NIOSH Personal Protective Technology Program

Plan to Implement the National Academies Evaluation Recommendations

May 21, 2010

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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.

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.

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.

PPT Program Tactics for Achieving Goals

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

- **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, increase wearability, utility and comfort.

- **Develop standards for PPT**

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 with the ISO, ANSI, NFPA, ASTM, and the International Safety Equipment Association (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 PPT performance, use and maintenance. User involvement in Standards development Organizations (SDO) activities increases emphasis for comfort, utility, and wearability.

- **Certify respirators and evaluate PPT**

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

- **Conduct Surveillance**

Surveillance data will enable the program to quantify knowledge gaps and identify research needs. Surveillance data serves as both an input to NIOSH activities and an output for stakeholder use.

- **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 which encourage inputs to all PPT Program activities and facilitate transfer of outputs (products and services) and outcomes (results) to all stakeholders. Outreach for

example may be in the form of presentations and exhibits at conferences, websites, and listserv postings, etc.

- **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. The PPT Program will work with the NIOSH Office of Program & Planning to apply program planning and evaluation tools such as the National Academies' Evaluation Framework document in order to implement comprehensive program reviews at regular intervals.

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 obtained scientific input from NIOSH's Board of Scientific Counselors (BSC) at its Spring 2009 meeting and stakeholder feedback through a public comment period. The BSC Review of the PPT Program is provided as Appendix B. The PPT Program Response to the BSC Review of the PPT Program is provided as Appendix C. Appendix D provides a summary of the public comments submitted to the docket and the PPT Program response to those comments.

In Appendix C, the PPT Program comments on three underlying themes noted in the BSC Review.

1) The processes to achieve objectives outlined in the action steps require better definition.
2) Potential synergies and overlaps are evident in the Plan.
3) The use of Centers of Excellence.

Appendices E and F provide examples of the detail available for each segment of the Implementation plan to address 1) above. The detail provided in these appendices provides the steps necessary for the PPT Program to move forward with the action steps; however, the detail is excessive to provide every worksheet in this version of the plan available for the general public. For this reason only the two examples are provided.

The PPT Program 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

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 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. outputs from National Occupational Research Agenda (NORA) Town hall meetings, standards development committee updates), the Mine Improvement and New Emergency Response

(MINER) Act of 2006, the Homeland Security Council's Domestic Chemical Defense 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 U.S. Respirator Users (2007)* (http://www.cdc.gov/niosh/review/public/111/) and the NA's *Measuring Respirator Use in the Workplace (2007)*(http://www.iom.edu/CMS/3740/29908/40062.aspx). The PPT Program response to the *IOM Committee on Personal Protective Equipment (PPE) Preparing for an Influenza Pandemic: PPE for Healthcare Worker Report (2007)* (http://www.cdc.gov/niosh/review/public/129/) also was considered.

The PPT Program Customer Satisfaction Survey (CSS) results from 2005 and 2008 (http://www.cdc.gov/niosh/npptl/default.html) were an additional input. These surveys were conducted through an Interagency Agreement with the U.S. Office of Personnel Management (OPM). The Assessment and Training Assistance Services Group (ATAS) of the Center for 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 public-sector organizations.

PPT Program preplanning included NIOSH-wide brainstorming sessions conducted to identify potential activities and strategies for addressing the NA recommendations. Subsequently, the PPT Program partnered with OPM/CTS to help define and prioritize the information gathered as 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 Federal government.

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

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 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 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.

Implementation Plan Scope

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, private-sector 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.

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.

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.

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.

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.

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.

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.

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	☑	☑	☑		☑
CBRN Respirators	✓	✓	✓	✓	
Escape Respirators	✓	✓	✓	✓	
FFRs	☑	☑	☑	☑	
Industrial Respirators	✓	✓	✓	✓	
Goal 2: Reduce Exposure to Dermal Hazards	☑	☑	☒		☑
Protective Garments	☑	☑	☑	✓	
Protective Gloves	✓	✓	☒	✓	
Protective Footwear	☑	☑	☒		
Goal 3: Reduce Exposure to Injury Hazards	☑				☑
Protective Headgear					
Protective Garments	☑	☑	☑		
Protective Gloves	✓	✓	☒		
Protective Footwear	✓	✓	☒		
Hearing Protection	☑	✓		✓	
Protective Eyewear					
Fall Protection	☑	✓		✓	
Goal 4: Broad-based PPT Issues	☑				☑
Sensors	✓	✓		✓	
Decontamination	✓	✓	☑	✓	
Nanotechnology	✓	✓		✓	
Human Factors	✓	✓			
Interfaces/Integration	☑	☑	☑	☑	
Surveillance	☑		☑	☑	
Barriers to PPT use	☑	☒	☒	☑	
Organizational Behavior and Motivation	☑	☒	☒	☑	
Information Dissemination	☑	☒	☒	☑	

Legend:
✓ - Existing Program Activity
☑ - Expansion of Existing Program Activity OR Initiation of New Program Activity
☒- Beyond 5 Years

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.

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.

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

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

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

ISSUE 1.4: Promote technology development, standards, and certification of integrated PPT components and ensembles

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.

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.

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.

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).

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.

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.

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.

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

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

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

FY 09 PPT Program Activities Related to Recommendation 1

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.

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:

- NIOSH is collaborating with partners to develop and test respirator breakthrough for multi-contaminant cartridges where contaminants represent firefighting overhaul exposures.
- 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.
- NIOSH has two research projects underway to advance the state of technology for closed circuit breathing systems for mine disasters and other emergencies.
- NIOSH will evaluate self-contained enclosures to assess the performance of the enclosures and the physiological and psychological suitability of use of the enclosures.
- 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.
- 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

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.

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.

The NA Report in its second recommendation states:

> *The PPT Program should:*
>
> - *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*
> - *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.*

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

These two issues are:

2.1 Coordinate intramural and extramural research activities
2.2 Expand the extramural research program

ISSUE 2.1: Coordinate intramural and extramural research activities

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

*Subsequent to publication of the report, the committee noted that the recommendation was not intended to be limited to COEs, but should also include extramural funding mechanism such as cooperative agreements, contracts and grants.

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

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

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

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

ISSUE 2.2: Expand the extramural research program

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.

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.

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 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.

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

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

ACTION STEP 2.2.1.2: Assign these defined duties and responsibilities within the PPT Program.

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

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

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

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

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

FY 09 PPT Program Activities Related to Recommendation 2

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

The PPT Program has established an annual PPT Program Stakeholder Meeting as part of its Outreach and Communications activities to encourage stakeholder input into the program 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 featured. The PPT Program, in cooperation with NIOSH OEP, invited NIOSH grant recipients (see Table 2), NIOSH Education and Research Centers (ERC), and NIOSH State Based Surveillance program personnel to participate and report on their PPT related activities at this meeting. Requests for presentation/poster were sent to these potential participants. Approximately 10 extramural activities participated in the meeting. This year's event was the first time the intramural and extramural activities deliberately participated together in an organized event. Both intramural and extramural participants appreciated the enthusiasm and richness of the discussion and information presented.

922 **Table 2 PPT Related Grant Recipients and Projects**
923

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

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

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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.

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
- 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.

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.

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

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

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

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

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

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

ISSUE 3.6: Explore approaches for disseminating respirator certification test results data

Stakeholders and end users have shown a desire for NIOSH to provide certification test data to 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, 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.

In evaluating the certification data generating process, several strengths appeared. This current 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

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 in-class 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

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.

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

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

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

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

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?

- What technologies can be used to reduce the burden of, and eventually eliminate the need for initial and annual respirator fit testing?
- Can laboratory methods by developed and validated to "predict" the physiological and psychological human responses to PPE ensemble use? If so, what technologies can be integrated into the PPT to serve as effective countermeasures.

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

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

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

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

ISSUE 4.3: Develop systems integration strategies for PPT and components

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

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

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

Research, systems-level testing, and technologies to provide new or improved seamless integration or interoperability of PPT are needed to address the multi functional needs for PPT within all NORA sectors. Issues specific to ensembles and their certification as an assembly of component PPT must be considered as well as understanding how workers combine various PPT 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

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

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

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

ACTIVITY 4.3.1: Identify activities to address seamless PPT component integration and interoperability.

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

ACTION STEP 4.3.1.2: Develop or improve existing "systems-level" PPT testing.

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

FY 09 PPT Program Activities and Projects Related to Recommendation 4

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

- NIOSH is conducting research to improve the reliability and level of respiratory 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 are underway in this research area.
- NIOSH is conducting research to understand the unique requirements of healthcare workers and to develop innovative materials, technologies and respiratory protection to meet their needs. Eight projects are underway in this research area.
- NIOSH is evaluating the effectiveness of current PPT and nanofiber based filter media to assess their performance against aerosol particles. Four projects are underway in this research area.
- NIOSH is developing technologies that reliably sense or model PPT performance and fostering their deployment to ensure users receive effective protection. Two projects are underway in this research area.

All of these research projects are conducted by PPT Program intramural staff at NPPTL and 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 to continue for several years. For example, the Anthropometrics research roadmap (Action Step 4.2.1.1) outlines a plan of research projects through 2018.

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

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

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

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

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

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?
- What is the type and frequency of PPT use within each such occupation?
- What health outcomes are potentially associated with the given exposures?
- What health outcomes are observed in the given occupations?

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.

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.

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 experienced with PPT usage, what PPT failures are experienced, and the barriers to use.

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

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

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

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.

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

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

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

ISSUE 5.2: Conduct random periodic field testing of PPE

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.

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

Appendix A: List of Acronyms

A

AFF	Agriculture, Forestry, and Fishing
AFRL	Air Force Research Lab (Wright-Patterson AFB)
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
AORN	Association of periOperative Registered Nurses
AP	Air-Purifying
ARTBA	American Road and Transportation Builders Association
ASSE	American Society of Safety Engineers
ASTM	American Society for Testing and Materials International
ATAS	Assessment and Training Assistance Services Group

B

BREATHE	Better Respirator Equipment and Technology for Healthcare Employees
BSC	Board of Scientific Counselors

C

CAN	common accounting number
CBRN	chemical, biological, radiological, and nuclear
CCER	closed-circuit escape respirator
CC-SCBA	closed-circuit self-contained breathing apparatus
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
COE	Centers of Excellence
COPPE	Committee on Personal Protective Equipment
CPIP	Certified Product Investigation Process
CSS	Customer satisfaction survey
CTS	Center for Talent Services (OPM)

D

DHHS	Department of Health and Human Services
DoD	Department of Defense
DOJ	Department of Justice
DRDS	Division of Respiratory Disease Studies (NIOSH)
DSHEFS	Division of Surveillance, Hazard Evaluations and Field Studies (NIOSH)
DSR	Division of Safety Research (NIOSH)

E

EMS	emergency medical services
ERC	Education and Research Center

F

FDA	U.S. Food and Drug Administration
FFR	filtering facepiece respirator
FOA	Funding Opportunity Announcements
FY	fiscal year

G

H

HCW	Healthcare Worker
HELD	Health Effects Laboratory Division/NIOSH
HHE	health hazard evaluation/NIOSH

HHS	Health and Human Services
I	
IAB	Interagency Board for Equipment Standardization and Interoperability
IAFC	International Association of Fire Chiefs
IAFF	International Association of Firefighters
IOM	Institute of Medicine
ISO	International Organization for Standardization
J	
K	
K	Thousand
L	
M	
MINER	Mine Improvement and New Emergency Response
MIST	man-in-simulant testing
MSHA	Mine Safety and Health Administration (DOL)
N	
NA	the National Academies
NAS	National Academy of Sciences
NFPA	National Fire Protection Association
NHIS	National Health Interview Survey
NIHL	noise induced hearing loss
NIJ	National Institute of Justice
NIOSH	National Institute for Occupational Safety and Health
NIOSH OD	Office of the Director, NIOSH
NIST	National Institute of Standards and Technology
NORA	National Occupational Research Agenda
NPPTL	National Personal Protective Technology Laboratory
NRC	National Research Council
NTRC	NIOSH Nanotechnology Research Center
O	
OD	Office of the Director
OEP	Office of Extramural Programs
OPM	U.S. Office of Personnel Management
OSHA	Occupational Safety and Health Administration (DOL)
P	
PAPR	powered air-purifying respirator
PPE	personal protective equipment
PPT	personal protective technology
PRL	Pittsburgh Research Laboratory
PS&B	Personnel Salaries and Benefits
PSD	Policy & Standards Development branch
Q	
R	
R&D	research and development
RDECOM	Research, Development and Engineering Command
RFA	Request for Announcements

RFP	Request for Proposals
RPD	respirator protective device
S	
SAR	supplied-air respirator
SARS	Severe Acute Respiratory Syndrome
SCBA	self-contained breathing apparatus
SCSR	self-contained self-rescuer
SDO	Standards Development Organizations
T	
TEB	Technology Evaluation Branch (NPPTL)
TI	Traumatic Injury
TIL	total inward leakage
TRB	Technology Research Branch (NPPTL)
TSWG	Technical Support Working Group
U	
V	
VA	U.S. Department of Veterans Affairs / Veterans Health Administration
W	
Y	
Z	

Appendix B: BSC Review of PPT Program

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BSC Review of PPT Program (Draft)

The following key issues are to be considered by the BSC during the review process:

1. **Is the National Academies (NA) evaluation report fair and appropriate in assessing impact and relevance?**

The NA evaluated relevance of the PPT Program to improvements in occupational safety and health and its impact in reducing workplace illnesses and injuries. The NA has taken a thoughtful approach to evaluating relevance and impact. Both of these criteria are difficult to assess.

Relevance was evaluated based on the priority of the work carried out and the strength and plausibility of its association with improvements in workplace protection. The NA examined 12 of the program's objectives across three main domains: research, respirator certification, and policy and standards setting. On this basis, the NA assigned a score of 4 on a 1-5 scale (1=lowest, 5=highest) for relevance.

Impact was evaluated based on the contributions to intermediate and end outcomes linked to worker health and safety. On this basis, the NA assigned a score of 4 on a 1-5 scale (1=lowest, 5=highest) for impact.

The Program is working in priority areas and is engaged in transferring its research into improved products and processes. It has made contributions to end outcomes and well-accepted intermediate outcomes. However, the NA report identifies areas where improvements are possible and provided five targeted recommendations. Thus, the scoring of 4 in both areas is appropriate and fair.

2. **Is the NIOSH Program Implementation Plan complete?**
   a. **Does it adequately address NA recommendations?**
   b. **Does the BSC agree with the strategic directions of the Plan?**

Table 1 lists each NA recommendation, the NIOSH response to the recommendation and the BSC review of the response. Overall, the Program Implementation Plan is complete. It is an ambitious plan that has the potential to transform the program. The plan addresses each of the NA recommendations in detail, is largely appropriate and, in some cases, commendably goes beyond what the NA recommended.

The approach described in Recommendation 1 (293) will enable the PPT Program to continue on a path to fulfilling its mission of preventing work-related injury, illness, and death by advancing

the state of knowledge and application of personal protective technologies and the vision described in the NA PPT Evaluation Report. However, the plan to coordinate activities within NIOSH and with other agencies is not clear. The "action steps" are more like goals. There needs to be a process to implement these goals. For example, how will coordination with other agencies be achieved? The Outreach and Training component is a welcome addition to the actions that NIOSH will take and goes beyond the NA recommendations.

The activities described under Recommendation 2 (755), i.e., expanding the extramural program and coordinating intramural and extramural activities provide a feasible approach for enhancing the extramural component of the PPT Program. The proposed activities are in the spirit of what the NA has recommended, but NIOSH has not addressed the development of Centers of Excellence (COE) for PPT. While this may be acceptable, NIOSH needs to provide a reason for not funding COEs.

The plan to enhance the respirator certification program described under Recommendation 3 (891) is mostly reasonable. NIOSH plans to conduct feasibility studies for expediting rulemaking and registration. While it is important to conduct feasibility studies, there needs to be a process for taking the results of the study and moving them to implementation. This process needs to be described. The plans to enhance the product and site audit mechanisms are appropriate. However, the plan for dissemination of respirator certification test results does not seem as efficient as just presenting test results on a NIOSH website dedicated to this purpose.

Recommendation 4 (1248), the plan to increase research on the Use and Usability of PPT, is well thought out and detailed. There is a significant potential for synergy between these activities and the Outreach and Training activities (Recommendation 1 activities). NIOSH should coordinate these two sets of activities. It also seems that NA wants to set these research priorities above the ones that NIOSH will determine in Recommendation 2. While this may be appropriate, NIOSH should develop a process to develop research priorities that provides a balance between Recommendation 4 and other research.

The PPT Program approach for surveillance discussed for Recommendation 5 (1456) is a reasonable approach to acquire data-driven input to help guide the Program. The steps listed are concrete and address the NA recommendation. There is the potential for significant overlap between activities related to Recommendations 4 and 5. This recommendation addresses the issue of relevance and impact of the PPT Program and is an opportunity for the Program to collect data to evaluate these on an ongoing basis. The results of these surveillance activities should be very useful in targeting the outreach activities that have also been proposed as part of Recommendation 1.

3. If NIOSH Program disagrees with the NA review, is sufficient justification provided?

Overall, the NIOSH Program does not disagree with the NA review. However, in response to Recommendation 2 (755) (development of Centers of Excellence), NIOSH has instead proposed a set of activities that do not include this component. While these activities may well achieve the same goal, NIOSH needs to provide a justification for not funding Centers of Excellence.

4. Are there cross-cutting implications or recommendations that result from the NA reviews that would further the development of NIOSH's strategic plans?

There are several activities that have the potential for significant overlap and synergy. There is a significant potential for synergy between activities relating to Recommendation 4 (Increasing research on the use and usability of PPT), Recommendation 5 (surveillance program to assess use and effectiveness of PPT in workplaces) and the Outreach and Training activities (Recommendation 1) activities. For example, the results of surveillance activities and use and usability research should be very useful in targeting the outreach activities that have also been proposed as part of Recommendation 1. It is worthwhile to consider how activities relating to these three recommendations can be coordinated. Such coordination may not only improve the relevance and impact of the PPT Program but may also result in cost savings.

5. Does the BSC have additional recommendations to NIOSH program or senior management and what plans are in place for monitoring and feedback to the BSC?

The NA recommendations are comprehensive and provide a roadmap for significantly enhancing the PPT Program. There are some themes in these recommendations that are worth emphasizing, especially since resource constraints will always exist.

(a) Consolidation of PPT-related activities at NIOSH under the PPT Program. There is also a need to set priorities among the various recommendations due to the above mentioned resource constraints. Which of the items in the plan will have greater priority?

(b) Recognition of overlaps between various activities under the five recommendations and taking advantage of the synergy between these activities. This is especially true for surveillance activities, use and usability research, and outreach activities.

(c) Better tracking of relevance of impact is possible through surveillance, registration and audit activities, and use and usability research.

(d) Several plans refer to conducting feasibility studies. There needs to be a well-defined process for incorporating the findings from such studies into action plans. There needs to be a process for reporting on the progress of the implementation.

NA Recommendation	NIOSH Response	BSC Comments
Recommendation 1: Implement and sustain a comprehensive NPPTP		The NIOSH response is appropriate. They recognize that implementing this recommendation will ensure implementation of the 2001 congressional mandate for a comprehensive and state-of-the-art federal program for PPT. It will also unify PPT-related activities within NIOSH. Table 1 provides an overall summary of activities in the PPT Program. There are also a number of planned activities (pp 15-16) that address various recommendations relating to this item.
Oversee, coordinate, and where appropriate, conduct research across all types of occupational PPT and across all relevant occupations and workplaces;	• Will establish integrated PPT program and improve coordination with other federal agencies. Several action steps are listed (page 10).	The steps listed are appropriate and needed. But the "action steps' are more like goals. There needs to be a process to implement these goals. For example, how will coordination with other agencies be achieved ?
Participate in policy development and standards setting across all types of occupational PPT;	• Will ensure that 42 CFR Part 84 is systematically updated and maintained to use current technologies for performance and testing. • Participate in PPT consensus standard development. • Review existing standards ; support development of global respirator standards • Support development of standards for non-respiratory PPE through surveillance	The steps listed are concrete and address the NA recommendation.

• 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, private-sector 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.	• Improve current NIOSH respirator certification program with focus on operational efficiency, integrity and fairness of evaluation. • Identify administrative and technical gaps in the standard and assure that PPE performance is not adversely affected by ensemble components. • Develop strategy with standards development organizations for PPE as integrated ensemble. • Lead development and implementation of strategy for non-respiratory PPE certification. • Seek NA to conduct workshop for the above.	The steps listed are concrete and address the NA recommendation.
	Outreach and Training programs for optimal use and acceptance of PPT by workers: • Disseminate PPT materials to workers who rely on it. • Disseminate emerging relevant PPT information.	The outreach and training component is a welcome addition to the actions that NIOSH will take and goes beyond the NA recommendations.
Recommendation 2: Establish PPT Research Priorities and Expand the Extramural Program		
• 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	• Expand the extramural research program • Establish process for enabling PPT program to engage with extramural program.	The proposed activities are in the spirit of what NA has recommended, but NIOSH has not addressed the development of COE for PPT. While this may be acceptable, NIOSH needs to provide a reason for not

practice interventions. • 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.	• Coordinate intramural and extramural research activities ○ Develop process to coordinate PPT program activities with NIOSH OEP to implement funding of extramural research. ○ Enhance NIOSH-supported Centers with PPT-related activities	funding COEs.

Recommendation 3 Enhance the Respirator Certification Program:		
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.	• Conduct feasibility study to identify approaches to expedite rulemaking for respirator standards • Explore possibility of requesting stakeholders for suggestions for updating 42 CFR Part 84 • Explore possibility of coordinating testing with private labs	While it is important to conduct feasibility studies, there needs to be a process for taking the results of the study and moving them to implementation. This process needs to be described.
	Develop a process for updating certification fees and pursue a fee update through rule making	The action items are clearly described. However, on p. 24, the title of the section 3.2 should be changed to "Process for updating certification fees".
Develop a mechanism for registering the purchase of NIOSH-certified respirators so that post-marketing notifications and recalls can be accomplished expeditiously and effectively.	NIOSH will conduct a feasibility study for developing a mechanism for this purpose, followed by implementing registration programs and assess their effectiveness.	The steps listed are concrete and address the NA recommendation. While the benefits of registration are clear enough for NIOSH, it is not clear that NIOSH has the legal authority for post-marketing notifications and recalls, unlike FDA.

		Need some discussion.
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.	Develop a product audit program that is robust and statistically sound, i.e., the number of product audits should be based on statistical sample of the total number and classes of NIOSH-certified respirators. A computer program has been developed for assigning priorities for testing of different respirators.	NIOSH concedes funding limitations that prevent it from being statistically sound. The proposed approach is logical, appropriate, and better.
	• Improve site audit methodology. • Develop database to administer and manage program. • Schedule audits in a timely manner. • Integrate site audit data into certified product investigation process.	The proposed steps are appropriate.
Disseminate respirator certification test results data (e.g., breathing resistance).	Explore approaches for disseminating respirator certification test results data: • Explore potential approaches to enable extramural researchers to compare performance indicators of in-class respirators. • Explore the feasibility of developing a public forum for stakeholders/end users to share qualitative respirator performance information obtained from personal respirator use experiences. • Identify potential training opportunities to ensure proper selection and use of respiratory protection.	The proposed approaches do not seem as efficient as just presenting test results on a NIOSH website dedicated to this purpose.
Recommendation 4: Increase Research on the Use and Usability of PPT. Such research should examine human factors		

and ergonomics, as well as individual behaviors and organizational behaviors, particularly workplace safety culture		
	Define barriers to and facilitators of PPT use • Prioritize activities necessary to support PPT research, surveillance, standard development, and PPT evaluation. • Use surveillance and research findings to develop communication products to make it easier for users (across NORA sectors) to select and use appropriate PPE. • Work with partners to develop training methods to enhance the workplace safety culture in all NORA sectors. Develop innovative PPT designs and test methods to improve comfort, fit, and usability Conduct a multi-faceted research program to improve the comfort and fit of PPE. • Implement the Anthropometric Research Roadmap to update and improve respirator fit test panels. • Conduct research to improve fit of body, hand, head, eye, and foot protective equipment, and protective ensembles. • Develop new test methods to quantitatively assess respirator ensemble comfort. Evaluate current test methods to determine if the comfort of	• There is a significant potential for synergy between these activities and the Outreach and Training activities (Recommendation 1 activities). • It also seems that NA wants to set these research priorities above the ones that NIOSH will determine in Recommendation 2.

	the respirator/certified ensemble can be quantified by an existing method or revision of the method.	
	Develop systems integration strategies for PPT and components	
Recommendation 5: The PPT Program 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.		There is the potential for significant overlap between activities related to Recommendations 4 and 5. This recommendation addresses the issue of relevance and impact of the PPT Program and is an opportunity for the Program to collect data to evaluate these on an ongoing basis. The results of these surveillance activities should be very useful in targeting the outreach activities that have also been proposed as part of Recommendation 1.
• 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; • Build on existing government and private-sector surveys and surveillance activities that collect PPT-relevant data and facilitate linkages to other datasets.	• Establish a comprehensive surveillance program • Collaborate with existing government and private sector organizations which collect PPT-relevant surveillance data across all industry sectors • Develop surveillance strategies across all industry sectors to determine use and effectiveness of PPT • 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	The steps listed are concrete and address the NA recommendation.

• Require random periodic field-testing of an adequately sized sample of PPT to assess effectiveness, usability, and durability with reasonable accuracy and precision;	• Conduct field research to assess and critically appraise PPT use, effectiveness, usability, and durability across all types of PPT • 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	The steps listed are concrete and address the NA recommendation.

Appendix C: PPT Program Response to BSC Review of PPT Program

The PPT Program has analyzed the review provided by the NIOSH BSC and provides the following comments.

The PPT Program appreciates the thoughts and valuable input provided by the BSC review and especially the acknowledgment that the Program has developed an ambitious plan that has the potential to positively transform the program. The PPT Program would like to comment on three underlying themes as noted in the BSC Review.

1) The processes to achieve objectives outlined in the action steps require better definition.
2) Potential synergies and overlaps are evident in the Plan.
3) The PPT Program needs to specifically address why no Centers of Excellence were proposed.

1. The processes to achieve objectives outlined in the action steps require better definition.

The PPT Program recognizes the importance of the BSC comments regarding the various proposed action steps and understands the need to better define processes that will ensure their proper implementation.

The PPT Program underwent a detailed process to address the NA Recommendations and generate its implementation plan. This planning process included:

- Office of Personnel Management (OPM) facilitation of the planning process,
- brainstorming sessions with PPT Program staff to identify potential program and research gaps,
- establishing of Program teams to address each recommendation (while considering the gaps that were identified) and to generate the Draft Implementation Plan
- utilizing the Institute of Medicine (IOM) Committee on PPE (COPPE) for the Workforce to solicit external comment on the Draft Implementation Plan, and
- revising the Draft Implementation Plan by PPT Program management into a detailed version for implementation, and a more general strategy (omitting some details) for BSC review.

Similar processes previously have been used by the Program when it prepared an action plan to address the recommendations provided by the IOM in the *PPE for Healthcare Worker: Preparing for an Influenza Pandemic* report (2008), as well as developing the Anthropometrics Research Roadmap in response to the IOM *Assessment of the NIOSH Head-and-Face Anthropometric Survey of Respirator Users* (2007).

Similar processes are followed for other broad-based Program efforts, including, strategic planning, proposed rule development and implementation for respirator certification, project planning and development, and project and program peer review. These processes are designed to leverage scientific and strategic approaches, intramural expertise and input, and interested party and stakeholder engagement to ensure all issues are effectively addressed.

Provided below is an outline which demonstrates the extent to which the action steps and processes have been defined for implementation throughout the PPT Implementation Plan. Section 1.3 and 3.6 action step worksheets are provided as examples (see additional handouts, appendices E & F). Similar detail is available for all action steps in the Plan.

The outline includes the following components:

- Defining the Challenge Worksheet: Each recommendation was identified as a "challenge" and each challenge had "issues" associated with it that needed to be addressed. For each issue addressed, the program identified the desired outcome necessary to address the issue. The Program also defined the current conditions. The Program further described negative consequences if the issues were not addressed.
- SWOT Analysis: Each challenge and associated issue was analyzed relative to the strengths, weaknesses, opportunities, and threats (SWOT).
- Action Planning Worksheets: The "Defining the Challenge" worksheets and the "SWOT Analysis" Worksheets were assessed and used as the background and foundation to assist in creating Action Planning Worksheets for each issue. These Worksheets described the "action steps" necessary to address the issues and a brief summary of the actions required, resources necessary to implement the action steps, implementation timeframes, key success indicators, and responsible parties necessary to conduct the actions.

Similar processes, modified to the particular initiative, will be used for all feasibility and other studies as proposed in the Plan. Extensive use of PPT Program staff and open stakeholder forums will be integral to all of these efforts.

2. Potential synergies and overlaps are evident in the Plan.

The PPT Program acknowledges the BSC observation regarding the evident overlaps in the PPT Implementation Plan, as well as the opportunities for synergies within its various components.

The Program considers recommendation 1 to provide the foundation for the overall plan. The Implementation Plan was written to address the NA recommendations as they are described in the NA Evaluation Report; however, effective management and coordination of the PPT Program will ensure related activities leverage resources to achieve common goals. The Implementation Plan currently is being incorporated in the overall PPT Program Strategic Plan to ensure resources are efficiently used and to avoid duplication of effort. The PPT Program Strategic Plan will provide detail to describe priorities that include gaps described in the NA

Evaluation, those described in other NA Reports, and other priorities based on national policies, previously identified gaps, and emerging issues.

A key mechanism to identify the opportunities for synergies and the elimination of duplicative efforts is presented below in the discussion of a proposed Consortium for PPT.

3. The PPT Program needs to specifically address why no Centers of Excellence were proposed.

The PPT Implementation Plan did not exclude Centers of Excellence as one of the funding mechanisms that will be considered in the design of an extramural PPT research program. Rather, Centers of Excellence were intentionally included because they are a potentially productive way to accomplish certain research goals.

During the development of its Implementation Plan, the PPT Program initiated conversations with the NIOSH Office of Extramural Programs (OEP) to begin developing an approach to establish a more robust extramural research program.

Extramural research programs sponsored by agencies such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) have developed a wide range of award mechanisms to meet the agency's research goals. These mechanisms include the traditional investigator-initiated research awards, such as R01, R03, and R21, conference grants (R13), Small Business Innovation Research (SBIR; R43 and R44), translation research (R18), cooperative agreements (U60), training grants (T01, T02, T03, T15), career development awards (K01), and dissertation research awards (R36). The mechanisms also include larger awards called Research Program Projects (P01) and Specialized Center Cooperative Agreements, which include Centers of Excellence. NIOSH uses two types of Center awards. One is the Specialized Center Cooperative Agreement (U54) and the other is the Education and Research Training Grant (T42).

Depending on the needs and goals of the agency, the timeframe of commitment, and the availability of funds, the PPT Program and the extramural program office will work together to design an appropriate extramural program approach using specific funding mechanisms. Currently, NIOSH has several standing program announcements that invite applications year round for research in all areas of occupational safety and health (R01, R03, R13, R21, SBIR, and K01). Any qualified individual with a good idea related to PPT can apply for funding through these award mechanisms all through the year. NIOSH's extramural program draws attention to the research goals in a specific area like PPT by including links to these goals that are posted on NIOSH websites in their funding opportunity announcements. For the SBIR program, NIOSH specifically identifies PPT as an area of interest.

When there is a specific goal or set of goals that the extramural program wants to address with specific funding, and the extramural community possesses subject matter expertise which is spread throughout the country at different institutions, generally a Request of Applications (RFA) is published for an R01 mechanism which describes the targeted goals, and the funding

that is available (typically $1-3M per year for 3-5 years). This mechanism is very efficient in quickly targeting a research priority for attention by the top researchers across the country. This mechanism is also the most commonly and effectively used way for soliciting the best proposals from the extramural community in a targeted priority area.

Sometimes individual institutions have several highly qualified researchers with different expertise in a common research priority area. Bringing together all of these researchers as a group can result in a synergy in which the combined efforts have a larger impact and more immediate success than funding several projects individually. When this is the case, the NIOSH extramural program may propose to utilize a Research Program Project (P01), a Research Program Cooperative Agreement (U60), or a Specialized Center Cooperative Agreement (U54). Research Program Projects are used to support a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective. Each research project is usually under the leadership of an established investigator. The grant can provide support for certain basic resources (e.g., equipment, facilities, subject cohorts) used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort. The projects as a whole should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.

A Research Program Cooperative Agreement is like a Research Program Project except that it also includes substantial Federal programmatic staff involvement. This involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award. While the Federal government is involved, the investigators have primary authorities and responsibilities to define research objectives and approaches, and to plan, conduct, analyze, and publish results, interpretations and conclusions of their studies.

Specialized Center Cooperative Agreements can be used to support any part of the full range of research and development from very basic to very applied. The spectrum of activities comprises a multidisciplinary attack on a specific research priority area. This mechanism differs from a program project mechanism in that a Center is usually developed in response to an announcement of the programmatic needs of the Institute and subsequently receives continuous attention from Federal program staff. Centers may also serve as regional or national resources for special research purposes, with funding component staff helping to identify appropriate priority needs.

The decision whether to use a Center mechanism or a traditional investigator-initiated research award mechanism is one that must carefully consider several key factors including: 1) the existing expertise in the extramural community, 2) whether that expertise is concentrated within one or several research institutions or spread throughout the country, 3) the timeframe to successfully achieve research goals, 4) the amount of funds available, and 5) whether the Federal

government can more quickly and efficiently accomplish its purposes using a contract mechanism rather than an assistance mechanism.

When resources are limited, as they currently are for extramural PPT research sponsored by NIOSH, there are significant drawbacks to the use of Center or Program Project mechanisms. This is because awarding a single Center or Program Project typically involves funding several subprojects that together constitute sums typically over $1M per year. As an example, if NIOSH has a research objective to develop a new respirator design for use among healthcare workers, and there are four research/engineering/clinical institutions in the country with the expertise to design and test such a respirator, and if NIOSH has only $1M available, then NIOSH will loose access to the best researchers at three institutions if only one Center is awarded. A better solution might be to fund the top scientists at these four institutions with individual awards and then to unite these investigators formally in a consortium. This is just an example of the considerations that NIOSH must make in determining the best mechanism for funding an extramural program in PPT, and illustrates why a one-size-fits-all approach such as only using Centers of Excellence or only using R01 awards is not an appropriate approach for designing an extramural research program. Each mechanism, and combination of mechanisms has an appropriate application, and the task of the NIOSH PPT Program and the NIOSH Office of Extramural Programs is to work together to design and implement the best approach to accomplish the Institute's goals.

Appendix D: PPT Program Response to Docket# 146 Comments

Date Comment received	Commenting Organization	Overview of comments	PPT Program Response
30 Mar 09	Kevin Kerik Manager, Responsible Care Methanex Corporation 1800 Waterfront Centre, 200 Burrard Street, Vancouver, B.C., Canada, V6C 3M1 Direct 604-661-2635 Cell 604-218-2792 kkerik@methanex.com	Requested invitation to participate in project or be kept advised of its progress.	We recommended Mr. Kerik join our listserv to keep informed of progress in the PPT Program.
1 Apr 09	Carol S. Lawrence RN BSN Dallas Fire-Rescue Dept. Retired 1200 N. Sharpshire Waxahachie, TX 75165 nitengail8@aol.com	Determined that the proposed plan is a good one, but suggested that for maximum utilization, that the language regarding recommendations should be simplified. It was noted that there are thousands of small departments across the US, who would benefit from these recommendations, but if they do not have a Hazardous Materials Team (or others with similar expertise), then they may not have the training resources to fully benefit from the recommendations; it was further suggested that retired personnel with many years of experience may be of some assistance in implementing this plan at these smaller departments.	The PPT Program Strategic Plan language will incorporate Intermediate Goals that will more adequately describe the relationship of the recommendations to address particular stakeholder needs. Additionally, outreach products will be developed in collaboration with the appropriate stakeholder groups to alleviate the concerns addressed in this comment.
15 Apr 09	Claire A. Kammer Manager, Government Affairs Underwriters Laboratories, Inc. 1850 M Street, NW Suite 1000 Washington, DC 20036 Claire.A.Kammer@us.ul.com Tel: (202) 296.8092 Fax (202) 872.1576	"The outlined plans for implementation of the National Academies' recommendations form a strong platform for continued enhancements to advance the program's mission." Particular emphasis was placed on the proposed plans for product testing and certification beyond the current respirator scope. NPPTL was encouraged to give thoughtful consideration to the role that third party certification bodies can	The PPT Program understands that there are no nationally recognized central authorities for non-respiratory personal protective technologies (PPT). The National Academies (NA) Report defines this as one of the most significant weaknesses of the national efforts concerning worker health and safety protection. NIOSH certification of respirators has had a significant positive impact on the quality of respirators available in the workplace. However, there is no analogous federal process for ensuring the certification of the efficacy of PPT other than those for respiratory protection (e.g., eye

Date Comment received	Commenting Organization	Overview of comments	PPT Program Response
	Cell (202) 374.3536	play in the advancing the safety of personal protective equipment and ensembles. Also, the efforts of the program and its partners in addressing interface issues between respirators and other ensemble components were specifically noted. The standards process, as it is designed, was deemed the best platform for addressing these and other issues. "By putting in place the appropriate requirements in the standard and working with certification organizations and test laboratories to ensure compliance with those protocols, your organization can help ensure that the products making up the full PPE ensemble are working together effectively to protect workers, regardless of where certified and tested." A collaboration with the program was proposed to determine the appropriate balance between government and private laboratories in ensuring that safer products and systems are available to protect the American workforce.	protection, hearing protection, protective clothing). Consequently, the program has requested the Institute of Medicine of the National Academies provide recommendations regarding the certification and testing issues that should be addressed to understand and improve the efficacy and effectiveness of personal protective equipment used across industry sectors with an emphasis on healthcare. This task will include efforts to address certification of non-respiratory PPE, such as protective garments, gloves, and eyewear.
20 Apr 09	Don B. Thompson, Ph.D. Research Assoc. Professor, and Assoc. Director, TPACC Department of Textile Engineering, Chemistry and Science Box 8301, 2401 Research Drive North Carolina State University Raleigh, NC 27695-8301 (919)515-6781 Fax: -2294	NCSU commented on all five recommendations emphasizing the need to compare test methods for whole garments, developing Centers of Excellence, conducting research on comfort and fit assessments, usability and surveillance. Comments specific to the recommendations were: [1] Implement and Sustain a Comprehensive National Personal Protective Technology Program	The PPT Program appreciates the detailed docket entry provided by NCSU regarding the five IOM recommendations. The PPT Program will use this entry as an input to the prioritization process currently underway for FY11. The PPT Implementation Plan did not exclude Centers of Excellence as one of the funding mechanisms that will be considered in the design of an extramural PPT research program. Rather, Centers of Excellence were intentionally included because they are a potentially productive way to accomplish certain research goals.

Date Comment received	Commenting Organization	Overview of comments	PPT Program Response
		The proposed plan was seen as a template for creating better PPTs and enhanced user compliance. The key to achieving its goals was defined as: "appropriate funding and significant growth of the program to make other protective technologies as robust as the respiratory program." [2] Establish PPT Research Centers of Excellence and increase Extramural PPT Research Omission of COEs in the Implementation Plan was defined as "a significant gap for the program." Establishing such centers would allow the development of coordinated research agendas that will accelerate and enhance technologies leading to safer workplaces. It was suggested that the research agendas could be driven by boards that include program staff, as well as users, other researchers, and subject matter experts. [3] Enhance the Respirator Certification Process The Implementation Plan was seen as having "an excellent vision for the respirator certification process." [4]Increase Research on the Use and Usability of PPT "The plan for recommendation 4 has excellent elements. Research on user acceptance should include both surveillance activities and laboratory research. Inclusion of holistic approaches recommended in the proposal for	The decision whether to use a Center mechanism or a traditional investigator-initiated research award mechanism is one that must carefully consider several key factors including: 1) the existing expertise in the extramural community, 2) whether that expertise is concentrated within one or several research institutions or spread throughout the country, 3) the timeframe to successfully achieve research goals, 4) the amount of funds available, and 5) whether the Federal government can more quickly and efficiently accomplish its purposes using a contract mechanism rather than an assistance mechanism. Extramural research programs sponsored by agencies such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) have developed a wide range of award mechanisms to meet the agency's research goals. These mechanisms include the traditional investigator-initiated research awards, such as R01, R03, and R21, conference grants (R13), Small Business Innovation Research (SBIR; R43 and R44), translation research (R18), cooperative agreements (U60), training grants (T01, T02, T03, T15), career development awards (K01), and dissertation research awards (R36). The mechanisms also include larger awards called Research Program Projects (P01) and Specialized Center Cooperative Agreements, which include Centers of Excellence. NIOSH uses two types of Center awards. One is the Specialized Center Cooperative Agreement (U54) and the other is the Education and Research Training Grant (T42). Each mechanism, and combination of mechanisms has an appropriate application, and the task of the NIOSH PPT Program and the NIOSH Office of Extramural Programs is to work together to design and implement the best approach to accomplish the Institute's goals.

Date Comment received	Commenting Organization	Overview of comments	PPT Program Response
		PPT assessment and certification is an excellent approach. Holistic testing should be a part of standards, and doing so would go far toward achieving the goal of this recommendation." [5]Assess PPT Use and Effectiveness in the Workplace Using a Life-Cycle Approach "The development of appropriate databases should be a focus of ongoing activities at NPPTL, and connecting them with research activities will be an important aspect of making the surveillance activity valuable to developing new conditioning and testing methodologies that can be used in the development of new standards."	
20 Apr 09	Lisa Tomlinson Director of Government Affairs APIC—Association for Professionals in Infection Control and Epidemiology, Inc. 1275 K Street, NW, Suite 1000 Washington, DC 20005-4006 Direct Dial: (202) 454-2606 Main Number: (202) 789-1890 Fax Number: (202) 789-1899 Email: ltomlinson@apic.org Web: www.apic.org Kathy Warye Chief Executive Officer	APIC requested to be included as a partner to the proposed efforts. Comments specific to the recommendations were: [1] Implement and Sustain a Comprehensive National Personal Protective Technology Program It was strongly suggested that standards and PPT requirements for Health Care Workers be evaluated in relationship to operational needs within workplace settings, which are different from industrial occupational settings. [2] Establish PPT Research Centers of Excellence and increase Extramural PPT Research	The PPT Program currently has a significant number of initiatives to address PPE for HCW. These efforts are available through NIOSH Docket 129 [http://www.cdc.gov/niosh/docket/NIOSHdocket0129.html]. HCW issues are a priority to the Program as evidenced by the extensive research program, formal, and informal collaborations. See PPT Program Response to Don Thompson, 20 Apr 09 on Page D-2 – D-3.

Date Comment received	Commenting Organization	Overview of comments	PPT Program Response
		The establishment of Research Centers of Excellence, and the collaboration needed with intramural and extramural programs to improve PPT were supported. Clearly-defined processes for identifying and selecting these centers were seen as essential. [4]Increase Research on the Use and Usability of PPT This recommendation was defined as the one that "is fundamental to the success of all the others. We strongly support the need to identify barriers to the use of PPT and functionality of equipment. We believe equipment should be designed in a manner that does not require repeated or ongoing fittings/measurements in order to be used, and designed based on scientific evidence related to true risk of exposure." [5]Assess PPT Use and Effectiveness in the Workplace Using a Life-Cycle Approach The proposed process for field testing was observed to allow for developers and certifiers to glean valuable on site information that can be used to continually improve products if deficits are identified on the front lines. It was suggested that specific criteria be developed for PPT evaluation which are objective and independent of individual manufacturer influence by qualified individuals who understand the specific needs of HCW and the science behind specific protection needs.	
20 Apr 09	Daniel Glucksman Public Affairs Director	Comments included:	The PPT Program is taking several steps to prioritize the actions identified in the Implementation Plan. First, the

Date Comment received	Commenting Organization	Overview of comments	PPT Program Response
	International Safety Equipment Association 1901 North Moore St., Suite 808 Arlington, VA 22209 703-525-1695 x19 * 703-795-6064 (cell) Daniel K. Shipp President	"Prioritize the Action Items" It was noted that it is unlikely that NIOSH will have the resources to adequately address all of the recommendations in the IOM report. "Therefore it is essential that NIOSH prioritize the action steps based on its understanding and research findings of both hazards in the workplace and the ability of PPT to mitigate those hazards." "Surveillance Must Come First" "The most important function in this document is surveillance. This is because a complete surveillance program will help direct NIOSH time, funds and efforts to where they can do the most to make certain America's workers who need PPE will have it and use it when they need it… NIOSH must conduct substantial surveillance before certifying PPE and conducting evaluations of PPT and PPE ensembles and systems." "Field Evaluation of PPT" Issue 5.2, "Conduct random field testing of PPE," was described as "of great importance to a wide array of stakeholders. To address this issue, ISEA recommends NIOSH expands its federal partners to include import regulators, such as U.S. Customs and the Commerce Department's International Trade Administration… NIOSH could take a key leadership role in conducting this type of product surveillance." [1] Implement and Sustain a Comprehensive	Program has increased the amount of funding dedicated to surveillance activities in an effort to inform the Program on the research gaps on which to focus and the workplace issues to address. We agree that adequate surveillance will help inform the program direction and priorities to enhance the current priorities which have evolved from national interest issues (pandemic influenza preparedness, CBRN standards development, mine escape technologies, nanotechnology research). The Program believes the planned effort to expand extramural activity will enhance current initiatives to conduct field evaluation of PPT. Also, we appreciate the list of suggested partners provided by ISEA.

Date Comment received	Commenting Organization	Overview of comments	PPT Program Response
		National Personal Protective Technology Program "NIOSH's international reputation, including that of the NPPTL, is strong. NIOSH experience, presence and involvement globally should be able to provide the opportunity to influence and incorporate not only global respiratory protection standards, but also standards for other PPT such as protective apparel and gloves." "ISEA supports Recommendation 1, Implement and Sustain a Comprehensive National Personal Protection Program, and encourages NIOSH to rely on industry partners such as trade associations, standards-setting organizations and other stake holders to coordinate the evaluation, testing and certification of PPT. This includes the harmonization and adoption, where appropriate, of global standards for PPE."	
20 Apr 09 12 May 09 (Revised)	Roger Barker NC State University College of Textiles Raleigh, NC 27598 Roger_Barker@ncsu.edu	A strong statement concerning COEs was given: [2] Establish PPT Research Centers of Excellence and increase Extramural PPT Research "The response and planned activities are only partially responsive to this recommendation… The response sidesteps the specific recommendation to develop and support centers of excellence that work closely with NIOSH intramural and research programs to improve PPT, increase field research... Furthermore, the proposed actions to coordinate extramural research and prioritize needs for research in PPT, ignores the potential areas where technology leveraging have already been identified which	See PPT Program Response to Don Thompson, 20 Apr 09 on Page D-2 – D-3.

Date Comment received	Commenting Organization	Overview of comments	PPT Program Response
		could immediately be supported through creation of focused COEs. These areas include dermal protection, respirator classification, PPT component operability, and barriers to use of PPT by workers. These research aspects are not addressed NIOSH educational training centers. As recognized by the committee report, this will require the formation of new research oriented COEs which can develop unique research agendas and synergies with NPPTL." "The proposed implementation plan has many fine points which should be beneficial to NPPTL and NIOSH, and most importantly to worker safety and health. However, in my opinion, the proposed implementation plan seriously misses the intentions regarding the need for COE's, which is among the most clearly and unequivocally stated recommendations in the committee's report."	
6 May 09	Robert Hickman Reno County Health Dept 209 W 2nd Hutchinson, Kansas 6750 bob.hickman@renogov.org	Two specific comments were offered: 1. Continue the research into better fit for PPE to improve use and compliance by workers, 2. Update the fit test requirements in two ways a. reduce some of the excessive requirements for low impact occupations (most Healthcare) no need for jogging, extreme movements, alter the taste test timing to take place after the fit evaluation to reduce test time requirements (will improve utilization by employers if time is reduced), b. Continue with the proposal for initial medical evaluation and fit testing, reduce the requirement for annual testing unless conditions require (change in status-physical, change in	Research is underway to address the topics raised in this comment. Specifically, the Anthropometrics research roadmap identifies efforts planned over the next 5 years. Additionally, introducing total inward leakage (TIL) into the certification requirement should result in improved technology.

Date Comment received	Commenting Organization	Overview of comments	PPT Program Response
		health/medical, and change in job function/PPE needs).	
29 May 09	Sandra Prickitt, AOHP Executive President Association of Occupational Health Professionals in Healthcare MaryAnn Gruden Association Community liaison 412/578-6792 magaohp@Yahoo.com	AOHP recognized that the PPT Program Plan was designed to optimize the dissemination of research findings to provide the highest level of protection for the national workforce in a timely manner.	The PPT Program has partnered with AOHP to conduct focus groups with HCW to identify outreach and research opportunities to refine the priorities and address HCW needs.

Appendix E: Action Planning Issue 1.3

Challenge:			
Implement and sustain a comprehensive National Personal Protective Technology program.			
Issue:			
Certification for all PPE, with the exception of respiratory protection, is not required; consequently certification of all PPE is not available to enable users to know that products have been thoroughly tested and comply with safe performance standards.			
Desired Outcome:			
A comprehensive certification program is in place to enable users to know that products have been thoroughly tested and comply with safe performance standards.			
Current Conditions:			
The PPT certification branch has limited personnel, facilities and equipment to carry out all types of PPT certifications.	Excellent coverage of Certification within the PPT Program related to reducing exposure to inhalation hazards.	No coverage of Certification within the PPT Program related to reducing exposure to dermal hazards.	No coverage of Certification within the PPT Program related to reducing exposure to injury hazards.
• NIOSH has the federal mandate under CFR 84 to certify respirators. • Currently, certifications are only related to respirator type PPT. NIOSH website & PPT Program Portfolio Matrix of goals & activities. • NPPTL is not an accredited third party certification agency nor an accredited Laboratory. Expert opinion. • While NPPTL has a mandate to conduct research on PPT, NIST has the mandate to do compliance assessment. Expert opinion. • Protective clothing and equipment used by emergency responders (law enforcement, fire	• NIOSH has been certifying respirators for many years and has a thorough understanding of the product line. The facility is equipped with the necessary instrumentation and personnel to accomplish certification of respiratory products. NIOSH has confidence in the products that are certified and tested at NIOSH facility. Procedures are in place and known for Standard Test Procedures (STPs) related to the testing and certification of respirators. NAS report & Senior staff opinion.	• NIOSH does not have a federal mandate for certification of dermal hazard PPT products (protective clothing, protective gloves and protective footwear).	• NIOSH does not have a federal mandate for certification of injury hazard PPT products (Headgear, eye, hearing fall).

service, emergency medical service, and corrections) and healthcare providers are not tested and certified by a federal laboratory under a Code of Federal Regulation • NPPTL does not have the facilities and equipment necessary to carry out assessment			
Current Conditions:			
Current gaps in certification of all other PPT.			
• Address Special Populations • Review Special Considerations specific to environments, industry, etc. that may have specific needs that need addressed such as similar to Health Care Workers (HCW). • Assess and define all other types of PPE that NIOSH/NPPTL would like to certify. • Define criteria for test subjects to meet regular population and special populations. • Manufacturer training must be provided for certain types of non-respirator PPE as part of the approval process and documented to effectively train users across Industry Cross Sectors			
Consequences:			

- Protective clothing and equipment not offering adequate levels of quality and protective performance will be used by workers.
- The performance and certification of other PPE is not federally mandated and enforced.
- Relationship building with other agencies and manufacturers will be diminished to advance non-respirator PPE within the labs.

Challenge: Implement and sustain a comprehensive National Personal Protective Technology program.

Issue: Certification for all PPE, with the exception of respiratory protection, is not required; consequently certification of all PPE is not available to enable users to know that products have been thoroughly tested and comply with safe performance standards.

	Strengths	***Weaknesses***
Internal	• Certification, evaluation, and testing of industrial workplace designed NIOSH-approved respiratory protective devices and sub-components since 1973 • Certification of industrial/NFPA respirators to NIOSH-certified CBRN protection standards for emergency responder use since 2001-2002 • Emergence of a NIOSH technical research branch specific to the research and development of personal protective equipment technologies advancing the public health state of the national fire service • Resourcing of a NIOSH policy and standards development branch specific to the development of new PPE standards and the adaptation or creation of existing NIOSH policy documents specific to unique workplace interpretations (terrorism, natural disaster, hazardous materials release, etc.) • Collating the historical processes of a NIOSH respirator certification program into one technology evaluation branch within NPPTL-NIOSH since 2001	• Limited facilities or agreements with other labs. • Limited funding. • Limited expertise. • Special Considerations specific to environments, industry, etc. that may have specific needs that need addressed such as similar to Health Care Workers (HCW). • National personal protective equipment evaluation, testing, and efficiency of use laboratory infrastructure does not exist for all types of personal protective technology available for use in US workplaces • Professional development programs for federal employees that would allow them to remain technically competent, professional competitive and uniquely qualified/focused on NIOSH PPT Program strategic goals and objectives. • Turn-over of federal employees with key PPT skills • Difficulties in recruitment of new employees interested in applying state-of-the-art technology skills to the advancement of NPPTL PPE/PPT development and evaluation objectives.

	Opportunities	***Threats***
External	• Provide certification for those products that do not presently have a certification program • Address special populations' needs, define the physical effects of wearing non-respirator PPE, mandate manufacturer training for PPE as part of the approval, document user experiences to help improves testing and standards. • Develop and design effective certifiable training methods and maintain a high level of user awareness. • Define criteria for test subjects to meet regular population and special populations. • Provide audit services to the DOJ-NIJ to confirm future NIJ CBRN PPE performance standards and core requirements are properly using NIOSH-certified respirators offering CBRN protection • Provide NIOSH-NPPTL liaison to recognized federal laboratories and centers of excellence actively pursuing personal protective technology development, production, and/or product quality assurance and field use assessment • Development of technical working groups with like federal laboratories or private sector laboratories or associations focused purely on the advancement of existing and next generation personal protective equipment technologies for use in a diverse workplace or a variable emergency response community.	• Competition from private sector • Inability to keep pace with updated standards • Limited funding required to set up the lab to perform Non-Respirator PPE. • New facilities or rental facilities to conduct the testing and certification of Non-Respirator PPE not being adequate for other PPE Types. • NIOSH or NIOSH-NPPTL outreach being stonewalled or blocked from participating and actively pursuing sole or joint objectives related toward the advancement of public health and safety in the production of the next generation of PPE for use by all or specific types of workers/responders • NIOSH not present at key sister federal agency budget forecast meetings and resulting in NIOSH or NIOSH-NPPTL not being allocated sustainment or improvement funds for PPT certification development.

Challenge *(IOM Recommendation)* 1.0 Implement and sustain a comprehensive National Personal Protective Technology program.	
Issue 1.3 Certification for all PPT, with the exception of respiratory protection, is not a federal requirement. As a result, certification of all PPT to enable users to know that products have been thoroughly tested and comply with state of the art performance standards is not available.	
Desired Outcome (*Change necessary to address the issue)* 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.	
Activity Output Goal *(Brief and concise actionable solution to address issue)* 1.3.1 Lead the development and implementation of a strategy for non-respiratory PPE certification.	
Key Success Indicators ***(KSIs)(Performance Measures)***	NIOSH is collaborating with 3rd party laboratories and other govt. agencies to certify non-respiratory PPE. Standard Test Procedures developed and verified to certify non-respiratory PPE.
Potential Benefits to the Organization: *(impact and relevance)*	Impact: All PPT/PPE will be thoroughly tested and comply with safe performance standards as respirators . Relevance: All PPE is certified by a Primary National and International Certification Lab for conformance to standards developed and performance of the product.
Linkage to organizational strategic goals: (all NIOSH sector and cross sector) PPT Program Strategic Goals 1-3	

Action Step 1.3.1.1 Conduct an Institute of Medicine (IOM) Workshop through the Committee on PPE for the Workforce (COPPE) to initiate a strategy for other than respirator PPE certification.	
Action Step Summary *(3-5 Sentence Description)*	A workshop similar to the PPE for HCW workshop will be organized by IOM to address options for PPT certification. The workshop discussion will include strengths and weaknesses for the various certification options to include: government certification testing (e.g., respirators), testing in government-approved labs (e.g., bulletproof vests), third-party testing (e.g., personal flotation devices), and other options. An output of this workshop will be a report with options and recommendations for non-respiratory PPT certification. The workshop is anticipated to be an FY 2010 activity.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	A strategic plan in place to implement certification for other than respirators. Establishment of at least one PPT Program for PPE certification.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Manpower: 1 – ADS, Director, Deputy Director, TEB personnel to participate in workshop Third party laboratories and other federal laboratories Budget Total: $350,000 for IOM workshop and support; Equipment: none.
Implementation Timeframe	Yrs 0-1: Conduct IOM Workshop to identify issues and provide recommendations. Yrs 1-2: Digest IOM report and identify partners to collaborate on implementation.
Responsible Parties	NPPTL – ADS: Lead IOM Workshop and Action Plan development in collaboration with partners and appropriate internal personnel

Action Step 1.3.1.2 Develop an implementation plan for addressing the recommendations in the IOM Report on Non-respiratory PPT Certification.	
Action Step Summary *(3-5 Sentence Description)*	The implementation plan will include options for PPT in-house expansion, options for certification through third party labs and alternative arrangements for certification such as collaboration between the PPT Program and an established COE. The objective is to lead the development of a national strategy for PPE/PPT Certification.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	Establishment of at least one third party lab for PPE certification or enhanced capacity in an existing federal laboratory.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Manpower: 1- General Engineer; 1- Laboratory Technicians Budget Total: $150,000 / year Equipment: $100K intramural use.
Implementation Timeframe	Yrs 2-3: Start after completion of action step 1.3.1.1 Yrs 3-4: Auditing Onsite of Third Party Laboratories prior to being accepted by NIOSH as a certifying Authority. Select and chose a PPE for certification. Start process to establish a lab to support non-respiratory PPE certification. Yrs 4-5: Contract with laboratories and/or establish some in-house capability to perform the certification of the product or perform testing of the product or begin construction of federal lab capacity. Develop a baseline for all test procedures.
Responsible Parties	NPPTL -- Physical scientist or General Engineer: Lead the collaboration and concept development. NPPTL -- Laboratory Technicians: Develop test procedures Perform certification as per Standard Test Procedures Contractor – run extramural lab This action step is contingent upon a funding increase.

Appendix F: Action Planning Issue 3.6

Challenge:			
Enhance the Respirator Certification Program			
Issue:			
Stakeholders and end users have shown a desire for NIOSH to provide certification test data to enable end users to make an informed decision when purchasing and selecting respirators.			
Desired Outcome:			
Establish a transparent process to increase end user confidence in respirator performance.			
Current Conditions :			
Current certification test criteria are developed to evaluate and determine if a respirator passes minimum and maximum limits which have been established by public comment and rulemaking. The passing of certification testing required for an approval is presumed sufficient evidence that the respirator fills the minimum requirements of the appropriate functional class. The standard test procedures (STP) are complex and the numerical test data are difficult to interpret independent of other criteria. A significant amount of certification test data is presented as pass/fail	Certification test data is proprietary to the manufacturer and not available through FOIA. There are a number of requests for information through this FOIA process. Ref: Freedom of Information Act (NIOSH FOIA Standard, allowable documents)	NIOSH currently has limited data on evaluating life cycle performance of respirators and publishes results from only the SCSR and Fire Fighter Equipment Evaluation programs. Ref: Fire Fighter Fatality Investigation and Prevention Program (Fire Fighter Equipment Evaluation Reports) Long Term Field Evaluation Program (SCSR evaluation Reports)	Technology Research Branch (TRB) releases comparison research data in some publications. Ref: TRB Project Portfolio TRB Project Reports/Publications
42CFR Part 84 (Subparts H, I, J, K, L, N and KK, respirator minimum requirements) Standard Test Procedures (STP's)	42CFR Part 84 (84. 31 (e), test data release limitations, 84.65 (d), documents to be held as confidential)		

(all procedures list minimum, maximum or passing requirements) Standard Application Process (Section E , Respirator Test Selection Guide) Brain Storming Session (Challenge #3, Issue D, Test are pass/fail and not compared to other respirators)	Brain Storming Session (Challenge #3, Issue D, FOIA Officer)		

Consequences:

Selected Researchers could benefit if they understood and had access to certification test data but those parties who don't understand STP's and the interpretation of that data would also have access to certification test data and allow them to misrepresent the data. Due to the demand on available resource, providing certification test data to manufacturers would strain the certification program.

Challenge:

Enhance the Respirator Certification Program

Issue:

Stakeholders and end users have shown a desire for NIOSH to publicize the numerical data generated during the certification testing of respirators to the general public.

Desired Outcome:

Establish a transparent process to increase end user confidence in respirator performance.

Current Conditions :

Some stakeholders suggest that end users would benefit from a comparative rating of specific respirators within the same classes of respirator performance.	The current information dissemination does not adequately inform users of the most suitable respirator for their circumstances.		

42CFR Part 84			

Consequences:

Selected Researchers could benefit if they understood and had access to certification test data but those parties who don't understand STP's and the interpretation of that data would also have access to certification test data allowing them to misrepresent the data. Due to the demand on available resource, providing certification test data to manufacturers would strain the certification program.

Challenge: Enhance the Respirator Certification Program

Issue: Stakeholders and end users have shown a desire for NIOSH to publicize the numerical data generated during the certification testing of respirators to the general public.

	Strengths	***Weaknesses***
Internal	Part of system which supports and prevents misleading advertising. Follows process where Policy and Standards sets specific test criteria through public rule making which results in interdependent parameters. Certification test data is protected to ensure an unbiased certification process. Allows manufacturers to experiment with new approaches without fear of data being seen by competitors. NIOSH Certification testing has more credence than third party entity that performs respirator evaluations.	Perception by some stakeholders that respirator selection would be enhanced through access to the certification test data.
	Opportunities	***Threats***
External	Expand on the NIOSH International Brand Recognition. Emerging health threats which affect respirator use Terrorist attack Expanding Government Requirements calling for NIOSH Certified Respirators	NIOSH would lose credibility. System designed to prevent misleading advertising would be subverted. Certification process would be in chaos. Manufacturers may choose to avoid NIOSH approval in order to protect new technologies and approaches. Public rule making process could be jeopardized. No logical end to requests for specific data Increased cost to NIOSH to support certification testing.

		Economic Impact Funding affected by Congress Negative Stakeholder Perception and dissatisfaction

<table>
<tr><td colspan="2">Challenge (IOM Recommendation)
3.0 Enhance the Respirator Certification Program</td></tr>
<tr><td colspan="2">Issue
3.6 Stakeholders and end users have shown a desire for NIOSH to provide certification test data to 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 because respirator test facilities are not designed for comparative testing, service life and penetration testing stop when specified result is achieved, and test data is proprietary to the manufacturer and may not represent actual results under use conditions. Currently, there are no means to perform comparative respirator testing outside of the Testing and Evaluation Branch by organizations with test facilities designed for this purpose or gather stakeholder/end user feedback on respirator performance.</td></tr>
<tr><td colspan="2">Desired Outcome (Change necessary to address the issue)
Establish a transparent process to increase end user confidence in respirator performance.</td></tr>
<tr><td colspan="2">Activity Output Goal (Brief and concise actionable solution to address issue)
3.6.1 Expand the Technology Research Branch’s role to obtain quantitative certification test results to compare performance indicators of in-class respirators.</td></tr>
<tr><td>Key Success Indicators
(KSIs)(Performance Measures)</td><td>Identification of the NIOSH respirator certification tests that can provide useful quantitative test data for comparisons of respirators.

Identification of lifecycle respirator parameters.

Implementation of a program that results in the dissemination of comparative in-class respirator performance and/or lifecycle respirator parameter data.

The existence of an in-class respirator performance indicator and/or lifecycle respirator parameter database.

Receive and tabulate feedback from stakeholders/end users regarding satisfaction/dissatisfaction with comparative in-class respirator performance indicator and/or lifecycle respirator parameter database.

Usage of comparative in-class respirator performance and/or lifecycle respirator parameter database by stakeholders/end users.</td></tr>
<tr><td>Potential Benefits to the Organization:
(impact and relevance)</td><td>Impact: Establishment of a procedure and mechanism to perform and document comparative in-class respirator performance testing.
Establishment of a procedure and mechanism to perform lifecycle respirator parameters testing.
Database of comparative in-class respirator performance and/or lifecycle respirator parameters for use by stakeholders/end users.
Introduce competition between manufacturers by providing performance measures.
Stakeholders/end users provided quantitative data for selection of respirators based on protection level and cost.

Relevance: Expand the Technology Research Branch’s role to conduct research in developing comparative matrices.
Through user selection of best-performing product, manufacturers will be induced to improve respirator performance.
Through usage of database, educate the consumer on the scope and meaning of “NIOSH Certified”.
Selected Researchers could benefit if they understood and had access to comparative in-class respirator performance and/or lifecycle respirator parameter data.
Assessment of life cycle performance of respirators can be performed with expansion in Technology Research Branch’s role.</td></tr>
</table>

Linkage to organizational strategic goals: (all NIOSH sector and cross sector)
SG-1, Reduce exposure to Inhalation Hazards

Action Step 3.6.1.1 Develop a program for the dissemination of comparative in-class respirator performance data.	
Action Step Summary *(3-5 Sentence Description)*	A mechanism for additional testing of respirators submitted for certification to permit in-class performance comparisons and/or lifecycle respirator parameter testing shall be developed. This shall be followed by development of a "draft" program describing the dissemination of comparative in-class respirator performance data and/or lifecycle respirator parameters by the Technology Research Branch. This program and NIOSH intentions for its implementation shall subsequently be presented to respirator manufacturers, stakeholders, and end-users to solicit input and collaboration. Finally, their feedback shall be incorporated and the dissemination of comparative in-class respirator performance and/or lifecycle respirator parameter data program shall be finalized.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	Identification of the NIOSH respirator certification tests that can provide useful quantitative test data for comparisons of respirators. Identification of lifecycle respirator parameters.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Manpower: Five (5) FTE at the following levels; General engineer (0.5), Physical Scientist (0.5), Management and Program Assistant (0.2), Administrative (0.2) General Engineers (2) Physical Scientists (1) Management and Program Assistant (1) Administrative (1)
Implementation Timeframe	Years: 0-1 Explore those test systems that can provide useful quantitative test data that permits the determination of performance ratings for comparisons of tested respirators. Identify lifecycle respirator parameters. Develop a mechanism for additional testing of respirators submitted for certification to permit in-class performance comparisons and/or lifecycle respirator parameter testing. Develop a "draft" program describing the dissemination of comparative in-class respirator performance and/or lifecycle respirator parameter data. Years: 1-2 Prepare "draft" dissemination of comparative in-class respirator performance data and/or lifecycle respirator parameter program for presentation to stakeholders. Present intentions to respirator manufacturers, stakeholders, and end-users to solicit input and collaboration. Conduct stakeholder meetings. Incorporate feedback and finalize the dissemination respirator data program. Develop final dissemination of comparative in-class respirator performance and/or lifecycle respirator parameter data program.

Responsible Parties	NIOSH – General engineer: Lead the dissemination respirator data program effort. Physical Scientist: Support the dissemination of respirator data program effort. Management and Program Assistant: Support the dissemination of respirator data program effort Administrative: Support the dissemination of respirator data program effort. External – NIOSH OD, CDC Leadership and Staff, HHS Leadership and Staff will be needed to support this effort. Manufacturer, stakeholder and end-user participation, feedback and follow-up on dissemination of respirator data program.

Action Step 3.6.1.2 Implement a comprehensive program to disseminate comparative in-class respirator performance data.	
Action Step Summary *(3-5 Sentence Description)*	The database for logging test results, setting up test laboratory space and the required utilities, and installation of respirator test systems into the test labs shall be performed. Standard operating procedures for the test systems and other documentation shall be prepared and approved. The program for dissemination of comparative in-class respirator performance and/or lifecycle respirator parameter data shall subsequently be implemented by first identifying and obtaining respirators to be tested. Testing of respirators shall commence and the building of the comparative in-class respirator performance and/or lifecycle respirator parameter database shall continue.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	Implementation of a program that results in the dissemination of comparative in-class respirator performance and/or lifecycle respirator parameter data.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Equipment: Computer and software to maintain data , test laboratory equipment, instruments, and supplies Manpower: Eleven (11) FTE at the following levels; General engineer (0.5), Physical Scientist (0.5), Computer Scientists (0.25) Engineering Technicians (0.75), Chemists (0.5), Administrative (0.2) General Engineers (2) Physical Scientists (1) Computer Scientist (1) Engineering Technicians (4) Chemists (2) Administrative (1)
Implementation Timeframe	Years: 2-3 Specify database and prepare data input/output procedures. Specify required test laboratories/components and laboratory procedures. Prepare test facilities/procedures for implementation. Establish stakeholders/end users' feedback process on data base use. Years: 3-5 Implement program for dissemination of comparative in-class respirator performance and/or lifecycle respirator parameter data. Perform testing of previously certified respirators and respirators submitted for certification to build database.

Responsible Parties	NIOSH – General engineer: Lead the dissemination of respirator data program effort. Physical Scientist: Support the dissemination of respirator data program effort. Computer Scientist: Perform database programming and support. Engineering Technician: Install, operate and maintain respirator test systems. Chemist: Install, operate, and maintain respirator test systems. Administrative: Support the dissemination of respirator data program effort. External – NIOSH OD, CDC Leadership and Staff, HHS Leadership and Staff will be needed to support this effort.

Action Step 3.6.1.3 Assess the effectiveness of the program to disseminate comparative in-class respirator performance data.	
Action Step Summary *(3-5 Sentence Description)*	The establishment of the comparative in-class respirator performance and/or lifecycle respirator parameter database shall be announced to the manufacturers, stakeholders and end users. The monitoring of the database usage shall commence and continue after the announcement. Manufacturer, stakeholder, and end user comments shall be received and categorized. Based on this information, the effectiveness of this effort shall be analyzed and assessed.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	The existence of an in-class respirator performance indicator and/or lifecycle respirator parameter database. Receive and tabulate feedback from stakeholders/end users regarding satisfaction/dissatisfaction with comparative respirator performance indicator and/or lifecycle respirator parameter database. Usage of comparative in-class respirator performance and/or lifecycle respirator parameter database by stakeholders/end users.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Equipment: Computer and software to maintain data, test laboratory equipment, instruments, and supplies Manpower: Five (5) FTE at the following levels; General engineer (0.5), Physical Scientist (0.5), Computer Scientist (0.2), Administrative (0.2) General Engineers (2) Physical Scientists (1) Computer Scientist (1) Administrative (1)
Implementation Timeframe	Years: 4-5 Announce the establishment of the comparative in-class respirator performance indicator and/or lifecycle respirator parameter database. Monitor database usage. Receive/categorize stakeholder/end user database usage comments. Analyze the effectiveness of this effort.
Responsible Parties	NIOSH – General engineer: Lead the dissemination of respirator data program effort. Physical Scientist: Support the dissemination respirator data program effort. Computer Scientist: Computer and software support. Administrative: Support the dissemination of respirator data program effort. External – NIOSH OD, CDC Leadership and Staff, HHS Leadership and Staff will be needed to support this effort. Manufacturer, stakeholder and end-users participation, feedback and follow-up on dissemination of respirator data program.

Challenge *(IOM Recommendation)* 3.0 Enhance the Respirator Certification Program	
Issue 3.6 Stakeholders and end users have shown a desire for NIOSH to provide certification test data to 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 because respirator test facilities are not designed for comparative testing, service life and penetration testing stop when specified result is achieved, and test data is proprietary to the manufacturer and may not represent actual results under use conditions. Currently, there are no means to perform comparative respirator testing outside of the Testing and Evaluation Branch by organizations with test facilities designed for this purpose or gather stakeholder/end user feedback on respirator performance.	
Desired Outcome (*Change necessary to address the issue)* Establish a transparent process to increase end user confidence in respirator performance.	
Activity Output Goal *(Brief and concise actionable solution to address issue)* 3.6.2 Establish a Center of Excellence outside of NIOSH to act as a third party entity that compares ergonomic respirator parameters and reports to the general public.	
Key Success Indicators ***(KSIs)(Performance Measures)***	Identification of ergonomic respirator parameters that can be qualitatively and/or quantitatively assessed. Identification of lifecycle respirator parameters. Implementation of a program that results in the dissemination of comparative in-class ergonomic and/or lifecycle respirator parameters. The existence of an in-class respirator comparative ergonomic and/or lifecycle respirator parameter database. Receive and tabulate feedback from stakeholders/end users regarding satisfaction/dissatisfaction with comparative ergonomic and/or lifecycle respirator parameter database. Usage of comparative in-class ergonomic and/or lifecycle respirator parameter database by stakeholders/end users.

Potential Benefits to the Organization: *(impact and relevance)*	Impact: Establishment of a "Center of Excellence" outside of NIOSH to assess respirator ergonomic and/or lifecycle (i.e., comfort, ease of use, design issues, etc.) parameters. Establishment of procedure and mechanism to perform and document comparative in-class ergonomic and/or lifecycle respirator parameter assessments. Database of comparative in-class ergonomic and/or lifecycle respirator parameters for use by stakeholders/end users. Improved product performance to be enjoyed by stakeholders/end users due to competition between manufacturers. Stakeholders/end users provided qualitative and/or quantitative data for selection of respirators based on ergonomics. Relevance: Expand NIOSH connection with respirator stakeholders/end users via extension through third party "Center of Excellence". Through user selection of most ergonomic product, manufacturers will be induced to improve ergonomic respirator parameters to be competitive with other manufacturers. Selected Researchers could benefit if they understood and had access to comparative in-class ergonomic and/or lifecycle respirator parameters. Assessment of life cycle performance of respirators could be performed with expansion in NIOSH-sponsored third party Center of Excellence.
Linkage to organizational strategic goals: (all NIOSH sector and cross sector) SG-1, Reduce exposure to Inhalation Hazards	

Action Step 3.6.2.1 Develop a program for the dissemination of comparative in-class respirator parameters.	
Action Step Summary *(3-5 Sentence Description)*	A mechanism for the logging and posting of public comments onto web-based communication centers such as a "message center" or "blog" shall be developed. This shall be followed by the development of a "draft" program describing the logging and posting of comparative in-class respirator performance information by stakeholders/end users using the web-based communication centers. This program and NIOSH intentions for its implementation shall subsequently be presented to respirator manufacturers, stakeholders, and end-users to solicit input and collaboration. Finally, their feedback shall be incorporated and the program finalized.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	Identification of the types of web-based communication centers that could permit logging and posting of comparative in-class respirator performance information by stakeholders/end users.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Manpower: Four (4) FTE at the following levels; General engineers (0.5), Computer Scientist (0.5), Management and Program Assistant (0.2) General Engineers (2) Computer Scientist (1) Management and Program Assistant (1)

Implementation Timeframe	Years: 0-1 Identify the types of web-based communication centers that can be established to permit the logging and posting of comparative in-class respirator performance information by stakeholders/end users. Develop a mechanism and procedures for the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center. Develop a "draft" program describing the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center. Years: 1-2 Prepare "draft" program describing the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center for presentation to stakeholders. Present intentions to respirator manufacturers, stakeholders, and end-users to solicit input and collaboration. Conduct stakeholder meetings. Incorporate feedback and finalize the program for the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center . Develop final program for the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center.
Responsible Parties	NIOSH – General engineer: Oversee the web-based respirator performance communication program effort. Computer Scientist: Provide support to the web-based respirator performance communication program effort. Management and Program Assistant: Support the General Engineer in oversight of the web-based respirator performance communication program effort. External – NIOSH OD, CDC Leadership and Staff, HHS Leadership and Staff will be needed to support this effort. Manufacturer, stakeholder and end-users participation, feedback and follow-up on the web-based respirator performance communication program.

Action Step 3.6.2.2 Implement a comprehensive program to disseminate comparative in-class respirator parameters.	
Action Step Summary *(3-5 Sentence Description)*	The database for logging test results, setting up test laboratory space and the required utilities, and installation of respirator test systems into the test labs shall be performed. Standard operating procedures for the test systems and other documentation shall be prepared and approved. The program for dissemination of comparative in-class ergonomic and/or lifecycle respirator parameter data shall subsequently be implemented by first identifying and obtaining respirators to be tested. Testing of respirators shall commence and building of the comparative in-class ergonomic and lifecycle respirator parameter database shall continue.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	Implementation of a program that results in the dissemination of comparative in-class ergonomic and/or lifecycle respirator parameters.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Equipment: Computer and software to maintain data , test laboratory equipment, instruments, and supplies Manpower: Two (2) FTE at the following levels; General engineer (0.5), Management and Program Assistant (0.2). Twelve (12) Center of Excellence Personnel (COE) at the following levels: COE Lead Engineer (0.75), COE Engineers (0.75), COE Computer Scientist (0.50) COE Engineering Technicians (0.75), Chemists (0.5), COE Administrative (0.2). General Engineers (1) Management and Program Assistant (1) COE Lead Engineer (1) COE Engineers (2) COE Computer Scientist (1) COE Engineering Technicians (5) Chemists (2) COE Administrative (1)
Implementation Timeframe	Years: 2-3 Specify database and prepare data input/output procedures. Specify required test laboratories/components and laboratory procedures. Prepare test facilities/procedures for implementation. Establish stakeholders/end users' feedback process on database use. Years: 3-5 Implement program for dissemination of comparative in-class ergonomic and/or lifecycle respirator parameter data. Perform testing of previously certified respirators and respirators submitted for certification to build database.

Responsible Parties	NIOSH – General engineer: Oversee the dissemination of comparative in-class ergonomic respirator parameter data program effort. Management and Program Assistant: Support the General Engineer in oversight of the dissemination of comparative in-class ergonomic respirator parameter data Program conducted by the Center of Excellence. External – COE Lead Engineer: Lead the dissemination of comparative respirator parameter data program effort. COE Engineer: Support the dissemination of comparative respirator parameter data program effort COE Computer Scientist: Perform database programming and support. COE Engineering Technician: Install, operate and maintain respirator test systems. COE Administrative: Support the dissemination of comparative respirator parameter data program effort. NIOSH OD, CDC Leadership and Staff, HHS Leadership and Staff will be needed to support this effort.

Action Step 3.6.2.3 Assess the effectiveness of the program to disseminate comparative in-class ergonomic respirator parameter data.	
Action Step Summary *(3-5 Sentence Description)*	The establishment of the comparative in-class ergonomic and/or lifecycle respirator performance database shall be announced to the manufacturers, stakeholders and end users. The monitoring of database usage shall commence and continue after the announcement. Manufacturer, stakeholder, and end user comments shall be received and categorized. Based on this information, the effectiveness of this effort shall be analyzed and assessed.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	The existence of an in-class respirator comparative in-class ergonomic and/or lifecycle respirator parameter database. Receive and tabulate feedback from stakeholders/end users regarding satisfaction/dissatisfaction with comparative ergonomic and/or lifecycle respirator parameter database. Usage of comparative in-class ergonomic and/or lifecycle respirator parameter database by stakeholders/end users.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Manpower: Two (2) FTE at the following levels; General engineer (0.5), Management and Program Assistant (0.2). Four (4) Center of Excellence Personnel (COE) at the following levels: COE Lead Engineer (0.5), COE Engineer (0.5), COE Computer Scientist (0.25), COE Administrative (0.2). General Engineers (1) Management and Program Assistant (1) COE Lead Engineer (1) COE Engineer (1) COE Computer Scientist (1) COE Administrative (1)

Implementation Timeframe	Years: 4-5 Announce the establishment of the comparative in-class ergonomic and/or lifecycle respirator parameter database. Monitor database usage. Receive/categorize stakeholder/end user database usage comments. Analyze the effectiveness of this effort.
Responsible Parties	NIOSH – General engineer: Oversee the dissemination of comparative respirator parameter data program effort. Management and Program Assistant: Support the General Engineer in oversight of the dissemination of comparative respirator parameter data Program conducted by the Center of Excellence. External – COE Lead Engineer: Lead the dissemination of comparative respirator parameter data program effort. COE Engineer: Support the dissemination of comparative respirator parameter data program effort COE Computer Scientist: Perform database programming and support. COE Administrative: Support the dissemination of comparative respirator parameter data program effort. NIOSH OD, CDC Leadership and Staff, HHS Leadership and Staff will be needed to support this effort. Manufacturer, stakeholder and end-users participation, feedback and follow-up on dissemination of respirator parameter data.

Challenge *(IOM Recommendation)* 3.0 Enhance the Respirator Certification Program
Issue 3.6 Stakeholders and end users have shown a desire for NIOSH to provide certification test data to 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 because respirator test facilities are not designed for comparative testing, service life and penetration testing stop when specified result is achieved, and test data is proprietary to the manufacturer and may not represent actual results under use conditions. Currently, there are no means to perform comparative respirator testing outside of the Testing and Evaluation Branch by organizations with test facilities designed for this purpose or gather stakeholder/end user feedback on respirator performance.
Desired Outcome (*Change necessary to address the issue)* Establish a transparent process to increase end user confidence in respirator performance.
Activity Output Goal *(Brief and concise actionable solution to address issue)* 3.6.3 Establish web-based communication centers through which stakeholders/end users can share qualitative respirator performance information gleaned from personal respirator use experiences.

Key Success Indicators ***(KSIs)(Performance Measures)***	Identification of the types of web-based communication centers that could permit logging and posting of comparative in-class respirator performance information by stakeholders/end users. Implementation of a web-based program that results in the communication of comparative in-class end-user respirator performance information between stakeholders/end users. The existence of comparative in-class stakeholder-/end-user generated respirator performance information data banks and their supporting web-based communication centers. Receive and tabulate feedback from stakeholders/end users regarding satisfaction/dissatisfaction with web-based communication centers and information databanks. Usage of web-based communication centers by stakeholders/end users.
Potential Benefits to the Organization: *(impact and relevance)*	Impact: Establishment of a procedure and mechanism to obtain and document comparative in-class respirator qualitative performance data generated by stakeholder/end users. Database of web-based stakeholder/end user qualitative assessments of in-class respirator performance based on stakeholder/end user personal experiences. Improved product performance to be enjoyed by stakeholders/end users due to competition between manufacturers. Stakeholders/end users provided qualitative data for assessment of respirators based on stakeholder/end user experiences. Relevance: Expand NIOSH connection with respirator stakeholders/end users via extension through web-based communication. Establishment of a database containing stakeholder/end user personal experiences with in-class respirators. Through user selection of most favorably rated product, manufacturers will be induced to improve respirator performance to be competitive with other manufacturers. Heighten stakeholder/end user awareness of NIOSH involvement in respirator product improvement.
Linkage to organizational strategic goals: (all NIOSH sector and cross sector) SG-1, Reduce exposure to Inhalation Hazards	

Action Step 3.6.3.1 Develop a program for the dissemination of comparative in-class respirator parameters.	
Action Step Summary *(3-5 Sentence Description)*	A mechanism for the logging and posting of public comments onto web-based communication centers such as a "message center" or "blog" shall be developed. This shall be followed by the development of a "draft" program describing the logging and posting of comparative in-class respirator performance information by stakeholders/end users using the web-based communication centers. This program and NIOSH intentions for its implementation shall subsequently be presented to respirator manufacturers, stakeholders, and end-users to solicit input and collaboration. Finally, their feedback shall be incorporated and the program finalized.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	Identification of the types of web-based communication centers that could permit logging and posting of comparative in-class respirator performance information by stakeholders/end users.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Manpower: Four (4) FTE at the following levels; General engineers (0.5), Computer Scientist (0.5), Management and Program Assistant (0.2) General Engineers (2) Computer Scientist (1) Management and Program Assistant (1)
Implementation Timeframe	Years: 0-1 Identify the types of web-based communication centers that can be established to permit the logging and posting of comparative in-class respirator performance information by stakeholders/end users. Develop a mechanism and procedures for the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center. Develop a "draft" program describing the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center. Years: 1-2 Prepare "draft" program describing the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center for presentation to stakeholders. Present intentions to respirator manufacturers, stakeholders, and end-users to solicit input and collaboration. Conduct stakeholder meetings. Incorporate feedback and finalize the program for the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center . Develop final program for the logging and posting of comparative in-class respirator performance information by stakeholders/end users using a web-based communication center.

Responsible Parties	NIOSH – General engineer: Oversee the web-based respirator performance communication program effort. Computer Scientist: Provide support to the web-based respirator performance communication program effort. Management and Program Assistant: Support the General Engineer in oversight of the web-based respirator performance communication program effort. External – NIOSH OD, CDC Leadership and Staff, HHS Leadership and Staff will be needed to support this effort. Manufacturer, stakeholder and end-users participation, feedback and follow-up on the web-based respirator performance communication program.

Action Step 3.6.3.2 Implement a comprehensive program to disseminate comparative in-class respirator parameters.	
Action Step Summary *(3-5 Sentence Description)*	Computer Scientists shall perform design and specification of the web-based communication centers that permit the logging and posting of comparative in-class respirator performance information by stakeholders/end users. This shall be followed by implementation of the program. Prior to the initial operation of the web-based communication centers, an announcement of the web-based communication centers' existence shall be made.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	Implementation of a web-based program that results in the communication of comparative in-class end-user respirator performance information between stakeholders/end users.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Equipment: Computers and software to maintain database Manpower: Five (5) FTE at the following levels; General engineers (0.5), Computer Scientists (0.5), Management and Program Assistant (0.2). General Engineers (2) Computer Scientists (2) Management and Program Assistant (1)
Implementation Timeframe	2-3 yrs: Specify web-based communication centers. Implement program for the logging and posting of comparative in-class respirator performance information by stakeholders/end users using web-based communication centers. Announce the existence of the web-based communication centers.
Responsible Parties	NIOSH – General Engineer: Oversee the web-based respirator performance communication program effort. Computer Scientist: Perform web-based communication center programming and support. Management and Program Assistant: Support the General Engineer in oversight of the web-based respirator performance communication program effort. External – NIOSH OD, CDC Leadership and Staff, HHS Leadership and Staff will be needed to support this effort.

Action Step 3.6.3.3 Assess the effectiveness of the program to disseminate comparative in-class ergonomic respirator parameter data.	
Action Step Summary *(3-5 Sentence Description)*	Monitoring of the web-based communication centers shall commence and continue. Stakeholder and end user comments shall be reviewed and categorized. Based on this information, the effectiveness of this effort shall be analyzed and assessed.
Key Success Indicators ***(KSIs)(Specific to Action Step)***	The existence of comparative in-class stakeholder-/end-user generated respirator performance information data banks and their supporting web-based communication centers. Receive and tabulate feedback from stakeholders/end users regarding satisfaction/dissatisfaction with web-based communication centers and information databanks. Usage of web-based communication centers by stakeholders/end users.
Resources ***(fiscal, manpower, external budget, infrastructure)***	Manpower: Three (3) FTE at the following levels; General engineer (0.5), Computer Scientist (0.5), Management and Program Assistant (0.2). General Engineer (1) Computer Scientist (1) Management and Program Assistant (1)
Implementation Timeframe	Years: 3-4 Monitor web-based communication centers' usage. Categorize stakeholders/end users' comments. Analyze the effectiveness of this effort.
Responsible Parties	NIOSH – General engineer: Oversee the web-based respirator performance communication program effort. Computer Scientist: Perform web-based communication centers' usage monitoring and reporting. Management and Program Assistant: Support the General Engineer in oversight of the web-based respirator performance communication program effort. External – NIOSH OD, CDC Leadership and Staff, HHS Leadership and Staff will be needed to support this effort. Manufacturer, stakeholder and end-users participation, feedback and follow-up on the web-based respirator performance communication program effort.