations.

314
315 These five issues are:

- 316 1.1 Organize research across all types of PPT and across all occupations and workplaces
- 317 1.2 Participate in policy development and standards setting across all types of PPT
- 318 1.3 Oversee certification of all PPT, including an assessment of certification mechanisms
- 319 1.4 Promote technology development, standards, & certification of integrated PPT
- 320 components & ensembles
- 321 1.5 Conduct outreach programs for optimal use and acceptance of PPT by workers

322
323 This first and most comprehensive recommendation of the NA Report is a direct effort to ensure
324 full implementation of the 2001 congressional mandate for a comprehensive state-of-the-art
325 federal program focused on PPT. This comprehensive program will be built on the current PPT
326 Program and will unify responsibility and oversight for national occupational safety and health
327 PPT activities within NIOSH. The comprehensive program activities will be developed around
328 the core activities: Research (intramural and extramural); Policy & Standards Development; and
329 Certification. Other activities and program elements essential to grow and sustain the
330 comprehensive program include: greater extramural opportunities, outreach and program
331 evaluations.

332
333 Except for its widely recognized efforts involving respirators, the PPT Program currently does
334 not have national recognition as the primary federal laboratory that conducts PPT/PPE related
335 research, standards development and product certification. In fact, there are no nationally
336 recognized central authorities for non-respiratory PPT. The NA Report defines this as one of the
337 most significant weaknesses of the national efforts concerning worker health and safety
338 protection. Resource constraints and a program driven by national priorities such as counter
339 terrorism, mining disasters, and pandemic influenza have limited efforts to expand the PPT

340 Program into other occupational safety and health areas.

341
342 The core Program activities of research, policy and standards development and certification will
343 evolve to include more effective coordination with the NIOSH Office of Extramural Programs
344 (OEP) to pursue new extramural research for the PPT program.

345
346 The Program intends to take a lifecycle approach to addressing PPT knowledge gaps. The
347 activities will serve to extend the reach of the program to include disciplines and activities
348 beyond the scope of the existing core program.

349
350 Outreach will form the cornerstone for stakeholder/partnership building and facilitate program
351 technology transfer. Workers, employers, end-users, and trade associations are targeted as part
352 of the PPT Program outreach plan.

353
354 Partners contribute to program outputs by participating in activities of the program, such as
355 public meetings and stakeholders meetings, customer satisfaction surveys, and focus groups.
356 Stakeholders facilitate the flow of information into and out of the program to assist in developing
357 strategic and implementation plans.

358
359 An essential component of the comprehensive PPT Program will be the program science strategy
360 which uses evaluation and assessment activities to “build in” quality. It is incumbent on the PPT
361 Program to ensure a robust portfolio of evaluation and assessment activities to ensure program
362 research protocols, proposals, and outputs are based on quality science. Evaluation activities will
363 extend to third party evaluation of the PPT Program by a recognized organization such as the
364 NA. The PPT Program will work with the NIOSH Office of Planning and Performance to apply
365 program planning and evaluation tools such as the NA Evaluation Framework document to
366 implement comprehensive program reviews at regular intervals.

367
368 NIOSH will ensure the continued use of the IOM standing Committee on PPE for the Workplace
369 (COPPE) as an important activity in the PPT Program tactics for achieving objectives. The
370 COPPE, established in 2005 at NIOSH’s request, is an activity that aids the PPT Program in
371 conducting quality research on PPT by providing the highest-level scientific evaluations and
372 assessments of the Program’s projects and activities as input into the Program’s portfolio of
373 research activities. The COPPE activity also contributes to the Program’s Outreach tactic by
374 providing outputs that are disseminated to stakeholders. NIOSH will ask the IOM to convene the
375 COPPE periodically to enable the assembled committee members to engage with Program
376 personnel, other NIOSH personnel and stakeholders in ongoing discussions regarding strategic
377 issues relevant to PPT. NIOSH will also ask the IOM to convene the COPPE to conduct
378 evaluations, workshops and discussions with PPT management to provide NIOSH with the
379 highest-quality scientific input through the delivery of formal reports and informal input to
380 improve the quality of PPT projects, outputs and outcomes. The PPT Program also may sponsor
381 IOM and NRC studies of identified areas, similar to previous Program sponsored IOM and NRC
382 studies that have examined specific issues (anthropometric research, planning for pandemic
383 influenza and surveillance) identified by the standing committee and by NIOSH staff. These
384 efforts have validated priorities and provided input to strategic planning activities. In the
385 absence of a NORA Sector Council, the COPPE serves the PPT Program by providing external

386 scientific expertise to explore emerging issues and discuss PPT knowledge gaps and national
 387 needs. Table 1 summarizes current PPT Program activities and anticipated expansion for the
 388 first five years and beyond.
 389

390 **Table 1 Proposed Expanded NIOSH PPT Program**
 391

PROGRAM GOALS and ACTIVITIES	Research	Policy and Standards Development	Certification	Outreach	Extramural Involvement
Goal 1: Reduce Exposure to Inhalation Hazards	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
CBRN Respirators	✓	✓	✓	✓	
Escape Respirators	✓	✓	✓	✓	
FFRs	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Industrial Respirators	✓	✓	✓	✓	
Goal 2: Reduce Exposure to Dermal Hazards	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Protective Garments	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	✓	
Protective Gloves	✓	✓	<input type="checkbox"/>	✓	
Protective Footwear	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
Goal 3: Reduce Exposure to Injury Hazards	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>
Protective Headgear					
Protective Garments	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
Protective Gloves	✓	✓	<input type="checkbox"/>		
Protective Footwear	✓	✓	<input type="checkbox"/>		
Hearing Protection	<input checked="" type="checkbox"/>	✓		✓	
Protective Eyewear					
Fall Protection	<input checked="" type="checkbox"/>	✓		✓	
Goal 4: Broad-based PPT Issues	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>
Sensors	✓	✓		✓	
Decontamination	✓	✓	<input checked="" type="checkbox"/>	✓	
Nanotechnology	✓	✓		✓	
Human Factors	✓	✓			
Interfaces/Integration	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Surveillance	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Barriers to PPT use	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Organizational Behavior and Motivation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Information Dissemination	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

392
 393 **Legend:**
 394 ✓ - Existing Program Activity

395 - Expansion of Existing Program Activity OR Initiation of New Program Activity

396 - Beyond 5 Years
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398
399

400 **ISSUE 1.1: Organize research across all types of PPT and across all**
401 **occupations and workplaces**

402

403 The PPT Program activities have emphasized the program’s four priority areas: pandemic
404 influenza preparedness, CBRN, nanotechnology, and mine escape. Efforts include traditional
405 industrial workplace respiratory protective device certification, policy and standards
406 development and research programs while pioneering advancements in emergency response and
407 preparedness strategies. Recently, the Program has expanded activities to include protective
408 garment research testing and evaluation. The Program should develop an approach to organize
409 (lead, conduct and monitor) research across all types of PPT and across all occupations and
410 workplaces.

411

412 **Desired Outcome:** A comprehensive PPT research program is conducted which contributes to
413 preventing work-related injury, illness, and death by advancing the state of knowledge and
414 application of PPT across all industry work sectors and across all major types of PPE.

415

416 The activities described here reflect the PPT Program plan for transforming current intramural
417 and extramural activities into a comprehensive nationally recognized PPT Program.

418

419 **ACTIVITY 1.1.1:** Establish an integrated PPT research program across NIOSH and improve
420 coordination with other federal agencies.

421

422 Enhancement and alignment of PPT research in inhalation, dermal, and injury related strategic
423 goals will be realized by identifying and prioritizing activities to reduce occupational related
424 risks, injuries, illnesses and fatalities. The PPT Program will continue to encourage collaboration
425 within NIOSH through participation on NORA Sector Councils, NIOSH cross sector steering
426 committees and by continuing to collaborate on industry sector and cross sector activities where
427 possible.

428

429 *ACTION STEP 1.1.1.1: Align NIOSH research to close knowledge gaps and reduce*
430 *exposures to inhalation hazards.*

431

432 *ACTION STEP 1.1.1.2: Align NIOSH research to close knowledge gaps and reduce*
433 *exposures to dermal hazards.*

434

435 *ACTION STEP 1.1.1.3: Align NIOSH research to close knowledge gaps and reduce*
436 *exposures to injury hazards.*

437

438 *ACTION STEP 1.1.1.4: Expand broad-based PPT research.*

439

440 *ACTION STEP 1.1.1.5: Research interaction between exposures, hazards and practices*
441 *in workplace and translate into PPT needs.*

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443 *ACTION STEP 1.1.1.6: Coordinate PPT efforts across federal agencies.*

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ISSUE 1.2: Participate in policy development and standards-setting across all types of PPT

Current NIOSH respirator standards are not updated rapidly enough to keep pace with available technology, global respirator standards are not realized, and current consensus standards do not address all PPT needs. The PPT Program has inadequate resources to comprehensively develop PPT standards for both respiratory and non-respiratory PPT.

Desired Outcome: PPT policy and standards development efforts are in place with strategies for creating knowledge that provides a basis for narrowing identified general and specific standards gaps to enable users to make informed decisions about PPT selection and use.

PPT Policy and Standards will be a primary driver for technology transfer of program science to the workplace. The comprehensive PPT Program will expeditiously develop state-of-the-art PPT federal standards (regulations) and support and participate with national/international consensus standards development organizations.

The primary federal standard development will be to ensure the current standard for respirator certification, 42 Code of Federal Regulations (CFR), Part 84, is systematically updated and maintained to use current technologies for both respirator performance and testing. The 42 CFR, Part 84 overhaul will develop respirator requirements to define minimum performance to ensure the reduction of inhalation hazards; operational requirements to ensure safe and effective use of the respirator, such as field of vision and communications; and requirements to ensure safe and effective use by specific user groups such as firefighters, healthcare workers (HCWs) and agriculture workers.

In addition to the federal standard, the comprehensive PPT Program will maintain an active role participating in PPT consensus standard development. The Program role will include identifying PPT research and standards gaps, and providing subsequent data driven research to support standards revisions and updates to maximize impact of PPT standards on workplace safety and health.

The PPT Program has two new regulatory proposals published for public comment and has several others under development. The approach to future enhancement to the respirator standards development is described under Recommendation 3 (Activity 3.1.1).

Gaps which need to be addressed in inhalation hazards include: supporting the development and evaluation of global respirator standards, developing standards for cleaning and decontaminating PPT and prioritizing the activities outlined to address Recommendation 3.

ACTIVITY 1.2.1: Improved worker safety and health through the development and use of PPT that meets national or international standards.

489 Contributing to the creation and improvement of consensus standards is not sufficient, if
490 products are not certified to those standards and properly used in the workplace. In order to
491 better understand the opportunities and gaps in current standards, the PPT Program will expand a
492 study conducted in 2004 that reviewed existing standards setting organizations and existing
493 standards for Respiratory Protective Devices (RPD).

494
495 *ACTION STEP 1.2.1.1: Perform gap analyses to identify standards needed for specific*
496 *types of PPE on an industry sector basis and use the results to define initiatives.*

497
498 *ACTION STEP 1.2.1.2: Support the development of global respirator standards.*

499
500 *ACTION STEP 1.2.1.3: Support the development of standards for non-respiratory PPE*
501 *through increased surveillance efforts.*

502
503 **ISSUE 1.3: Oversee certification of all PPT, including an assessment of**
504 **certification mechanisms**

505
506 Certification for all PPT, with the exception of respiratory protection, is not a federal
507 requirement.

508
509 **Desired Outcome:** A comprehensive certification program is in place to enable users to know
510 that products are thoroughly tested to establish compliance with state of the art performance
511 standards and are manufactured in quality facilities.

512
513 The comprehensive PPT Program will build on its long standing respirator certification program
514 to ensure PPE used to reduce exposure to inhalation, dermal, and injury hazards are evaluated to
515 establish conformance to recognized performance standards and manufactured according to a
516 recognized quality standard. The current NIOSH respirator certification program will build and
517 improve its focus on operational efficiency, integrity of evaluation and fairness in all evaluation
518 activities.

519
520 Integration of respirators in protective ensembles that provide both inhalation and dermal
521 protection will require the program to extend its reach to evaluate ensembles to ensure elements
522 of respiratory protection are maintained by the ensemble and that dermal protection capability is
523 demonstrated to recognized national and international standards through third party evaluation.
524 Program evaluation of some ensemble designs determined that some provisions of the NIOSH
525 certification of the specified respirators are invalidated by the interfacing with other PPE in those
526 designs.

527
528 PPT Program leadership is developing a process to address the identified administrative and
529 technical gaps in the standard and assure the PPE performance is not adversely affected by
530 interface interferences with other ensemble components. This process will be incorporated into
531 the standard application procedures for respirator approval and is being proposed for adoption
532 into the NFPA 1994 standard for use in the certification of ensembles under that standard.
533

534 This process for ensemble certification provides solutions to bridge technology and
535 administrative gaps to ensure no provisions of NIOSH certification of respirator protective
536 devices are invalidated by the interfacing with other PPE.

537
538 The process also acknowledges that some performance specifications for the ensemble may be
539 more restrictive and be preferentially enforced over corresponding respirator performance
540 requirements.

541
542 **ACTIVITY 1.3.1:** Lead the development and implementation of a strategy for non-respiratory
543 PPE certification.

544
545 *ACTION STEP 1.3.1.1: Request IOM conduct a workshop through the Committee on*
546 *PPE for the Workforce (COPPE) to initiate a strategy for non-respiratory PPE*
547 *certification.*

548
549 *ACTION STEP 1.3.1.2: Develop an implementation plan for addressing the*
550 *recommendations in the IOM Report on Non-respiratory PPT Certification.*

551
552 **ISSUE 1.4: Promote technology development, standards, and certification of**
553 **integrated PPT components and ensembles**

554
555 Few PPT Program initiatives are specifically designed to ensure technology development,
556 standards, and certification of integrated PPT components and ensembles to enable multiple
557 types of PPT (e.g. eye protection, hearing, protection, respirators, gloves, etc.) to be effectively
558 and seamlessly worn together.

559
560 **Desired Outcome:** A strategy is developed and implemented to provide users confidence that
561 multiple types of PPT have been evaluated and tested together to effectively protect workers and
562 enable users to make informed decisions about PPT selection and use.

563
564 The need for a “systems level” approach to body-worn PPT has received increased recognition in
565 the past several years. Issues exist relative to protective performance and the interoperability of
566 respirators, garments, gloves, footwear and other body worn equipment.

567
568 Technology advancements have made the application of body-worn sensors a reality and paved
569 the way for integrated PPT components and ensembles. These include the ability to monitor and
570 report physiological status, location/ tracking, communications, environmental hazards and PPT
571 service life status. Even person-wearable computers are a reality. The PPT Program has been
572 collecting and analyzing information on these matters in three sector areas (Agricultural,
573 Services and Healthcare).

574
575 Several issues concerning the effectiveness of ensembles are conformity assessment to
576 recognized performance standards and configuration management to ensure quality manufacture.
577 Today there are no standards in place or recognized authority to address this issue.

578
579 **ACTIVITY 1.4.1:** Conduct needs assessments, and develop multi-year PPT/PPE Program plans

580 addressing all industry sectors to establish a nationally recognized federal laboratory conducting
581 PPT/PPE research, standards development, and design and evaluation of fully integrated
582 protective ensemble system.

583
584 *ACTION STEP 1.4.1.1: Work with Standards Development Organizations (SDOs) to*
585 *develop a strategy for providing an appropriate standard to evaluate a configuration*
586 *encompassing various PPE as an integrated ensemble.*

587
588 *ACTION STEP 1.4.1.2: Expand on-going PPT Program efforts aimed at reducing*
589 *exposures to inhalation and dermal hazards for fire fighters, emergency services, and*
590 *HCWs to other industry sectors.*

591
592 **ISSUE 1.5: Conduct outreach programs for optimal use and acceptance of**
593 **PPT by workers**

594
595 **Desired Outcome:** An outreach program is in place which supports workers taking
596 responsibility for personal safety and encourages organizations to foster a culture where reducing
597 workplace illness, injury and death are priority.

598
599 Addressing a wide audience will encourage workers to take responsibility for personal safety and
600 encourage organizations to foster a culture where reducing workplace illness, injury and death
601 are priority. Outreach activities will include exhibits at various conferences and expositions,
602 presentations by staff at professional conferences, presentations through continuing education
603 activities such as webinars, community activities, NIOSH-sponsored public meetings, NIOSH-
604 sponsored stakeholder meetings, and utilization of the NIOSH electronic newsletter. These
605 activities will be used to create awareness and knowledge about the many issues regarding
606 selection and use of PPE. Program outreach activities have been able to identify interest and need
607 across many sectors, as well as identify technology gaps. Exhibits and staff presentations at
608 organizational conferences have enabled Program reach to various groups having unique needs.

609
610 Partners and stakeholders are essential contributors to the overall effectiveness of the Program.
611 Initial partnerships with stakeholders started with firefighters requiring protection against
612 chemical, biological, radiological, and nuclear agents. Partnerships have expanded to include
613 associations of HCWs (Association of periOperative Registered Nurses (AORN), Veterans
614 Health Administration (VA), safety generalists such as the American Industrial Hygiene
615 Association (AIHA) the American Society of Safety Engineers (ASSE), and the American Road
616 and Transportation Builders Association (ARTBA). The Program continues to expand its
617 outreach efforts with active participation in the NORA sectors to learn about industry sector PPT
618 needs.

619
620 Partners contribute to program outputs by participating in activities of the program, such as
621 public meetings and stakeholders meetings, customer satisfaction surveys, and focus groups.
622 Stakeholders facilitate the flow of information into and out of the program to assist in developing
623 strategic and implementation plans.

624
625 **ACTIVITY 1.5.1:** Develop an annual outreach strategy to encourage workers who rely on PPT

626 to take responsibility for personal safety and encourage organizations to foster a culture of
627 safety.

628
629 *ACTION STEP 1.5.1.1: Implement and revise the outreach plan annually to ensure high*
630 *priority worker needs are addressed based on Program inputs and priorities identified*
631 *through the strategic planning process.*

632
633
634 **ACTIVITY 1.5.2:** Promote educational and professional training of PPT in occupational safety
635 and health.

636
637 *ACTION STEP 1.5.2.1: Disseminate emerging relevant PPT information into training*
638 *and educational efforts.*

639
640 *ACTION STEP 1.5.2.2: Disseminate PPT materials to workers and workplaces which*
641 *rely on PPT.*

642 643 **FY 09 PPT Program Activities Related to Recommendation 1**

644
645 The majority of the PPT Program’s on-going work directly supports Recommendation 1. The
646 current PPT Program budget supporting these activities is approximately \$12M for FY09.

647
648 The Program has a number of activities in progress which will help transform the activities into a
649 comprehensive program. Intermediate goals and performance measures are under development
650 for all activities described in this plan. The following activities are underway or planned and not
651 described elsewhere in the plan:

- 652
653 • NIOSH is collaborating with partners to develop and test respirator breakthrough for
654 multi-contaminant cartridges where contaminants represent firefighting overhaul
655 exposures.
- 656
657 • NIOSH is collaborating with partners to disseminate the NIOSH published method to
658 estimate the permeation resistance of PPT material to sulfur (HD) and mustard (GB)
agents using liquid stimulant chemicals.
- 659
660 • NIOSH has two research projects underway to advance the state of technology for closed
circuit breathing systems for mine disasters and other emergencies.
- 661
662 • NIOSH will evaluate self-contained enclosures to assess the performance of the
enclosures and the physiological and psychological suitability of use of the enclosures.
- 663
664 • NIOSH intends to work with partners to develop outreach products and disseminate
665 research findings regarding decontamination, reuse, guidance and use of filtering
facepiece respirators under pandemic or other emergency situations.
- 666
667 • NIOSH has four research projects underway to improve protective clothing testing and
use practices to reduce worker exposure to dermal hazards.

- 668 • NIOSH has three research projects underway to improve emergency responder protective
669 clothing to reduce exposures to thermal, biological and chemical dermal hazards.
- 670 • NIOSH is partnering with construction stakeholders and safety professionals to research
671 and advance fall protection measures. Six projects are underway to support this research.
- 672 • NIOSH has four research projects underway to reduce noise-induced hearing loss (NIHL)
673 in the workplace.
- 674 • NIOSH has three research projects underway to reduce hand-arm vibration syndrome.
- 675 • NIOSH is collaborating with partners to establish anthropometric research databases to
676 develop improved sizing systems and configurations of fall protection harnesses for the
677 worker population. Two projects are underway to support this research.
- 678 • NIOSH is collaborating with safety equipment associations and the meat processing
679 industry to determine the anthropometry of Hispanic meat and poultry production
680 workers which can be used for the manufacturing of worker PPE. Two research projects
681 are underway to support this effort.
- 682 • NIOSH has four research projects underway to establish an anthropometry database of
683 firefighters for protective gear design applications.
- 684 • NIOSH has four research projects underway to conduct research to evaluate the
685 physiological and ergonomic impact of PPT on individual wearers.

686 The existing PPT Program's strategy and activities being conducted to address pandemic
687 influenza preparedness is of major importance. This emphasis evolved from the COPPE's
688 assessment that there was an urgent need to address the lack of preparedness regarding effective
689 PPE for HCW use during an influenza pandemic. This need was established from an IOM
690 workshop and subsequent report, *Preparing for an Influenza Pandemic: Personal Protective
691 Equipment for Healthcare Workers, September 2007.*

692
693 The IOM report identifies recommendations for research and policy actions in three critical
694 areas. The IOM recommendations in these areas are extensive, requiring the involvement of
695 numerous federal agencies, the private sector and international partners. The report recommends
696 the Department of Health and Human Services (DHHS) lead a focused research effort to
697 facilitate understanding of the transmission and prevention of seasonal and pandemic influenza.
698 NIOSH and the PPT Program are charged with assisting in this effort as it relates to
699 understanding transmission among healthcare workers, and conducting research to design and
700 promote the appropriate use of PPE.

- 701
702 • Understanding influenza transmission.
703 The current knowledge of key aspects of influenza transmission is rudimentary.
704 Increased understanding is required on the extent of droplet, aerosol, and contact
705 transmission, and the optimum ways to prevent transmission. Research initiatives are
706 needed to address these matters and the viability/infectivity of the airborne virus. As
707 these issues are more clearly understood, successful mitigation and prevention
708 strategies can be developed and deployed.
- 709 • Commit to worker safety and appropriate use of PPE.

710 Appropriate PPE use and healthcare worker safety should be a priority for all
711 individuals within the healthcare workplace, as well as being made an integral part of
712 the operation culture of their parent organizations. Additional research is needed to
713 improve the understanding of how human factors and behavioral issues related to the
714 ease and effectiveness of PPE use for extended periods of time and during diverse
715 work environments affect PPE use and compliance.

- 716 • Innovate and strengthen PPE design, testing and certification.

717 An integrated effort is needed to fully understand the unique requirements of
718 healthcare workers and to develop innovative materials, technologies, and products
719 that can meet their needs, as well as those of their patients. The use of PPE in any
720 specific workplace environment places unique demands on the design and
721 engineering of these products. This is of particular importance in the healthcare
722 industry where these products have to be focused on interactions between the workers
723 and their patients. The concerns are not only that the workers not be infected by the
724 patients, but also that they (the workers) also do not transmit infections to subsequent
725 patients through the equipment they use to protect themselves. Effective PPE, with
726 initial emphasis on filtering facepiece respirators, are designed, tested, certified, and
727 readily available for use by the healthcare workforce, for routine and non-routine
728 applications. Increased testing in the pre-market phase and conducting post-marketing
729 evaluations is vital to the development and effective use of such products.

730
731 The IOM report provided a set of recommendations to which the PPT Program responded with
732 an action plan in February 2008. The latest version of the plan is available in NIOSH Docket
733 129: (<http://www.cdc.gov/niosh/docket/NIOSHdocket0129.html>). Approximately \$400K
734 discretionary funds currently are dedicated in FY09 to support pandemic influenza preparedness
735 research initiatives. This research addresses critical aspects of the research gaps described in the
736 IOM report and then underscored as being important in the subsequent NA report.

737
738 All of these research activities are conducted by intramural NIOSH staff in collaboration with
739 various partners and stakeholders. Several projects involve close collaborations with the various
740 ASTM, ISO, and NFPA committees to transition PPT intramural program outputs into
741 recognized consensus standards and test methods. Project BREATHE cuts across several of the
742 research gaps identified in the IOM Report by seeking to develop a respirator optimized for the
743 healthcare sector featuring better integration with other PPE, less job interference, better fit, and
744 improved comfort.

745
746 Several other projects are focused on understanding critical issues related to concerns of a
747 possible respirator shortage caused by a pandemic. For example, one project involves
748 collaboration with the DoD Air Force Research Lab (AFRL), FDA and several universities with
749 funding provided by the DoD Technical Support Working Group (TSWG) to study
750 decontamination/reuse of filtering facepiece respirators. Establishing a better understanding of
751 respirator fit and performance are the goals of several other projects.

752
753 Additional details regarding the PPT Program's Strategic Goals and activities related to
754 Recommendation 1 can be located at: <http://www.cdc.gov/niosh/programs/ppt/projects.html>.

755 **Recommendation 2: Establish PPT Research Priorities and Expand**
756 **the Extramural Program**

757
758 The second recommendation of the NA Report addresses the need to expand the participation of
759 external research organizations in the PPT Program. As there are limits on NIOSH's intramural
760 resources, support for research outside of NIOSH is necessary to meet the PPT research needs
761 across all industry sectors. External involvement is imperative and will enable the NIOSH PPT
762 Program to expand upon existing expertise. The prioritization of research needs relating to the
763 PPT Program Strategic Goals via stakeholder input is an important step in defining the PPT
764 Program. Once the research needs are prioritized, NIOSH will undergo an internal process in
765 which the research needs are matched to NIOSH's existing expertise. The remaining unmet
766 research needs will become the focus for expanded extramural research efforts.

767
768 The NA Report states "Collaborative extramural partnerships, exemplified by centers of research
769 excellence in personal protective technologies, would serve to leverage the PPT Program's
770 resources and expertise and provide the coordinated intramural-extramural approach necessary
771 for advancing science and technology relevant to protecting workers through PPT." The NA
772 report emphasizes the need for extramural research collaboration for the purpose of expanding
773 the PPT Program. NIOSH interprets that it should create relationships with external research
774 communities that can assist a national research program designed to narrow the PPT research
775 gaps through the utilization of existing extramural capabilities.

776
777 The NA Report in its second recommendation states:

778
779 *The PPT Program should:*

- 780
- 781 • *Develop and support research centers of excellence (COE) that work closely with the NIOSH intramural*
782 *research program to improve PPT, increase field research, and explore and implement research to*
783 *practice interventions, and*
 - 784 • *Work with the NIOSH OEP to increase other research opportunities and enhance collaboration and*
785 *awareness of relevant PPT research efforts among intramural and extramural researchers.*
- 786

787 The PPT Program defined two issues that it must aggressively address in order to translate the
788 recommendation into practice as it conducts its operations.

789
790 These two issues are:

- 791 2.1 Coordinate intramural and extramural research activities
792 2.2 Expand the extramural research program
- 793

794 **ISSUE 2.1: Coordinate intramural and extramural research activities**

795
796 Currently the intramural and extramural PPT activities are not formally coordinated under a
797 comprehensive and unified PPT Program.

798
799 **Desired Outcome:** The PPT Program will conduct its activities with effective coordination with
800 the NIOSH OEP. OEP can recommend and facilitate implementation of appropriate mechanisms

801 which could be used to fund extramural research. Examples of award mechanisms include
802 grants and cooperative agreements [for investigator-initiated research in response to NIOSH’s
803 general program announcements and from specific Requests for Applications (RFAs)], consortia,
804 Program Projects and COE, as well as the procurement of specific services through contracts. In
805 addition, existing NIOSH-supported Centers in education, agriculture, Worklife, and
806 construction could be enhanced by the introduction of an appropriate PPT-related set of
807 activities. Through effective coordination of intramural and extramural activities, the PPT
808 Program will seek to establish partnerships with or to support existing extramural expertise,
809 laboratory infrastructure, and outreach networks that would be costly, if not impossible to
810 duplicate in-house. Further, the core PPT Program activities of research, policy and standards
811 development, and certification will evolve to include more effective coordination with the
812 extramural programs managed by the NIOSH OEP.

813

814

815 **ACTIVITY 2.1.1:** Identify the PPT research needs that will be addressed by the extramural
816 research community.

817

818 *ACTION STEP 2.1.1.1: PPT research needs will be prioritized and matched to current*
819 *resources to identify gaps.*

820

821 *ACTION STEP 2.1.1.2: Unmet PPT research needs will be targeted by new funding*
822 *opportunities for the extramural research community.*

823

824 **ISSUE 2.2: Expand the extramural research program**

825

826 The unmet needs in the PPT Program research portfolio can be addressed by extramural
827 organizations which have existing expertise and infrastructure to address immediate as well as
828 emerging PPT research needs through an expansion of the extramural research program.

829

830 **Desired Outcome:** The PPT Program maximizes the relevance and impact of PPT research
831 through the coordination of extramural research activities to address unmet research needs.

832

833 The NIOSH OEP funds and manages grants and cooperative agreements that are based on
834 applications submitted in response to general and specific funding opportunity announcements
835 (FOA). The general FOAs cover all research areas within NORA. In addition, OEP publishes
836 specific FOAs that target areas of high programmatic relevance and others which address
837 specific Congressionally-mandated programs. When researchers draft their applications for
838 independent research projects they are generally encouraged to address the research areas within
839 NORA and to address the goals of the sectors or cross sectors (including PPT), and for specific
840 announcements (like RFAs) to address the targeted research areas outlined in the FOA.

841 Presently applications for PPT-related research are submitted to NIOSH’s general
842 announcements and to general announcements that NIOSH participates in with NIH (including
843 Small Business Innovation Research). To date NIOSH has not provided resources to support a
844 PPT-focused FOA through OEP due to limited funding.

845

846 **ACTIVITY 2.2.1:** Establish a coordinated activity within the PPT Program to interface with
847 OEP.

848
849 *ACTION STEP 2.2.1.1: Define the responsibilities for a coordination activity within the*
850 *PPT Program to interface with OEP to establish effective lines of communications.*

851
852 *ACTION STEP 2.2.1.2: Assign these defined duties and responsibilities within the PPT*
853 *Program.*

854
855 *ACTION STEP 2.2.1.3: Solicit extramural grant recipient participation in the annual*
856 *PPT Program Stakeholder meeting.*

857
858 **ACTIVITY 2.2.2:** Establish a process for the PPT Program to engage with the extramural
859 program through enhanced collaboration with OEP.

860
861 *ACTION STEP 2.2.2.1: The PPT Program will collaborate with OEP to provide research*
862 *concepts for inclusion into FOAs.*

863
864 *ACTION STEP 2.2.2.2: The PPT Program will provide support to extramural awardees.*

865
866 *ACTION STEP 2.2.2.3: The PPT Program will assist OEP in making maximal use of the*
867 *outputs from extramural awards.*

868

869 **FY 09 PPT Program Activities Related to Recommendation 2**

870

871 The PPT Program is aware of 37 existing OEP grants that are substantially PPT in scope. (see
872 Table 2)

873

874 The PPT Program has established an annual PPT Program Stakeholder Meeting as part of its
875 Outreach and Communications activities to encourage stakeholder input into the program
876 activities and facilitate transfer of outputs to stakeholders. NIOSH conducted its second annual
877 Stakeholders Meeting on March 3, 2009 in Pittsburgh, PA where all PPT Program activities were
878 featured. The PPT Program, in cooperation with NIOSH OEP, invited NIOSH grant recipients
879 (see Table 2), NIOSH Education and Research Centers (ERC), and NIOSH State Based
880 Surveillance program personnel to participate and report on their PPT related activities at this
881 meeting. Requests for presentation/poster were sent to these potential participants.

882 Approximately 10 extramural activities participated in the meeting. This year's event was the
883 first time the intramural and extramural activities deliberately participated together in an
884 organized event. Both intramural and extramural participants appreciated the enthusiasm and
885 richness of the discussion and information presented.

886

887
888

Table 2 PPT Related Grant Recipients and Projects

Grant	PI Name (Contact)	Title	Project Start	Project End
1 R01 OH009532-01	PENG, SYD S	<u>Coal Bumps Prediction in Longwall Coal Mines</u>	9/1/2008	8/31/2010
1 R01 OH009548-01	DEININGER, DEBRA J	<u>New Nanostructured Sensor Arrays for Hydride Detection</u>	8/1/2008	7/31/2009
1 R01 OH009550-01	WILLIAMS, MICHELE D.	<u>Novel Seismic Solution for Prompt Location of Entrapped Miners</u>	9/1/2008	8/31/2010
1 R03 OH009325-01	SUN, YUYU	<u>Antibiofilm tubing to reduce occupational exposure to biohazards in dentistry</u>	6/1/2008	5/31/2010
1 R03 OH009381-01	VOLCKENS, JOHN	<u>A Personal Sampler for Assessing Inhaled Nanoparticle Exposures</u>	7/1/2008	6/30/2010
1 R43 OH008206-01A2	SRINIVAS, GIRISH	<u>Escape Respirators for First Responders</u>	8/1/2006	8/30/2007
1 R43 OH008952-01A1	SCHANTZ, HANS GREGORY	<u>Improving Safety For Miners By Providing A Wireless Real Time Locating System</u>	8/1/2007	2/28/2008
1 R43 OH009016-01A2	KOSEK, JOHN A	<u>Advanced Gas Sensor</u>	6/30/2008	12/31/2008
1 R43 OH009018-01	FAULL, JOHN D	<u>Real-Time Personal Monitor for the Drycleaning Industry</u>	9/1/2007	9/30/2008
1 R43 OH009026-01	ROUTKEVITCH, DMITRI	<u>Advanced Personal Gas Detectors for Mining Applications</u>	4/1/2007	10/31/2007
1 R43 OH009027-01A1	SRINIVAS, GIRISH	<u>Firefighter Mask</u>	6/30/2008	6/30/2009
1 R43 OH009035-01	BUKSHUPUN, LEONID	<u>Polymer Web Sensing System</u>	4/1/2007	10/31/2007
1 R43 OH009178-01	LIS, STEVEN ANDREW	<u>Fiberoptic Personal Exposure Monitor for Diisocyanates</u>	8/1/2007	2/28/2008
1 R43 OH009191-01	DEMING, GLENN	<u>Personal Cooling System Control Algorithm Development and System Optimization</u>	9/1/2007	9/30/2008
1 R43 OH009349-01	SRINIVAS, GIRISH	<u>Cooling Suit for First Responders</u>	9/1/2007	9/30/2008
1 R43 OH009353-01	MAROTTA, CHRISTOPHER L	<u>Formaldehyde Sensor for Environmental and Industrial Monitoring</u>	9/1/2007	9/30/2008
1 R43 OH009459-01	MIZE, PATRICK DANIEL	<u>Durable Visible Light-activated Antiviral Coatings for Fabrics Used for Personal</u>	7/1/2008	12/31/2008
2 R44 OH007963-02A2	RAJAGOPALAN, SHYAMALA	<u>From Nanoparticles to Novel Protective Garments</u>	3/1/2003	6/30/2010
2 R44 OH008833-02	KLINE-SCHODER, ROBERT J	<u>Co-located Earphone/Microphone for Active Noise Reduction</u>	9/1/2008	8/31/2010
5 K01 OH009255-02	PETERS, THOMAS M.	<u>Personal Exposure to Engineering Nanoparticles</u>	9/1/2007	8/31/2010
5 R01 OH004085-05	REPONEN, TIINA	<u>Respiratory Protection Against Bioaerosols in Agriculture</u>	8/1/2007	7/31/2010
5 R01 OH008119-03	HARBER, PHILIP I.	<u>Respirator Effects in Impaired Workers</u>	7/15/2005	7/14/2009
5 R01 OH008165-03	GUFFEY, STEVEN E	<u>Enclosing hood effectiveness</u>	8/1/2006	7/31/2009
5 R01 OH008641-02	RABINOWITZ, PETER M	<u>Personal Exposure to Engineering Nanoparticles</u>	7/1/2007	6/30/2011
5 R01 OH008669-03	BRAMMER, ANTHONY	<u>Active Hearing Protectors and Audibility of Critical Communications</u>	8/1/2006	7/31/2011
5 R01 OH008806-03	O'SHAUGHNESSY, PATRICK T	<u>Assessment Methods for Nanoparticles in the Workplace</u>	7/1/2005	6/30/2008
5 R01 OH008807-03	XIONG, JUDY QIUJU	<u>Monitor & Characteriz Airborne Carbon Nanotube Particles</u>	8/1/2005	7/31/2009

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5 R01 OH008913-02	CHENG, YUNG-SUNG	<u>Development of a Highly Efficient Personal Sampler to collect Viable Bioaerosols</u>	9/1/2007	8/31/2010
5 R01 OH009141-03	DUTTA, PRABIR K	<u>Science To Achieve Results (STAR) Program</u>	8/1/2006	7/31/2009
5 R03 OH008354-02	SUN, YUYU	<u>Multipurpose Protective Clothes for Emergency Responders</u>	4/1/2005	8/16/2007
5 R44 OH007662-03	SUN, XIAOQING	<u>A Laser-Based Device for Work Site Stability Assessment</u>	7/1/2002	1/31/2009
5 R44 OH007664-03	LANGLEY, THEODORE D	<u>Measuring Human Fatigue with the BLT Prototype</u>	6/1/2002	7/31/2009
5 U50 OH007542-08	MAY, JOHN J	<u>The Northeast Center for Agricultural Health</u>	9/30/2001	8/31/2011
5 U50 OH007544-08	FENSKE, RICHARD	<u>Pacific Northwest Agricultural Safety and Health Center</u>	9/30/2006	9/29/2011
5 U54 OH008307-04	STAFFORD, ERICH J	<u>Centers for Construction Safety and Health</u>	8/1/2004	6/30/2009
5 U54 OH008307-04 subproject	SUSIE, PAM	<u>Centers for Construction Safety and Health</u>	7/1/2005	6/30/2009
5R01OH008080-04	LUNGU, CLADIU	<u>Adsorption of Gas Phase Contaminants</u>	8/1/2005	7/31/2009

889
890

891 **Recommendation 3: Enhance the Respirator Certification Program**

892
893 The third recommendation of the NA Report addresses the PPT Program’s respirator certification
894 function. It states:

895 *The PPT Program should continue to improve the respirator certification process. The program should:*

- 896 • *Expedite the revision of the respirator certification regulations. As a part of that effort, NIOSH should*
897 *revise the respirator certification fee schedules so that certification fees paid by the manufacturers fully*
898 *cover the cost of certification.*
- 899 • *Develop a mechanism for registering the purchase of NIOSH-certified respirators so that post-marketing*
900 *notifications and recalls can be accomplished expeditiously and effectively.*
- 901 • *Expand the audit programs to ensure that results of the product audit program are methodologically and*
902 *statistically sound and that the site audit program ensures standardized quality of audits performed by*
903 *NIOSH staff and contractors.*
- 904 • *Disseminate respirator certification test results data (e.g., breathing resistance).*
905

906
907
908 The PPT Program defined six issues that it must aggressively address in order to translate the
909 recommendation into operational practice.

910
911 These six issues are:

- 912 3.1 Explore ways to expedite respirator certification regulation revisions
- 913 3.2 Assess the feasibility of updating certification fees
- 914 3.3 Examine the possibility of registering the purchase of NIOSH-certified respirators
- 915 3.4 Explore the expansion of the product audit program
- 916 3.5 Consider expanding the site audit program
- 917 3.6 Explore approaches for disseminating respirator certification test results data

918 919 **ISSUE 3.1: Explore ways to expedite respirator certification regulation** 920 **revisions**

921
922 NPPTL has developed a modular approach for updating federal respirator certification
923 regulations, but has experienced delays in implementing this approach.

924
925 **Desired Outcome:** Improve respirator performance for end users by developing performance
926 based respirator certification standards in a modular fashion, addressing the subsections of the
927 current respirator certification standard in workable sections. Also, the PPT Program will
928 expeditiously evaluate state-of-the art and novel technologies to enable transparent approval
929 requirements and innovative respirators to move to market sooner, thereby increasing the
930 national inventory of respirators.

931
932 In 2009, the PPT Program is developing and/or updating the quality assurance module, closed
933 circuit escape respirator (CCER) module and the total inward leakage (TIL) standard module
934 using the rulemaking process. The quality assurance and CCER proposed rules have been
935 published in the Federal Register and for public comment.
936

937 While the process used in rulemaking results in focused changes to regulations, there are many
938 factors which influence the time required in moving regulations through to conclusion. These
939 include: the time frames for review and comment periods, the development of the economic
940 impact analysis and technical rationale of the regulation, the development of the underlying
941 scientific and technical bases supporting the regulatory requirements, public hearings, and
942 limited resources within the PPT Program.

943
944 The PPT Program has substantial control over the development of the science to support updates,
945 the development of technical criteria supported by solid science, and the vetting of the science
946 and basic technical approaches with outside experts and stakeholders. Similarly, the basic
947 economic factors related to options for change can be examined prior to rulemaking. These
948 activities have been time consuming and have continued beyond the initiation of the rulemaking
949 effort. To the extent that these activities can be more fully conceived and implemented prior to
950 rulemaking, rulemaking will be expedited.

951
952 The approach detailed below focuses on performance driven certification regulations versus
953 design specific standards. Their timely implementation will result in improved respirator
954 performance for end users and reduce confusion due to missing elements in 42 CFR, Part 84.
955 This proposed course of action will allow the PPT Program to expeditiously address new PPT
956 technologies and allow respirator manufacturers to introduce them more quickly into the market.

957
958 **ACTIVITY 3.1.1:** Establish strategies that will efficiently process respirator certification
959 regulations to conclusion.

960
961 *ACTION STEP 3.1.1.1: Conduct a feasibility assessment to identify approaches to*
962 *expedite rulemaking of respirator standards. Investigate and document “negotiated”*
963 *and “direct” final rule, and the use of Voluntary Consensus Standards.*

964
965 *ACTION STEP 3.1.1.2: Timely educate stakeholders of specific PPT proposals to enable*
966 *their support of respirator certification rulemaking updates.*

967
968 *ACTION STEP 3.1.1.3: Explore the possibility of requesting stakeholders to submit*
969 *information or suggestions for respirator certification rulemaking to update 42 CFR Part*
970 *84.*

971
972 *ACTION STEP 3.1.1.4: Explore the possibility of collaborating with private laboratories*
973 *to enable manufacturers to request their respirators be simultaneously assessed to*
974 *determine if they meet specific consensus standard performance requirements (e.g.*
975 *communications requirements, visual acuity) beyond those required in 42 CFR Part 84.*

976
977 **ISSUE 3.2: Assess the feasibility of updating certification fees**

978
979 The current certification fee schedule does not reflect today’s costs for performing certification
980 testing nor is the cost corrected for inflation.

981

982 **Desired Outcome:** The recovery of the cost for service can substantially supplement funds used
983 for the respirator certification and approval function, thereby reducing demands on internal
984 funding.

985
986 By statute, 31 USC 9701, the agency is supposed to consider whether a fee is 1) fair; and 2)
987 based on A) the costs to the Government; B) the value of the service or thing to the recipient; C)
988 public policy or interest served; and D) other relevant facts. The PPT Program will strive to
989 align the fees with the intention of the statute.

990
991 Certification-related fees are stated and mandated in 42 CFR Part 84 under subpart C, Fees for
992 current non-CBRN certification and testing processes. The listed fees do not comprehensively
993 include all activities conducted in the testing and evaluation of a respirator design for NIOSH
994 certification. Further, these fees have not been updated since the inception of the NIOSH
995 respirator certification program under 30 CFR part 11 enacted in 1972. In the case of the special
996 CBRN respirators, fees are determined every year in conjunction with the US Army RDECOM
997 and these fees do reflect the estimated actual certification and testing costs.

998
999 Changes or increases to the non-CBRN certification fees will need to be developed, and then
1000 published in the Federal Register (FR) as a Notice of Proposed Rulemaking (NPRM).

1001
1002 **ACTIVITY 3.2.1:** Determine certification fees that are consistent with the actual costs. The
1003 costs associated with all steps of the respirator certification process are to be included in this
1004 study. The study is to be inclusive from receiving the application through to the final letter
1005 issuance and application close out.

1006
1007 *ACTION STEP 3.2.1.1: Establish valid methods for determining the cost for each area of*
1008 *the respirator certification process, consistent with related federal policy and our*
1009 *authority to collect such costs.*

1010
1011 *ACTION STEP 3.2.1.2: Pursue a fee update through rulemaking.*
1012

1013 **ISSUE 3.3: Examine the possibility of registering the purchase of NIOSH-** 1014 **certified respirators**

1015
1016 With the exception of SCSR, there is no registration of ownership for NIOSH certified
1017 respirators. As a result, the PPT Program is unable to collect some key information and to
1018 communicate directly with users of approved respirators in the event of critical changes affecting
1019 their respirators. Specifically, the PPT Program lacks:

- 1020 • access to respirator specific surveillance data
- 1021 • access to respirator field-deployment strategies and practices
- 1022 • the ability to provide proactive, targeted NIOSH Respirator Notifications and
1023 Notices to the users of the equipment
- 1024 • the means to fully assess and understand environmental effects on respirator
1025 performance
- 1026 • a highly effective and expeditious means to execute respirator recall and retrofit
1027 actions

- 1028 • an effective means to determine the outcome of respirator recall and retrofit
- 1029 actions
- 1030 • a direct line of communications to end users
- 1031 • a quantitative means to evaluate and assess respirator life-cycles
- 1032

1033 **Desired Outcome:** Registration across multiple classes of respirators will enable a better
1034 understanding of respirator deployment, targeted distribution of user notices, enhanced
1035 surveillance, and knowledge leading to reduced injuries and fatalities. Knowledge gained will
1036 also serve as a model for evaluating respirator life-cycle performance that may be applied to
1037 other types of PPT.

1038
1039 Communicating important approval information to, and receiving information from, respirator
1040 owners/users is a priority of the PPT Program. The processes for issuing and monitoring
1041 certifications do not include a formal process to capture user/owner feedback regarding approved
1042 respirators, except the ability of users reporting problems with approved respirators. Further,
1043 few options are available for the program to disseminate critical user information such as recall
1044 notices, or other types of manufacturer service actions. This discontinuity is especially
1045 significant due to the general under-representation of user opinions among all stakeholder
1046 opinions.

1047
1048 The PPT Program currently uses a passive approach to distribute respirator user notices by
1049 means of postings on the world-wide-web and list serve. The creation of an easy-to-use
1050 registration for certain types of approved respirators would be a significant start to establishing
1051 an effective, two-way, communication avenue directly with those who depend on approved
1052 respirators.

1053
1054 Monitoring the operation of the MSHA's recently established SCSR registration program (which
1055 was developed with technical input from NIOSH) could provide valuable information as a pilot
1056 study for the further registration of other respirator types.

1057
1058 Experience gained through the registration of types which have an immediate impact on worker
1059 health such as escape respirators may lead to the knowledge of how to create similar programs
1060 for other approved respirator types. Not all types of respirators currently approved may lend
1061 themselves to effective registration. Registration of respirators will enhance the direct
1062 communication capabilities between NIOSH and end users.

1063
1064 **ACTIVITY 3.3.1:** Establish a practical mechanism for registering NIOSH-certified respirators.

1065
1066 *ACTION STEP 3.3.1.1: Conduct a feasibility study to determine which respirator types*
1067 *can be successfully registered.*

1068
1069 *ACTION STEP 3.3.1.2: Define and implement registration programs for selected*
1070 *additional types of respirators.*

1071
1072 *ACTION STEP 3.3.1.3: Assess the effectiveness of the registration programs.*
1073

1074 **ISSUE 3.4: Explore the expansion of the product audit program**

1075
1076 The number of product audits conducted per year should be based on a statistically significant
1077 representation (sample size) of the total number and classes of NIOSH-certified respirators. The
1078 existing program is limited by funding and may be too narrow to be methodologically and
1079 statistically sound.

1080
1081 **Desired Outcome:** A product audit program that is robust and statistically sound is established.

1082
1083 Due to current funding limitations, laboratory space and availability of dedicated staff, the
1084 product audit program focuses primarily on filtering facepiece respirators. These efforts are
1085 extensive and statistically sound; approximately half of the manufacturers are sampled every
1086 year. Expanding the program to other respirator types would present a more robust and
1087 scientifically backed product auditing program in those areas.

1088
1089 A Product Audit Logic Computer Program has been developed which allows assignment of
1090 priorities to respirators to be selected and tested. This logic program takes in many historical
1091 variables when considering the selection process. A program to test a sample of filtering
1092 facepiece respirators from every manufacturer on a known time frame is in the trial phase.

1093
1094 **ACTIVITY 3.4.1:** Generate a product audit program that it is robust and statistically sound.

1095
1096 *ACTION STEP 3.4.1.1: Determine the number of existing approvals that are active for*
1097 *each type of respirator and understand all approved respirator configurations.*

1098
1099 *ACTION STEP 3.4.1.2: Determine the appropriate sample size and testing frequency*
1100 *required for each type of respirator.*

1101
1102 *ACTION STEP 3.4.1.3: Initiate the acquisition and testing of respirators according to the*
1103 *developed sampling plan. Expand testing facilities as needed.*

1104
1105 *ACTION STEP 3.4.1.4: Analyze the testing results and use them to initiate investigations*
1106 *and adjust program requirements.*

1107
1108 **ISSUE 3.5: Consider expanding the site audit program**

1109
1110 The manufacturer site audit program targets each manufacturing site for a complete quality
1111 system audit every two years. Additionally, self-contained escape respirator manufacturers are
1112 audited every year. This program is statistically sound as it examines the entire population of
1113 approval holders within a known time frame. However, the perception exists that the site audit
1114 program needs to be better monitored to ensure that audits are conducted using valid
1115 methodology and appropriate data analysis.

1116
1117 **Desired Outcome:** A site audit program that uses valid methodology, is properly monitored,
1118 and is recognized as appropriate for its purposes.

1119

1120 Two major constraints of the existing program are lack of a database to administer and manage
1121 the program, and adequate resources to evaluate and administer the program. One planned
1122 action is to integrate a modern interactive computer database to administer, schedule and track
1123 these activities. This database will also provide document control for addresses, past audit
1124 reports and information supplied by manufacturers.

1125
1126 **ACTIVITY 3.5.1:** Improve monitoring and performance of Approval Holder Quality
1127 Management System Site Audits.

1128
1129 *ACTION STEP 3.5.1.1: Improve site audit methodology by ensuring that audits are*
1130 *closed in a timely manner.*

1131
1132 *ACTION STEP 3.5.1.2: Improve site audit monitoring through the development of an*
1133 *interactive computer database.*

1134
1135 *ACTION STEP 3.5.1.3: Improve site audit methodology by assuring that audits are*
1136 *scheduled in a timely manner.*

1137
1138 *ACTION STEP 3.5.1.4: Integrate site audit data into the certified product investigation*
1139 *process (CPIP), and site audit activities.*

1140
1141 **ISSUE 3.6: Explore approaches for disseminating respirator certification test**
1142 **results data**

1143
1144 Stakeholders and end users have shown a desire for NIOSH to provide certification test data to
1145 enable end users to make an informed decision when purchasing and selecting respirators.
1146 However, only pass or fail of an entire approval is currently released for several reasons,
1147 including NIOSH respirator test facilities not being designed or operated for comparative testing,
1148 service life and penetration tests stop when specified results are achieved, and test data may not
1149 represent actual results under use conditions. Currently there are no means to perform
1150 comparative respirator testing or to gather stakeholder/end user feedback on respirator
1151 performance by organizations other than NPPTL with test facilities designed for this purpose.

1152
1153 **Desired Outcome:** Explore the possibility of establishing processes to increase end user
1154 confidence in respirator performance.

1155
1156 In initiating the development of a project plan for the PPT Program to disseminate some level of
1157 certification or comparative test data for respirators, the current program operations and outputs
1158 were evaluated, along with analyzing the strengths and weaknesses of the data generating
1159 process used. Other organizations that perform similar operations and disseminate comparative
1160 data were investigated.

1161
1162 In evaluating the certification data generating process, several strengths appeared. This current
1163 process ensures an un-biased certification process as all respirators are tested to the same basic
1164 test levels. This program also allows the manufacturers to have their respirators that may have

1165 state of the art technologies or proprietary designs present be evaluated without fear of
1166 competitors gaining information before the products have been introduced to the market place.

1167
1168 **ACTIVITY 3.6.1:** Explore potential approaches to enable extramural researchers to compare
1169 performance indicators of in-class respirators.

1170
1171 **ACTIVITY 3.6.2:** Explore the feasibility of developing a public forum for stakeholders/end
1172 users to share qualitative respirator performance information obtained from personal respirator
1173 use experiences.

1174
1175 *ACTION STEP 3.6.2.1: Explore potential programs for disseminating comparative in-*
1176 *class respirator parameters.*

1177
1178 **ACTIVITY 3.6.3:** Identify potential training opportunities to ensure proper selection and use of
1179 respiratory protection.

1180
1181 **FY 09 PPT Program Activities and Projects Related to Recommendation 3**

1182
1183 \$3.4 million of PPT Program FY09 discretionary funds are allocated to support projects related
1184 to Recommendation 3.

1185
1186 Several of these projects are for research directly supportive of the Certification Program. The
1187 remaining projects support the administration, certification, auditing and include the pre and post
1188 certification activities which are mandated by 42 CFR Part 84. Some applied engineering
1189 research projects are included, as well as activities to both update existing regulations to
1190 accommodate developing technologies in equipment and testing, as well as develop new
1191 standards that are technology leading for increased worker safety and health. These activities are
1192 summarized here:

- 1193
- 1194 • NIOSH ensures the integrity of the national supply of respirators through the
1195 implementation of a respirator certification process with an emphasis on efficiency,
1196 integrity and fairness. NIOSH also sustains product and site audit programs to ensure the
1197 integrity of NIOSH certified respirators. Currently five projects are underway to support
1198 this goal. This goal should enable manufacturers to design and manufacture NIOSH
1199 approved respirators in facilities adhering to a NIOSH approved quality plan.
 - 1200 • NIOSH investigates, analyzes, and resolves concerns with certified respiratory protective
1201 products uniformly and fairly by reporting results of field problem investigations and
1202 evaluations and providing feedback to users to ensure workers safety and health risks are
1203 minimized. Currently three projects are underway to support this goal. This goal should
1204 enable the PPT Program to be responsive to users who solicit NIOSH for information on
1205 investigations/evaluations to resolve field problems with NIOSH approved respirators.
 - 1206 • NIOSH establishes contemporary respirator standards to facilitate the availability of
1207 NIOSH-approved respirators incorporating state-of-the-art technology in the protection of
1208 workers against known and emerging inhalation hazards. Currently eight projects are
1209 underway to support this goal. NIOSH also participates in the standards setting

1210 committees of other SDOs (e.g. ANSI, ASTM, NFPA, ISO) to expand the transfer of its
1211 scientific expertise and research outputs. The following standards modules will be
1212 developed and are projected as updates to 42 CFR Part 84 over the next five years. The
1213 year the PPT Program intends to enter the rulemaking process is identified.

- 1214
- 1215 2008 Quality Assurance (QA) Requirements and Closed Circuit Escape
1216 Respirators (CCER) the and Closed Circuit Self Contained Breathing
1217 Apparatus (CC-SCBA)
- 1218 2009 TIL testing for Half Masks and Filtering Facepiece Respirators (FFR),
1219 Powered Air Purifying Respirators (PAPR) and Supplied Air Respirators
1220 (SAR)
- 1221 2010 Air Fed Suits and TIL for remaining classes of respirators
- 1222 2011 Combination Units and Open Circuit SCBA
- 1223 2012 Chemical Cartridge and Chemical Canister Respirators

1224

1225 In addition to current ongoing activities, the Program has identified Activities associated with
1226 respirator certification regulations (Activity 3.1.1) and updating the fees (Activity 3.2.1) as the
1227 highest priorities for the Program. Additionally the activities associated with the audit program
1228 (Activity 3.4.1 and Activity 3.5.1) will be pursued as resources become available. The
1229 remaining activities (Activity 3.3.1 and Activities 3.6.1 & 3.6.2) are important, but have the
1230 lowest priority for the Program.

1231

1232 Answers to the following key research questions will enhance the current certification program.
1233

- 1234 • How to assess the accuracy and reliability of a newly proposed fit test procedure when a
1235 true measure of respirator fit does not exist?
- 1236 • How many donnings per respirator should be conducted, and how does the number of
1237 donnings affect the required number of human subjects?
- 1238 • How are respirators sampled from a population in a way that is feasible but statistically
1239 valid?
- 1240 • How to determine which facial dimensions should be used for certification fit testing, and
1241 then how to correlate this information to understandable and feasible sizing for the
1242 worker population?
- 1243 • How should information on multiple facial dimensions be assessed before associating
1244 them with fit test results?
- 1245 • How to analyze repeated measurements on the same subjects (either repeated fit tests or
1246 physiological tests) to accurately assess intrasubject variability?

1247

1248 **Recommendation 4: Increase Research on the Use and Usability of**
1249 **PPT**

1250
1251 The fourth recommendation of the NA report addresses the need for an expansion of the PPT
1252 Program’s research function. It states:

1253
1254 *The PPT Program should intensify its research directed at barriers to and facilitators of PPT use by*
1255 *workers. Such research should examine human factors and ergonomics, as well as individual behaviors and*
1256 *organizational behaviors, particularly workplace safety culture.*

1257
1258 The PPT Program defined three issues that it must aggressively address in order to translate this
1259 recommendation into operational practice.

- 1260
1261 These three issues are:
- 1262 4.1 Define barriers to and facilitators of PPT use
 - 1263 4.2 Develop innovative PPT designs and test methods to improve comfort, fit, and usability
 - 1264 4.3 Develop systems integration strategies for PPT and components

1265
1266 The PPT Program is currently 1) identifying significant PPT issues throughout the eight NORA
1267 industry sectors, 2) determining what research and sector specific training methods are necessary
1268 to enhance PPT use, and 3) identifying research necessary to assess the workplace safety culture.
1269 Implementation of the NIOSH Anthropometric Research Roadmap and synergistic research
1270 projects that address comfort as a safety issue, are also paramount to addressing PPT use among
1271 an increasingly diverse workforce.

1272
1273 Few workers require only one type of PPT to perform their jobs. Efforts to provide surveillance
1274 data, research, standards development and systems-level test methods can address issues of
1275 integration and interoperability of PPT and ensembles.

1276
1277 **ISSUE 4.1: Define barriers to and facilitators of PPT use**

1278
1279 The barriers to proper PPT use are virtually unknown in certain industry sectors, while varying
1280 significantly in others. These variations are the result of differing individual cultural perceptions
1281 about PPT use, human behavioral issues, and a lack of knowledge of what PPT is available ,
1282 feasible, or how to use it properly. The facilitators to proper PPT use and care in the workplace
1283 must be defined across all industry sectors and used as tools to remedy the nation’s inadequate
1284 and inappropriate use of PPT in the workplace.

- 1285
1286 A key scientific question related to this area is:
- 1287 • What roles can new technologies and/or improved training programs play in reducing the
1288 improper use of PPT across different industry sectors?

1289
1290 **Desired Outcome:** A fully integrated research, surveillance, and intervention system is
1291 established that adequately addresses barriers to PPE use, including required behavioral changes
1292 of workers, employers, and worksite managers.

1293

1294 Users often do not like to wear PPE because of issues of comfort, fit, or job interference.
1295 Experience, including the input on barriers to PPT use by emergency responders, has positively
1296 impacted the PPT Program’s response to these workers’ needs. Identifying approaches to
1297 research and document similar needs of workers in other sectors is critical to future PPT
1298 research, standards development, testing and deployment. Data collected about positive
1299 workplace safety culture and programs can be used to develop methods to promote PPT use and
1300 more safety conscious cultures throughout all industry sectors.

1301
1302 **ACTIVITY 4.1.1:** Identify activities to address research gaps to define the barriers to and
1303 facilitators of PPT use by workers across the nation’s industry sectors.

1304
1305 *ACTION STEP 4.1.1.1: Prioritize activities necessary to support PPT research,*
1306 *surveillance, standard development, and PPT evaluation.*

1307
1308 *ACTION STEP 4.1.1.2: Use surveillance and research findings to develop*
1309 *communication products to make it easier for users (across NORA sectors) to select and*
1310 *use appropriate PPE.*

1311
1312 *ACTION STEP 4.1.1.3: Work with partners to develop training methods to enhance the*
1313 *workplace safety culture in all NORA sectors.*

1314
1315 **ISSUE 4.2: Develop innovative PPT designs and test methods to improve**
1316 **comfort, fit, and usability**

1317
1318 PPT that is uncomfortable to use is a major cause of noncompliance and a significant barrier to
1319 use. Understanding that comfort is fundamentally a safety issue is a necessary prerequisite to
1320 improved PPT.

1321
1322 **Desired Outcome:** Research addresses PPT comfort and ease of use resulting from gender and
1323 ethnic differences in fit, as well as other issues that will occur within an increasingly diverse
1324 worker population.

1325
1326 The PPT Program has completed its Anthropometric Research Roadmap. Lessons learned from
1327 its development and implementation, along with surveillance research, can be translated to
1328 research initiatives designed to address comfort, sizing and fit of other types of PPT and
1329 ensembles. The intent is to expand the PPT Program’s efforts beyond respirators, using this
1330 strong knowledge base and NIOSH’s database of body measurements developed in the TI Cross
1331 sector. Improvements in the fit of body, hand, head, eye, and foot equipment and protective
1332 ensembles, are expected by identifying and addressing the physical, physiological, and
1333 psychological issues communicated to the PPT Program by PPT users.

1334
1335 Key scientific questions that need to be answered in this area include:

- 1336
1337
 - Which respirator attributes or characteristics can be used to “predict” end-user comfort
1338 and tolerability?

1339 • What technologies can be used to reduce the burden of, and eventually eliminate the need
1340 for initial and annual respirator fit testing?

1341 • Can laboratory methods be developed and validated to “predict” the physiological and
1342 psychological human responses to PPE ensemble use? If so, what technologies can be
1343 integrated into the PPT to serve as effective countermeasures.

1344
1345 **ACTIVITY 4.2.1:** Conduct a multi-faceted research program to improve the comfort and fit of
1346 PPE. The PPT Program is conducting research to develop a new respirator test panel and
1347 develop or modify test methods to quantitatively assess respirator comfort. NIOSH will assess
1348 how lessons learned from the anthropometric studies and comfort test methods can be used to
1349 improve the fit, comfort, and use of other types of PPT.

1350
1351 *ACTION STEP 4.2.1.1: Implement the Anthropometric Research Roadmap to update and*
1352 *improve respirator fit test panels.*

1353
1354 *ACTION STEP 4.2.1.2: Conduct research to improve fit of body, hand, head, eye, and*
1355 *foot protective equipment, and protective ensembles.*

1356
1357 *ACTION STEP 4.2.1.3: Develop new test methods to quantitatively assess respirator*
1358 *ensemble comfort. Evaluate current test methods to determine if the comfort of the*
1359 *respirator/certified ensemble can be quantified by an existing method or revision of the*
1360 *method.*

1361
1362 **ISSUE 4.3: Develop systems integration strategies for PPT and components**

1363
1364 Research is needed to drive improved design and testing of interfaces among different PPT and
1365 components. Current interfaces do not provide seamless integration of PPT components
1366 resulting in reduced usability, comfort, and protection for the wearer as well as logistical
1367 challenges for safety managers and employers.

1368
1369 **Desired Outcome:** A multi-faceted research, testing, and standards development program is
1370 defined and conducted that evaluates PPT integration and interoperability of components to
1371 improve usability of PPT across all NORA sectors.

1372
1373 Many hazardous workplace situations require workers to simultaneously use multiple types of
1374 PPE to combat the challenges created by multiple threats to their safety and health. The
1375 components are often certified as individual components and are purchased without
1376 consideration to their compatibility or interoperability.

1377
1378 Research, systems-level testing, and technologies to provide new or improved seamless
1379 integration or interoperability of PPT are needed to address the multi functional needs for PPT
1380 within all NORA sectors. Issues specific to ensembles and their certification as an assembly of
1381 component PPT must be considered as well as understanding how workers combine various PPT
1382 components together into an unevaluated assembly. The composite use of PPT components
1383 within specific industry sectors into combinations not planned by their manufacturers can result

1384 in net gain or loss of overall protection against multiple hazards from that expected to be
1385 provided by the of PPT if used individually.

1386
1387 Key scientific questions that need to be addressed in this area include:

- 1388
- 1389 • What types of PPE combinations are most common and which integration issues are the
1390 most likely to lead to improper use and/or reduced protection?
 - 1391 • How well do existing systems-level PPE tests improve and/or facilitate the integration
1392 and interoperability of PPT ensembles?

1393
1394 **ACTIVITY 4.3.1:** Identify activities to address seamless PPT component integration and
1395 interoperability.

1396
1397 *ACTION STEP 4.3.1.1: Assess current best practices and identify collaborations for*
1398 *ensuring compatibility among PPE components by industry sector.*

1399
1400 *ACTION STEP 4.3.1.2: Develop or improve existing “systems-level” PPT testing.*

1401
1402 *ACTION STEP 4.3.1.3: Develop new or modified technologies to improve / facilitate*
1403 *seamless integration and interoperability of PPE.*

1404 1405 **FY 09 PPT Program Activities and Projects Related to Recommendation 4**

1406
1407 In FY09, \$700K discretionary funds are supporting projects addressing Recommendation 4.

- 1408
- 1409 • NIOSH is conducting research to improve the reliability and level of respiratory
1410 protection provided to workers by influencing respirator designs and test methods to
1411 improve comfort, fit, and usability of respirators for the global workforce. Nine projects
1412 are underway in this research area.
 - 1413 • NIOSH is conducting research to understand the unique requirements of healthcare
1414 workers and to develop innovative materials, technologies and respiratory protection to
1415 meet their needs. Eight projects are underway in this research area.
 - 1416 • NIOSH is evaluating the effectiveness of current PPT and nanofiber based filter media to
1417 assess their performance against aerosol particles. Four projects are underway in this
1418 research area.
 - 1419 • NIOSH is developing technologies that reliably sense or model PPT performance and
1420 fostering their deployment to ensure users receive effective protection. Two projects are
1421 underway in this research area.

1422 All of these research projects are conducted by PPT Program intramural staff at NPPTL and
1423 many of them are focused on understanding/improving the fit of PPE or
1424 understanding/mitigating the burden imposed by wearing PPE. Most of these projects are slated
1425 to continue for several years. For example, the Anthropometrics research roadmap (Action Step
1426 4.2.1.1) outlines a plan of research projects through 2018.

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Two of these projects are collaborations with other federal agencies and universities and receive cost-share funding from the DoD TSWG. Several projects work closely with the various ASTM, ISO, and NFPA committees to transition PPT Program outputs into recognized standards and test methods. Project BREATHE (**B**etter **R**espirator **E**quipment **A**nd **T**echnology for **H**ealthcare **E**mloyees) cuts across several research gaps by seeking to develop a respirator optimized for the healthcare sector featuring better integration with other PPE, less job interference, better fit, and improved comfort.

The program has identified the following projects from among those described in Recommendation 4 as having the highest priority for the next 5 years:

- Establish partnerships and collaborations to identify the research gaps and define the barriers to PPT use across industry sectors.
- Conduct research studies to correlate laboratory test methods (both bench tests and human subject testing) with real end-user experiences (field study) and determine how the laboratory tests can be used to predict respirator comfort, tolerability, and ease of use.
- Incorporation of new technologies to improve the comfort and usability of closed-circuit respirators for emergency and mine escape .
- Investigate the efficacy of user seal checks to improve the science of assessing respirator fit and respirator fit test methods .
- Use of round-robin systems level testing At multiple test facilities to compare the performance of SF6, corn oil, and man-in-simulant testing (MIST) protocols for evaluation of ensemble performance.
- Conduct research studies to expand the Assigned Protection Factor (APF) concept beyond respirators to other types of PPE (e.g. gloves) and PPE ensembles.

Details about ongoing activities related to this recommendation can be found at:
<http://www.cdc.gov/niosh/programs/ppt/projects.html>.

1456 **Recommendation 5: Assess PPT Use and Effectiveness in the**
1457 **Workplace Using a Life-Cycle Approach**

1458
1459 The fifth recommendation of the NA Report addresses the need for the expansion of the PPT
1460 Program’s surveillance activities. It states:

1461
1462 *The PPT Program, in collaboration with relevant NIOSH divisions and other partners, should oversee an*
1463 *ongoing surveillance and field testing program to assess PPT use and effectiveness in the workplace. These efforts*
1464 *should emphasize a life-cycle approach by including both pre-market and interval post-market testing of PPT and*
1465 *include data collection on issues ranging from training to decontamination. Enhanced efforts could:*

- 1466
- 1467 • *Assess and critically appraise PPT use and effectiveness across all types of PPT (e.g., gloves, eye*
1468 *protection, respirators) and across relevant industry sectors and workplace environments;*
 - 1469 • *Require random periodic field-testing of an adequately sized sample of PPT to assess effectiveness,*
1470 *usability, and durability with reasonable accuracy and precision;*
 - 1471 • *Build on existing government and private-sector surveys and surveillance activities that collect PPT-*
1472 *relevant data and facilitate linkages to other datasets.*
- 1473

1474 The PPT Program segmented the three parts of this recommendation into two issues. The first
1475 and third parts were combined to address a comprehensive surveillance program. The second
1476 remained as stated, to address random periodic field testing of PPT.

1477
1478 These two issues are:

- 1479 5.1 Establish a comprehensive surveillance program
1480 5.2 Conduct random periodic field testing of PPE

1481
1482 **ISSUE 5.1: Establish a comprehensive surveillance program**

1483
1484 **Desired Outcome:** A comprehensive surveillance program, including the definition of key
1485 indicators, provides timely assessment of the use of major types of PPE in major industry sectors
1486 and workplace environments.

1487
1488 The PPT Program realizes that surveillance data are a primary component necessary to
1489 understand the occupational safety and health issues and understand the PPT needs in the
1490 workplace. The PPT Program has made a concerted effort to identify ongoing surveillance
1491 activities with which the PPT Program could collaborate to move toward closing some of the
1492 knowledge gaps within the program. These collaborations are a first step toward establishing a
1493 comprehensive surveillance strategy.

1494
1495 The activities outlined below have been recommended by internal NIOSH researchers,
1496 stakeholders across all industry sectors, and through the NA Committee Report *Measuring*
1497 *Respirator Use in the Workplace (2007)* as well as the *PPT Program Evaluation Report (2008)*.

1498
1499 Ultimately, the PPT Program needs to transfer laboratory findings to achieve public health
1500 impact. Surveillance for PPT research helps identify activities for future research or surveillance
1501 which may have the highest potential impact on worker health outcomes, and may influence

1502 what effectiveness research should be conducted. Key research questions which could be
1503 answered for each sector with effective surveillance include:

- 1504 • Which occupations have the highest respiratory-related exposures?
- 1505 • What is the type and frequency of PPT use within each such occupation?
- 1506 • What health outcomes are potentially associated with the given exposures?
- 1507 • What health outcomes are observed in the given occupations?

1508
1509 **ACTIVITY 5.1.1:** Establish a systematic surveillance approach for assessing secondary data
1510 sources and collaborating with existing government and private sector organizations which
1511 collect PPT-relevant surveillance data across all industry sectors.

1512
1513 *ACTION STEP 5.1.1.1: Use the Secondary Source effort underway for the Agriculture,*
1514 *Forestry, and Fishing (AFF) Sector to identify next steps for addressing the PPT needs in*
1515 *the AFF sector as a model for approaching all other industry sectors.*

1516
1517 **ACTIVITY 5.1.2:** Develop surveillance strategies across all industry sectors to determine what
1518 PPT is used in the various sectors and workplace environments, what shortcomings are
1519 experienced with PPT usage, what PPT failures are experienced, and the barriers to use.

1520
1521 *ACTION STEP 5.1.2.1: Address gaps identified through the surveillance assessments of*
1522 *Action Step 5.1.1.1.*

1523
1524 **ACTIVITY 5.1.3:** Develop a better understanding of PPT issues in field usage through
1525 assessment of surveillance results.

1526
1527 *ACTION STEP 5.1.3.1: Develop and implement approaches (including those developed*
1528 *with focus groups) to clarify findings from surveillance activities and establish*
1529 *intervention strategies.*

1530
1531 **ACTIVITY 5.1.4:** Identify available data sources where analyses could provide an indication of
1532 the effectiveness of PPT currently used in the field in preventing illness and injury.

1533
1534 *ACTION STEP 5.1.4.1: Examine the feasibility of enhancing the state-based surveillance*
1535 *program to include PPT surveillance activities.*

1536
1537 *ACTION STEP 5.1.4.2: Review injury and illness data reported by companies that are*
1538 *represented in workplace inspection data and attempt to correlate PPT usage to injury*
1539 *and illness data.*

1540
1541 *ACTION STEP 5.1.4.3: Implement and assess intervention strategies to evaluate the*
1542 *effectiveness of the interventions put into practice.*

1543
1544 **ISSUE 5.2: Conduct random periodic field testing of PPE**

1545

1546 Limited research results are available to assess and critically appraise PPT use, effectiveness,
1547 usability, and durability across all types of PPT (e.g. gloves, eye protection, respiratory
1548 protection, protective garments) across all industry sectors.
1549

1550 **Desired Outcome:** PPT initiatives are in place to support the generation of standards and test
1551 methods for periodic field testing of PPT that will ensure it is performing as intended.
1552 Ultimately, effective operation of PPT and expected protection for workers under actual field
1553 conditions is envisioned.
1554

1555 An initiative to assess PPE use in roadway construction has been in place since 2004. This effort
1556 began with a series of focus groups, followed by the establishment of a protocol to assess
1557 workplace use of PPE, followed by the implementation of recommended interventions and
1558 eventual follow-up assessment the effectiveness of the interventions. The initiative currently is
1559 in the final phase, i.e. assessing the effectiveness of the interventions. Upon completion of this
1560 activity, the PPT Program will assess the feasibility of replicating this approach or developing an
1561 alternative approach for other industry sectors and sub-sectors.
1562

1563 Current drivers and means of assessment beyond the initial certification process are primarily
1564 through the site and product audit activities for respirators. Recommendations to expand the
1565 current audit activities are described in Recommendation 3.
1566

1567 **ACTIVITY 5.2.1:** Conduct field research to assess and critically appraise PPT use,
1568 effectiveness, usability, and durability across all types of PPT.
1569

1570 *ACTION STEP 5.2.1.1: Conduct research to address PPT use, effectiveness, usability,*
1571 *and durability across all types of PPT and all industry sectors.*
1572

1573 **ACTIVITY 5.2.2:** Implement a Demonstration and Sentinel Surveillance System for Healthcare
1574 to increase the knowledge base regarding effectiveness, usability, and durability across all types
1575 of PPT in the healthcare industry.
1576

1577 *ACTION STEP 5.2.2.1: Implement the Demonstration and Sentinel Surveillance System*
1578 *for Healthcare.*
1579

1580 **FY 09 PPT Program Activities and Projects Related to Recommendation 5**

1581
1582 \$800K of PPT Program discretionary funding is dedicated to support Recommendation 5 in
1583 FY09.
1584

1585 The Program is developing systematic surveillance activities in conjunction with the NIOSH
1586 Surveillance Cross-sector and other NIOSH Sector and Cross-sector activities to gather PPT
1587 related information to identify research, standards, certification, guidance, intervention, and
1588 outreach needs. Activities associated with this recommendation include:
1589

- 1590 • The PPE Surveillance Intervention Studies Project, which is a continuation of the
1591 intervention work in the Construction Sector.

- 1592 • Internal resources have been dedicated to write the research protocol and proposal for a
1593 Demonstration and Sentinel Surveillance System for Healthcare during FY09.
- 1594 • The PPT Program is assessing existing surveillance in the Agriculture, Forestry, and
1595 Fishing Sector to identify research gaps and PPT needs for this sector. If deemed
1596 appropriate, a similar approach will be implemented for other industry sectors. The order
1597 by which the other industry sectors will be assessed will be determined in collaboration
1598 with stakeholders. The Secondary Source Data Analysis Project will continue the work to
1599 assess the Secondary Sources for all Sectors.
- 1600 • The Program is implementing enhancements to secondary source data by supporting the
1601 National Health Interview Survey (NHIS) Occupational Health Supplement with several
1602 PPT questions.
- 1603 • NIOSH has two projects underway to assess the barriers to using PPT.
- 1604 • NIOSH has four projects underway to evaluate the effectiveness of current PPT.
- 1605 • Other non-surveillance current FY09 projects related to Recommendation 5 focus on PPT
1606 life-cycle issues, including decontamination of respirators and protective clothing. For
1607 example, one project is a collaborative effort with the DoD, AFRL, FDA and several
1608 universities with funding provided by the DoD TSWG to study the
1609 decontamination/reuse of filtering facepiece respirators. Other research areas explore
1610 issues related to end of service life and retirement of respirator cartridges and protective
1611 clothing ensembles.

1612 Additional details for these activities and all other broad-based/cross-cutting (activities identified
1613 under Strategic Goal 4) activities can be found at:
1614 <http://www.cdc.gov/niosh/programs/ppt/projects.html>.
1615

1616 **Appendix A: List of Acronyms**

1617		
1618	A	
1619	AFF	Agriculture, Forestry, and Fishing
1620	AFRL	Air Force Research Lab (Wright-Patterson AFB)
1621	AIHA	American Industrial Hygiene Association
1622	ANSI	American National Standards Institute
1623	AORN	Association of periOperative Registered Nurses
1624	AP	Air-Purifying
1625	ARTBA	American Road and Transportation Builders Association
1626	ASSE	American Society of Safety Engineers
1627	ASTM	American Society for Testing and Materials International
1628	ATAS	Assessment and Training Assistance Services Group
1629		
1630	B	
1631	BREATHE	Better Respirator Equipment and Technology for Healthcare Employees
1632	BSC	Board of Scientific Counselors
1633		
1634	C	
1635	CAN	common accounting number
1636	CBRN	chemical, biological, radiological, and nuclear
1637	CCER	closed-circuit escape respirator
1638	CC-SCBA	closed-circuit self-contained breathing apparatus
1639	CDC	Centers for Disease Control and Prevention
1640	CFR	Code of Federal Regulations
1641	COE	Centers of Excellence
1642	COPPE	Committee on Personal Protective Equipment
1643	CPIP	Certified Product Investigation Process
1644	CSS	Customer satisfaction survey
1645	CTS	Center for Talent Services (OPM)
1646		
1647	D	
1648	DHHS	Department of Health and Human Services
1649	DoD	Department of Defense
1650	DOJ	Department of Justice
1651	DRDS	Division of Respiratory Disease Studies (NIOSH)
1652	DSHEFS	Division of Surveillance, Hazard Evaluations and Field Studies (NIOSH)
1653	DSR	Division of Safety Research (NIOSH)
1654		
1655	E	
1656	EMS	emergency medical services
1657	ERC	Education and Research Center
1658		
1659	F	
1660	FDA	U.S. Food and Drug Administration
1661	FFR	filtering facepiece respirator
1662	FOA	Funding Opportunity Announcements
1663	FY	fiscal year
1664		
1665	G	
1666		
1667	H	
1668	HCW	Healthcare Worker
1669	HELD	Health Effects Laboratory Division/NIOSH
1670	HHE	health hazard evaluation/NIOSH

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1671	HHS	Health and Human Services
1672		
1673	I	
1674	IAB	Interagency Board for Equipment Standardization and Interoperability
1675	IAFC	International Association of Fire Chiefs
1676	IAFF	International Association of Firefighters
1677	IOM	Institute of Medicine
1678	ISO	International Organization for Standardization
1679		
1680	J	
1681		
1682	K	
1683	K	Thousand
1684		
1685	L	
1686		
1687	M	
1688	MINER	Mine Improvement and New Emergency Response
1689	MIST	man-in-simulant testing
1690	MSHA	Mine Safety and Health Administration (DOL)
1691		
1692	N	
1693	NA	the National Academies
1694	NAS	National Academy of Sciences
1695	NFPA	National Fire Protection Association
1696	NHIS	National Health Interview Survey
1697	NIHL	noise induced hearing loss
1698	NIJ	National Institute of Justice
1699	NIOSH	National Institute for Occupational Safety and Health
1700	NIOSH OD	Office of the Director, NIOSH
1701	NIST	National Institute of Standards and Technology
1702	NORA	National Occupational Research Agenda
1703	NPPTL	National Personal Protective Technology Laboratory
1704	NRC	National Research Council
1705	NTRC	NIOSH Nanotechnology Research Center
1706		
1707	O	
1708	OD	Office of the Director
1709	OEP	Office of Extramural Programs
1710	OPM	U.S. Office of Personnel Management
1711	OSHA	Occupational Safety and Health Administration (DOL)
1712		
1713	P	
1714	PAPR	powered air-purifying respirator
1715	PPE	personal protective equipment
1716	PPT	personal protective technology
1717	PRL	Pittsburgh Research Laboratory
1718	PS&B	Personnel Salaries and Benefits
1719	PSD	Policy & Standards Development branch
1720		
1721	Q	
1722		
1723	R	
1724	R&D	research and development
1725	RDECOM	Research, Development and Engineering Command
1726	RFA	Request for Announcements

PPT Program Draft Implementation Plan
Appendix A: List of Acronyms

1727	RFP	Request for Proposals
1728	RPD	respirator protective device
1729		
1730	S	
1731	SAR	supplied-air respirator
1732	SARS	Severe Acute Respiratory Syndrome
1733	SCBA	self-contained breathing apparatus
1734	SCSR	self-contained self-rescuer
1735	SDO	Standards Development Organizations
1736		
1737	T	
1738	TEB	Technology Evaluation Branch (NPPTL)
1739	TI	Traumatic Injury
1740	TIL	total inward leakage
1741	TRB	Technology Research Branch (NPPTL)
1742	TSWG	Technical Support Working Group
1743		
1744	U	
1745		
1746	V	
1747	VA	U.S. Department of Veterans Affairs / Veterans Health Administration
1748		
1749	W	
1750		
1751	Y	
1752		
1753	Z	
1754		