NIOSH Personal Protective Technology Program

Plan to Implement the National Academies Evaluation Recommendations

DRAFT

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Introduction

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

Mission Statement

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

Vision Statement

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

Definition and scope of the Program Area

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

PPT Program Goal Structure

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

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- Four PPT Cross-Sector Strategic Goals have been established:
 - Strategic Goal 1: Reduce Exposure to Inhalation Hazards.
 - Strategic Goal 2: Reduce Exposure to Dermal Hazards.
 - Strategic Goal 3: Reduce Exposure to Injury Hazards.
 - Strategic Goal 4: Broad-Based PPT Issues.

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

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PPT Program Tactics for Achieving Goals

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

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Conduct research on PPT

A comprehensive research program can reduce inhalation, dermal, and injury hazard knowledge gaps (e.g., understand performance of PPE against emerging hazards) and improve existing technologies to reduce exposure to the hazards.

Develop standards for PPT

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

• Certify respirators and evaluate PPT

PPT evaluation services, resultant recommendations and respirator certification services can help ensure effective PPT.

• Conduct outreach programs for optimal use and acceptance of PPT by workers

This tactic includes the development and use of effective communication tools and outreach techniques that encourage inputs to all PPT Program activities and facilitate transfer of outputs (products and services) and outcomes (results) to all stakeholders.

• Evaluate and assess programs and activities

Evaluation and assessment activities are essential components of the Program's tactic to "build in" quality. It is incumbent on the PPT Program to ensure a robust portfolio of evaluation and assessment activities to ensure program research protocols, proposals, and outputs are based on quality science. Evaluation activities will extend to third party evaluation of the PPT Program by a recognized organization such as the National Academies (NA).

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

- 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
- expansion over a five year timeframe, depending on resource availability. The plan also supports
- the PPT Program Goals identified above. The intent is to integrate the activities described into
- the PPT Program Strategic Plan as part of the annual strategic planning process.

Implementation Plan Development Process

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- 198 The PPT Program initially realized that the NA report provided it with broad and
- 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
- that these other studies and reports be considered during the development of the response to the
- 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
- 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
- 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.

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- 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
- standardized Customer Satisfaction Survey (CSS) to assess the quality of services provided by
- 221 public-sector organizations.

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- 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
- have a staff of personnel research psychologists who specialize in survey research,
- organizational assessment, outcome measurement, organizational development, and change
- management. This staff has a unique perspective on the challenges faced by agencies across the
- 230 Federal government.

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

Dynamic Nature of the Environment Supporting this Implementation Plan 236

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

240 stakeholders.

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

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

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

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

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

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

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

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

PPT Program Draft Implementation Plan Introduction – PPT Program Response to NA Evaluation

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

285286 Implementation Plan Scope

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

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

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

The National Personal Protective Technology Program should:

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

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

These five issues are:

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

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

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

Program into other occupational safety and health areas.

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

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

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

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

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

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

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

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Table 1 Proposed Expanded NIOSH PPT Program

PROGRAM GOALS and ACTIVITIES	Research	Policy and Standards Development	Certification	Outreach	Extramural Involvement
Goal 1: Reduce Exposure to Inhalation Hazards		\square	Ø		Ø
CBRN Respirators	✓	✓	✓	✓	
Escape Respirators	✓	✓	✓	✓	
FFRs	\square	✓	☑	Ø	
Industrial Respirators	√	√	√	✓	
Goal 2: Reduce Exposure to Dermal Hazards	✓	Ø	×		I
Protective Garments	\square	\square	☑	✓	
Protective Gloves	✓	√	X	✓	
Protective Footwear	☑	Ø	×		
Goal 3: Reduce Exposure to Injury Hazards	☑				Ø
Protective Headgear					
Protective Garments	☑	\square	☑		
Protective Gloves	✓	✓	×		
Protective Footwear	✓	√	X		
Hearing Protection	☑	✓		✓	
Protective Eyewear					
Fall Protection	Ø	√		✓	
Goal 4: Broad-based PPT Issues	✓				
Sensors	✓	✓		✓	
Decontamination	✓	✓	☑	✓	
Nanotechnology	✓	✓		✓	
Human Factors	√	✓			
Interfaces/Integration	\square	\square	☑	Ø	
Surveillance	\square		V	Ø	
Barriers to PPT use	\square	X	X	Ø	
Organizational Behavior and Motivation	\square	X	X	Ø	
Information Dissemination	\square	X	×	Ø	

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393 Legend:

- 394 ✓ Existing Program Activity
 - ☑ Expansion of Existing Program Activity OR Initiation of New Program Activity
- 396 ⊠- Beyond 5 Years

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

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

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

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

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

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

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

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

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

ACTION STEP 1.1.1.4: Expand broad-based PPT research.

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

ACTION STEP 1.1.1.6: Coordinate PPT efforts across federal agencies.

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.

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

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

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

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

ISSUE 1.3: Oversee certification of all PPT, including an assessment of certification mechanisms

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

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

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

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

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

	PPT Program Draft Implementation Plan Recommendation 1: Implement and Sustain a Comprehensive National Personnel Protective Technology Program
534 535 536 537	This process for ensemble certification provides solutions to bridge technology and administrative gaps to ensure no provisions of NIOSH certification of respirator protective devices are invalidated by the interfacing with other PPE.
538 539 540 541	The process also acknowledges that some performance specifications for the ensemble may be more restrictive and be preferentially enforced over corresponding respirator performance requirements.
542 543 544	ACTIVITY 1.3.1: Lead the development and implementation of a strategy for non-respiratory PPE certification.
545 546 547	ACTION STEP 1.3.1.1: Request IOM conduct a workshop through the Committee on PPE for the Workforce (COPPE) to initiate a strategy for non-respiratory PPE certification.
548 549 550 551	ACTION STEP 1.3.1.2: Develop an implementation plan for addressing the recommendations in the IOM Report on Non-respiratory PPT Certification.
552	ISSUE 1.4: Promote technology development, standards, and certification of
553	integrated PPT components and ensembles
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555 556 557 558 559	Few PPT Program initiatives are specifically designed to ensure technology development, standards, and certification of integrated PPT components and ensembles to enable multiple types of PPT (e.g. eye protection, hearing, protection, respirators, gloves, etc.) to be effectively and seamlessly worn together.
560 561 562 563	Desired Outcome: A strategy is developed and implemented to provide users confidence that multiple types of PPT have been evaluated and tested together to effectively protect workers and enable users to make informed decisions about PPT selection and use.
564 565 566	The need for a "systems level" approach to body-worn PPT has received increased recognition in the past several years. Issues exist relative to protective performance and the interoperability of respirators, garments, gloves, footwear and other body worn equipment.
567 568 569 570 571 572 573	Technology advancements have made the application of body-worn sensors a reality and paved the way for integrated PPT components and ensembles. These include the ability to monitor and report physiological status, location/ tracking, communications, environmental hazards and PPT service life status. Even person-wearable computers are a reality. The PPT Program has been collecting and analyzing information on these matters in three sector areas (Agricultural, Services and Healthcare).
574 575	Several issues concerning the effectiveness of ensembles are conformity assessment to

Several issues concerning the effectiveness of ensembles are conformity assessment to recognized performance standards and configuration management to ensure quality manufacture.

Today there are no standards in place or recognized authority to address this issue.

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

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

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

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

ISSUE 1.5: Conduct outreach programs for optimal use and acceptance of PPT by workers

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

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

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

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

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

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

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

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ACTIVITY 1.5.2: Promote educational and professional training of PPT in occupational safety and health.

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ACTION STEP 1.5.2.1: Disseminate emerging relevant PPT information into training and educational efforts.

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ACTION STEP 1.5.2.2: Disseminate PPT materials to workers and workplaces which rely on PPT.

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FY 09 PPT Program Activities Related to Recommendation 1

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

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

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 NIOSH is collaborating with partners to develop and test respirator breakthrough for multi-contaminant cartridges where contaminants represent firefighting overhaul exposures.

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• NIOSH is collaborating with partners to disseminate the NIOSH published method to estimate the permeation resistance of PPT material to sulfur (HD) and mustard (GB) agents using liquid stimulant chemicals.

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> NIOSH has two research projects underway to advance the state of technology for closed circuit breathing systems for mine disasters and other emergencies.

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 NIOSH will evaluate self-contained enclosures to assess the performance of the enclosures and the physiological and psychological suitability of use of the enclosures.

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 NIOSH intends to work with partners to develop outreach products and disseminate 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.

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

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

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

Understanding influenza transmission.

The current knowledge of key aspects of influenza transmission is rudimentary. Increased understanding is required on the extent of droplet, aerosol, and contact transmission, and the optimum ways to prevent transmission. Research initiatives are needed to address these matters and the viability/infectivity of the airborne virus. As these issues are more clearly understood, successful mitigation and prevention strategies can be developed and deployed.

Commit to worker safety and appropriate use of PPE.

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

• Innovate and strengthen PPE design, testing and certification.

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

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

All of these research activities are conducted by intramural NIOSH staff in collaboration with various partners and stakeholders. Several projects involve close collaborations with the various ASTM, ISO, and NFPA committees to transition PPT intramural program outputs into recognized consensus standards and test methods. Project BREATHE cuts across several of the research gaps identified in the IOM Report 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.

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

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

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

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

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

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The NA Report in its second recommendation states:

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The PPT Program should:

781 782 Develop and support research centers of excellence (COE) that work closely with the NIOSH intramural research program to improve PPT, increase field research, and explore and implement research to practice interventions, and

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Work with the NIOSH OEP to increase other research opportunities and enhance collaboration and awareness of relevant PPT research efforts among intramural and extramural researchers.

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

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These two issues are:

791 792 2.1 Coordinate intramural and extramural research activities

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ISSUE 2.1: Coordinate intramural and extramural research activities 795

2.2 Expand the extramural research program

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

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Desired Outcome: The PPT Program will conduct its activities with effective coordination with 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.

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

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

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

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ISSUE 2.2: Expand the extramural research program

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

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

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

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announcements and to general announcements that NIOSH participates in with NIH (including

Small Business Innovation Research). To date NIOSH has not provided resources to support a PPT-focused FOA through OEP due to limited funding.

846 847	ACTIVITY 2.2.1: Establish a coordinated activity within the PPT Program to interface with OEP.
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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.
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852	ACTION STEP 2.2.1.2: Assign these defined duties and responsibilities within the PPT
853	Program.
854	ACTION STEP 2.2.1.2. S. I
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 manager for the DDT Dragram to an ease with the automorphism
859	ACTIVITY 2.2.2: Establish a process for the PPT Program to engage with the extramural program through enhanced collaboration with OEP.
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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	ACTION STEF 2.2.2.2: The FFT Frogram will provide support to extramural awardees.
866	ACTION STEP 2.2.2.3: The PPT Program will assist OEP in making maximal use of the
367	outputs from extramural awards.
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869	FY 09 PPT Program Activities Related to Recommendation 2
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871	The PPT Program is aware of 37 existing OEP grants that are substantially PPT in scope. (see
372	Table 2)
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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 Stakeholders Meeting on March 3, 2009 in Pittsburgh, PA where all PPT Program activities were
877 878	featured. The PPT Program, in cooperation with NIOSH OEP, invited NIOSH grant recipients
379	(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.
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Table 2 PPT Related Grant Recipients and Projects

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

PPT Program Draft Implementation Plan Recommendation 2: Establish PPT Research Priorities and Expand the Extramural Program

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

Recommendation 3: Enhance the Respirator Certification Program

The third recommendation of the NA Report addresses the PPT Program's respirator certification function. It states:

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

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

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

These six issues are:

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

ISSUE 3.1: Explore ways to expedite respirator certification regulation revisions

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

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

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

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

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

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

ACTIVITY 3.1.1: Establish strategies that will efficiently process respirator certification regulations to conclusion.

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ACTION STEP 3.1.1.1: Conduct a feasibility assessment to identify approaches to expedite rulemaking of respirator standards. Investigate and document "negotiated" and "direct" final rule, and the use of Voluntary Consensus Standards.

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

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

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

ISSUE 3.2: Assess the feasibility of updating certification fees

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

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

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

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

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

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

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

ACTION STEP 3.2.1.2: Pursue a fee update through rulemaking.

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

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

access to respirator specific surveillance data

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access to respirator field-deployment strategies and practices the ability to provide proactive, targeted NIOSH Respirator Notifications and Notices to the users of the equipment

 the means to fully assess and understand environmental effects on respirator performance

 a highly effective and expeditious means to execute respirator recall and retrofit actions

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

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

other types of PPT.

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

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

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

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

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

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

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

ACTION STEP 3.3.1.3: Assess the effectiveness of the registration programs.

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

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

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

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

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

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

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

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

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

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

ISSUE 3.5: Consider expanding the site audit program

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

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

- Recommendation 3: Enhance the Respirator Certification Program 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 ISSUE 3.6: Explore approaches for disseminating respirator certification test 1141 results data 1142 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. However, only pass or fail of an entire approval is currently released for several reasons, 1146 1147 1148
 - including NIOSH respirator test facilities not being designed or operated for comparative testing, service life and penetration tests stop when specified results are achieved, and test data may not represent actual results under use conditions. Currently there are no means to perform comparative respirator testing or to gather stakeholder/end user feedback on respirator performance by organizations other than NPPTL with test facilities designed for this purpose.
 - **Desired Outcome:** Explore the possibility of establishing processes to increase end user confidence in respirator performance.
 - In initiating the development of a project plan for the PPT Program to disseminate some level of certification or comparative test data for respirators, the current program operations and outputs were evaluated, along with analyzing the strengths and weaknesses of the data generating process used. Other organizations that perform similar operations and disseminate comparative data were investigated.
- 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 test levels. This program also allows the manufacturers to have their respirators that may have 1164

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- state of the art technologies or proprietary designs present be evaluated without fear of competitors gaining information before the products have been introduced to the market place.
- ACTIVITY 3.6.1: Explore potential approaches to enable extramural researchers to compare performance indicators of in-class respirators.
 - **ACTIVITY 3.6.2:** Explore the feasibility of developing a public forum for stakeholders/end users to share qualitative respirator performance information obtained from personal respirator use experiences.

ACTION STEP 3.6.2.1: Explore potential programs for disseminating comparative inclass respirator parameters.

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

FY 09 PPT Program Activities and Projects Related to Recommendation 3

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

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

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

1210 1211 1212 1213	committees of other SDOs (e.g. ANSI, ASTM, NFPA, ISO) to expand the transfer of its scientific expertise and research outputs. The following standards modules will be developed and are projected as updates to 42 CFR Part 84 over the next five years. The year the PPT Program intends to enter the rulemaking process is identified.		
1214 1215 1216 1217	2008	Quality Assurance (QA) Requirements and Closed Circuit Escape Respirators (CCER) the and Closed Circuit Self Contained Breathing Apparatus (CC-SCBA)	
1218 1219 1220	2009	TIL testing for Half Masks and Filtering Facepiece Respirators (FFR), Powered Air Purifying Respirators (PAPR) and Supplied Air Respirators (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 1226 1227 1228 1229 1230 1231 1232	respirator certification highest priorities for (Activity 3.4.1 and Aremaining activities lowest priority for the	t ongoing activities, the Program has identified Activities associated with on regulations (Activity 3.1.1) and updating the fees (Activity 3.2.1) as the the Program. Additionally the activities associated with the audit program Activity 3.5.1) will be pursued as resources become available. The (Activity 3.3.1 and Activities 3.6.1 & 3.6.2) are important, but have the Program.	
1233 1234	How to asses	es the accuracy and reliability of a newly proposed fit test procedure when a	
1235	true measure	of respirator fit does not exist?	
1236 1237	-	onnings per respirator should be conducted, and how does the number of ect the required number of human subjects?	
1238 1239	How are resp valid?	pirators sampled from a population in a way that is feasible but statistically	
1240 1241 1242		rmine which facial dimensions should be used for certification fit testing, and correlate this information to understandable and feasible sizing for the lation?	
1243 1244	 How should them with fit 	information on multiple facial dimensions be assessed before associating test results?	
1245 1246		vze repeated measurements on the same subjects (either repeated fit tests or l tests) to accurately assess intrasubject variability?	
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Recommendation 4: Increase Research on the Use and Usability of PPT

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

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

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

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

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

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

ISSUE 4.1: Define barriers to and facilitators of PPT use

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

A key scientific question related to this area is:

 • What roles can new technologies and/or improved training programs play in reducing the improper use of PPT across different industry sectors?

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

- Users often do not like to wear PPE because of issues of comfort, fit, or job interference.

 Experience, including the input on barriers to PPT use by emergency responders, has positively impacted the PPT Program's response to these workers' needs. Identifying approaches to research and document similar needs of workers in other sectors is critical to future PPT research, standards development, testing and deployment. Data collected about positive workplace safety culture and programs can be used to develop methods to promote PPT use and more safety conscious cultures throughout all industry sectors.
 - **ACTIVITY 4.1.1:** Identify activities to address research gaps to define the barriers to and facilitators of PPT use by workers across the nation's industry sectors.

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

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

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

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

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

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

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

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

 Which respirator attributes or characteristics can be used to "predict" end-user comfort and tolerability?

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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 by 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 **ISSUE 4.3: Develop systems integration strategies for PPT and components** 1362 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 improve usability of PPT across all NORA sectors. 1371 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

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components together into an unevaluated assembly. The composite use of PPT components

within specific industry sectors into combinations not planned by their manufacturers can result

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

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 FY 09 PPT Program Activities and Projects Related to Recommendation 4 1405 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 improve comfort, fit, and usability of respirators for the global workforce. Nine projects 1411 are underway in this research area. 1412 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 research area. 1418 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 understanding/mitigating the burden imposed by wearing PPE. Most of these projects are slated 1424 1425 to continue for several years. For example, the Anthropometrics research roadmap (Action Step

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4.2.1.1) outlines a plan of research projects through 2018.

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1428 1429	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,				
1430	ISO, and NFPA committees to transition PPT Program outputs into recognized standards and test				
1431	methods. Project BREATHE (Better Respirator Equipment And Technology for Healthcare				
1432	Employees) cuts across several research gaps by seeking to develop a respirator optimized for				
1433	the healthcare sector featuring better integration with other PPE, less job interference, better fit,				
1434	and improved comfort.				
1435					
1436	The program has identified the following projects from among those described in				
1437	Recommendation 4 as having the highest priority for the next 5 years:				
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1439	• Establish partnerships and collaborations to identify the research gaps and define the				
1440	barriers to PPT use across industry sectors.				
1441 1442 1443	 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. 				
1444 1445	• Incorporation of new technologies to improve the comfort and usability of closed-circuit respirators for emergency and mine escape .				
1446 1447	• Investigate the efficacy of user seal checks to improve the science of assessing respirator fit and respirator fit test methods.				
1448 1449 1450	 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. 				
1451 1452	 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.

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

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

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

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

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

These two issues are:

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

ISSUE 5.1: Establish a comprehensive surveillance program

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

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

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

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

	PPT Program Draft Implementation Plan Recommendation 5: Assess PPT Use and Effectiveness in the Workplace Using a Life-Cycle Approach
1502 1503 1504	what effectiveness research should be conducted. Key research questions which could be answered for each sector with effective surveillance include: • Which occupations have the highest respiratory-related exposures?
1505	What is the type and frequency of PPT use within each such occupation?
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	 What health outcomes are potentially associated with the given exposures?
1507	 What health outcomes are observed in the given occupations?
1508 1509 1510 1511 1512	ACTIVITY 5.1.1: Establish a systematic surveillance approach for assessing secondary data sources and collaborating with existing government and private sector organizations which collect PPT-relevant surveillance data across all industry sectors.
1513 1514 1515	ACTION STEP 5.1.1.1: Use the Secondary Source effort underway for the Agriculture, Forestry, and Fishing (AFF) Sector to identify next steps for addressing the PPT needs in the AFF sector as a model for approaching all other industry sectors.
1516 1517	ACTIVITY 5.1.2. Develop sympollop as strategies agrees all industry sectors to determine what
1517	ACTIVITY 5.1.2: Develop surveillance strategies across all industry sectors to determine what 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	3-,
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.
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1527	ACTION STEP 5.1.3.1: Develop and implement approaches (including those developed
1528 1529	with focus groups) to clarify findings from surveillance activities and establish
	intervention strategies.
1530	ACTIVITY 5.1.4. Identify available data sources where analyses sould provide an indication of
1531 1532	ACTIVITY 5.1.4: Identify available data sources where analyses could provide an indication of the effectiveness of PPT currently used in the field in preventing illness and injury.
1532	the effectiveness of FFT currently used in the field in preventing filless and injury.
1534	ACTION STEP 5.1.4.1: Examine the feasibility of enhancing the state-based surveillance
1535	program to include PPT surveillance activities.
1536	p. og. am to memme 111 am termines.
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.
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1541	ACTION STEP 5.1.4.3: Implement and assess intervention strategies to evaluate the

ISSUE 5.2: Conduct random periodic field testing of PPE

effectiveness of the interventions put into practice.

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Recommendation 5: Assess PPT Use and Effectiveness in the Workplace Using a Life-Cycle App	proach

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

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

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

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

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

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

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

ACTION STEP 5.2.2.1: Implement the Demonstration and Sentinel Surveillance System for Healthcare.

FY 09 PPT Program Activities and Projects Related to Recommendation 5

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

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

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

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

Additional details for these activities and all other broad-based/cross-cutting (activities identified under Strategic Goal 4) activities can be found at:

1615 http://www.cdc.gov/niosh/programs/ppt/projects.html.

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1616	Appendix	A: List of Acronyms
1617		
1618 1619	A	Agriculture Forestry and Fishing
1620	AFF AFRL	Agriculture, Forestry, and Fishing
1621	AIHA	Air Force Research Lab (Wright-Patterson AFB) 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	В	
1631	BREATHE	Better Respirator Equipment and Technology for Healthcare Employees
1632	BSC	Board of Scientific Counselors
1633 1634	С	
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	Post and the second sec
1656	EMS	emergency medical services Education and Research Center
1657 1658	ERC	Education and Research Center
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	HCW	Healthears Werker
1668 1669	HCW HELD	Healthcare Worker Health Effects Laboratory Division/NIOSH
1670	HHE	health hazard evaluation/NIOSH
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1671	HHS	Health and Human Services
1672	1110	Trouble and Truman Scivices
1673	1	
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	V	
1682	K	Thousand
1683 1684	K	Thousand
1685	L	
1686	L	
1687	М	
1688	MINER	Mine Improvement and New Emergency Response
1689	MIST	man-in-simulant testing
1690	MSHA	Mine Safety and Health Administration (DOL)
1691		mile salety and result ritualism (202)
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 1705	NRC NTRC	National Research Council
1705	NIKC	NIOSH Nanotechnology Research Center
1707	0	
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 1720	PSD	Policy & Standards Development branch
1721	Q	
1722	~	
1723	R	
1724	R&D	research and development
1725	RDECOM	Research, Development and Engineering Command
1726	RFA	Request for Announcements

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1727	RFP	Request for Proposals
1728	RPD	respirator protective device
1729		Tophalo, protocuro acrico
1730	S	
		averalle de la consideration
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	Т	
1738	TEB	Tachnology Evaluation Propole (NIDDTL)
		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		LLC Department of Veterana Affaire (Veterana Llas III). A desiriatentia
	VA	U.S. Department of Veterans Affairs / Veterans Health Administration
1748		
1749	W	
1750		
1751	Υ	
1752		
1753	Z	
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