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CHAPTER 3 Reduce Exposure to Inhalation Hazards

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The Occupational Safety and Health Administration (OSHA) estimated, in the preamble to the 1998 final rule (63 FR 1152) for its respiratory protection standard (29 Code of Federal Regulations (CFR) 1910.134),[1] that 5 million workers wore respirators *at least some of the time while performing their job functions.* These workers were employed at approximately 1.3 million work establishments nationwide. This represents approximately 5% of all U.S. workers and about 20% of all work establishments. Approximately 900,000 of these establishments were determined to be "very small," i.e., having fewer than 20 employees.

OSHA's benefits analysis conducted in 1998 predicted that the standard would prevent many deaths and illnesses by protecting workers from exposure to acute and chronic health hazards. OSHA annual compliance estimates for the standard were an average of $22 per covered employee ($111 million total) in costs to avert hundreds of deaths and thousands of illnesses. In 1994, approximately 215 deaths, or 5% of all workplace fatalities, occurred as a result of exposure to harmful substances and environments. Also in 1994, 110 employees died from oxygen deficiency. OSHA stated that many of these deaths could have been prevented if employers had realized that respirators were needed. [2]

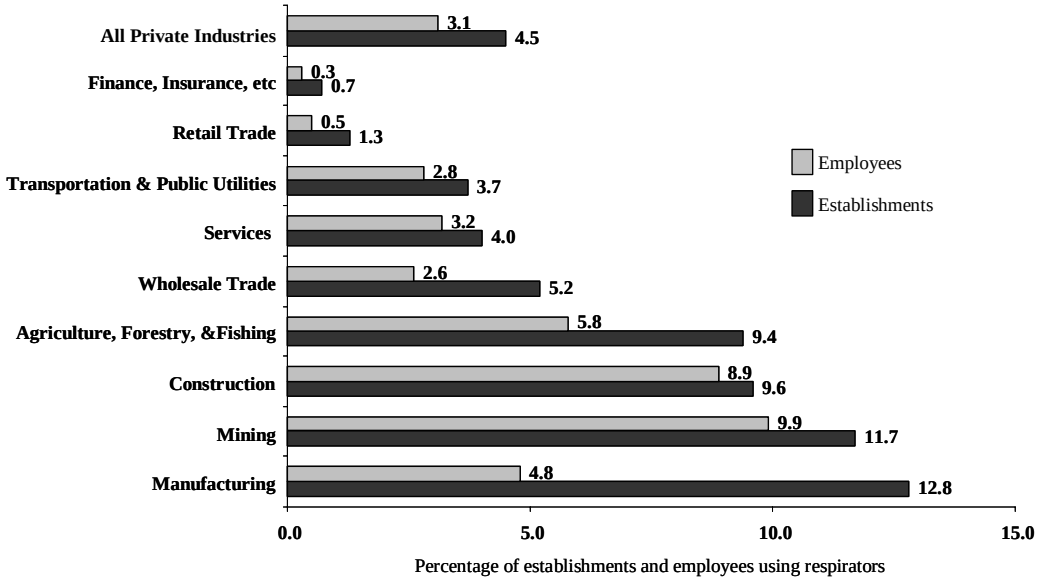
In August 2001, the National Institute for Occupational Safety and Health (NIOSH) and the Bureau of Labor Statistics (BLS) conducted a survey of respirator use and practices among private sector employers in the U.S. The results, methodology, and survey questionnaire were published in *Respirator Usage in Private Sector Firms, 2001* [3] The purpose of the survey was to gather information on respirator use and practices that could aid in guiding the Personal Protective Technology (PPT) Program respirator certification and research activities.

The 40,002 surveyed establishments were selected from a sample of 174,305 private sector establishments used in the 1999 BLS Survey of Occupational Injuries and Illnesses (SOII).[4] Most of the survey questions addressed respirator use that is "required" by regulation.[5] Survey questions were designed to gather information on types of respirators used, conditions under which respirators are used, the amount of usage by industries, and characteristics of respirator programs. The survey responses were used to estimate the numbers of establishments and numbers of employees who use respirators. Findings of the survey raise concerns that respirators are often not being used in the manner recommended by federal agencies. Proper respirator use could lead to decreased morbidity and mortality among workers.

Findings of the survey provide information on respirator use by private sector employers in the U.S. They show patterns of respirator use in the workplace and help identify research needed to improve respirator effectiveness and respirator training. There are, however, limitations to the data.

OSHA revised its estimates for respirator use in its 2006 final rule for Assigned Protection Factors (APF) for respirators used in accordance with the provisions of 29 CFR 1910.134. The newer estimates state that there were approximately 3.3 million respirator wearers at 281,776 work establishments *who regularly use respirators as a condition of their work*. OSHA cited the

NIOSH PPT Program co-sponsored 2001 NIOSH/BLS survey of respirator use in the private sector in the preamble discussion of that final rule. [3]



Note: Denominators are the BLS ES-202 estimates of the number of private-sector establishments or employees in each respective industry division

** "Services" has the highest number of employees using respirators (n = 1,160,300) and highest number of respirator-using establishments (n = 89,600).

Figure 3.1 - Employees and establishments with required respirator use by major industry division

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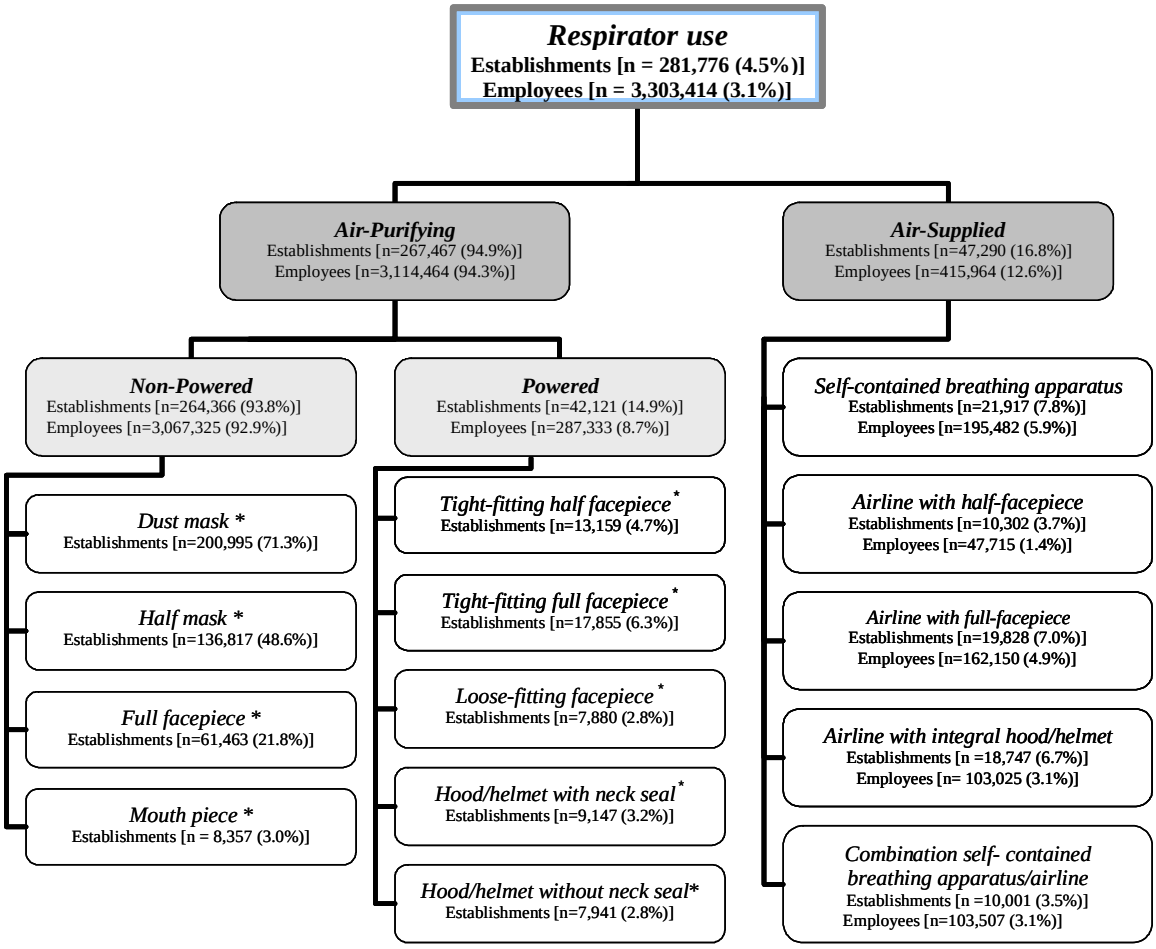
Figure 3.1 provides the percentage of employees and establishments using respirators based on the survey results published in the NIOSH/BLS study. [3] The results indicate that the services industry has the highest number of employees using respirators and the highest number of respirator-using establishments. These percentages do not reflect the respirator users in the public sector, the largest contingent of Chemical, Biological, Radiological, and Nuclear (CBRN) respirator users.

Many of the traditional, generally accepted practices on the proper use of respirators were based on common sense and good judgment instead of being science-based. The relatively few scientific studies that had been conducted in the decade prior to 2001 in some cases confirmed these beliefs, and in other cases, refuted them. Many principles of respiratory protection remain untested hypotheses that are often treated as facts.

The majority of the respirator standards and test procedures were developed prior to the creation of NIOSH's primary PPT Laboratory in Pittsburgh, and even predate the establishment of NIOSH. Often, aging standards actually prevent the introduction of new and advanced PPT into Personal Protective Equipment (PPE).

While the results provided in the NIOSH/BLS report provided important information regarding employer respiratory protection programs, there is a dearth of information providing insight into outcomes resulting from PPT Program activities.[6] The PPT Program realizes the importance of gathering measurable information that will focus on outcomes to inform the Program of research, policy and standards development, and certification gaps that should be filled by the program to effectively reduce exposures to inhalation hazards.



*Further breakdown is provided in *Respirator Usage in Private Sector Firms, 2001* [3]
Note: The percentages of establishments that use respirators do not add up to 100% because there can be more than one type of respirator used. The percentages for different types of respirator use are calculated using the total respirator use as the denominator. (establishments n = 281,776; employees n = 3,303,414).

Figure 3.2 - Respirator Types in Use in the United States, 2001

Figure 3.2 lists the types of respirators in each of the two categories and usage data. Respirators protect the user from exposure to inhalation hazards in two basic ways. The first is by removing contaminants from the air, classified as air-purifying respirators (APR). Respirators of this type include particulate respirators, which filter out airborne particles; and "gas masks" which filter out chemicals and gases. The filtering elements of APR must be removed and replaced as their capacity for removing contaminants from the air becomes consumed, unless the entire respirator is disposed. The second basic way that respirators protect the user is by supplying clean

respirable air from another source, classified as air-supplying respirators. Respirators that fall into this category include airline respirators, which use compressed air from a remote source; and self-contained breathing apparatus (SCBA), which include their own air supply.

Exposure to airborne hazards without proper respiratory protection can cause a number of diseases including tuberculosis, silicosis, asbestosis, chronic beryllium disease, lung cancer or hazards such as asphyxiation. Pneumoconiosis, a lung condition that caused more than135,000 deaths from 1968–2004, is one example of a disease that can be prevented, in part by the proper use of respirators.[7] Also, data for selected Standard Industrial Classifications taken from the OSHA database show that for 1993 more than 120,000 workers were estimated as being potentially exposed to crystalline silica at or above the NIOSH recommended exposure limit (REL).[8] Surveillance data estimate that silicosis has caused 16,641 deaths in the United States from 1968 to 2004.[7] Work by NIOSH investigators in the 1990s, including a series of field industrial hygiene studies in highway construction, documented gross overexposures to silica.[9, 10] The 2001 BLS/NIOSH respirator survey findings suggest that respiratory protection programs have widespread inadequacies – 96% of construction establishments with required respirator use had at least one indicator of a potentially inadequate respiratory protection program and 63% had at least five such indicators.[3]

When the National Personal Protective Technology Laboratory (NPPTL) was created in 2001, a core focus of its technical programs, as refined through its Strategic Planning activity, was to support the development, certification, deployment, and use of fully-integrated, intelligent personal protective ensembles for defined worker groups. Initial targets were emergency responders (including firefighters), miners, and healthcare workers. Ensembles for each of these worker groups must necessarily have a major component designed to provide respiratory protection. With this focus in mind, and building upon the long and successful history of its predecessor organizations in the area of respiratory protection, NPPTL thus defined its *first Strategic Goal as Reduce Exposure to Inhalation Hazards*.

An important aspect of the effort NPPTL placed on this goal (and its other two) was to ensure the development of a sound scientific basis for all recommendations and results from its activities. Other issues emphasized in 2001 were to develop engineering design criteria, new technologies, and new products. The PPT Program has taken a lead role and worked in partnership with academic institutions, and private and public sectors to develop new and emerging technologies and new products using innovative technologies.

NPPTL also conducted in 2001 a series of stakeholder meetings in support of its PPT Program. The intent was to define priority areas for its respiratory protection efforts. To prioritize research areas, the results from those meetings outlined a PPT Program that was pursued in six priority areas:

1) development, evaluation, and validation of performance tests;
2) face/size shape characteristics;
3) air purifying element;
4) respiratory physiology;
5) respirator use surveillance; and
6) recommendations for small businesses.

In response to continued interaction with stakeholders and numerous external factors, the list of priority areas has evolved to include:

7) CBRN protections;
8) nanotechnology initiatives;
9) pandemic influenza preparedness; and
10) improvements to mine escape respirators.

The PPT Program's efforts in these 10 priority areas have led to the definition of eight objectives. These are:

Objective 1 Ensure the integrity of the national inventory of respirators through the implementation of a just-in-time respirator certification process.

Objective 2 Develop CBRN respirator standards to reduce exposure to CBRN threats.

Objective 3 Ensure the availability of Mine Emergency Respirators for escape from mines.

Objective 4 Improve reliability and level of protection by developing criteria that influence PPE designs to better fit the range of facial dimensions of respirator users in the U.S. workforce.

Objective 5 Quantify the impacts of various PPE on viral transmission.

Objective 6 Evaluate the nanofiber-based fabrics and NIOSH-certified respirators for respiratory protection against nanoparticles.

Objective 7 Develop and make available end-of-service-life indicator (ESLI) technologies that reliably sense or model performance to ensure respirator users receive effective respiratory protection.

Objective 8 Gather information on the use of respirators in the workplace to identify research, intervention, and outreach needs.

The PPT program takes four tactical approaches for accomplishing the strategic goal of reducing exposure to inhalation hazards and its associated objectives. The four tactical approaches are:

- Conduct research on personal respiratory protective technologies,
- develop standards for personal respiratory protective equipment,
- certify and evaluate personal respiratory protective equipment, and
- conduct outreach programs for optimal use and acceptance of personal respiratory protective equipment by workers.

In 2007, the CDC initiated the Organizational Excellence Assessment (OEA) Performance measurement tool. Through this initiative, CDC is determining which objectives throughout the CDC should be measured. One key objective being evaluated under the OEA initiative is: "Expand our recognition, protect our credibility, and sustain the trust people have in us."

Respirator Certification is one of the NIOSH initiatives spotlighted in this CDC objective. The NIOSH Initiative is: *"Improve customer satisfaction with the NIOSH/NPPTL Respirator Certification Program, as measured by the Customer and Market Focus (CMF) Survey, specifically in the areas of Quality, Timeliness, and Recovery."*

This emphasis that NIOSH has placed on the respirator certification program demonstrates its importance within NIOSH and CDC, as well as the NIOSH commitment to enhancing and improving the PPT Program. This importance is echoed in the most recent National Academies report, [6], which states: "The panel is encouraged that the NPPTL leadership continues to place appropriate emphasis on its statutory mission of respirator certification, even as it enriches its program with attention to other objectives. It is proper to maintain this emphasis even as NPPTL moves forward in other areas." [6]

Another example of the emphasis for the PPT Program is the NIOSH PART performance measure relating to CBRN respirators. One of the NIOSH safety and health-focused goal for 2014 achievement is: 75% of professional firefighters and first responders have access to CBRN respirators.

The terms respirator certification and respirator approval are used interchangeably in this report.

Each of the eight objectives is described in the following sections of this chapter.

3.1 Ensure the Integrity of the National Inventory of Respirators Through the Implementation of a Just-in-Time Respirator Certification Process.

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Issue

A national inventory of respirators is needed to reduce exposure to inhalation hazards to protect workers. The integrity of this inventory must be assured so that the various types of respiratory devices required in different circumstances will perform as designed.

NIOSH is mandated by Congress to approve or certify respirators in accordance with the minimum requirements outlined in 42 CFR Part 84, 1996. This regulation requires that respirators submitted for evaluation against the terms of the standard must be accompanied by data that demonstrate the respirator under evaluation meets or exceeds the performance requirements described in the standard. Once certified, the quality assurance requirements of the standard require an ongoing effort by the approval holder for the purpose of assuring not only the material aspects, but the performance level of the certified product. Respirators are processed in a first-in first-out mode of operation within 90 days.[11]

Background

NIOSH is responsible for directing and conducting the respirator certification activity and its related laboratory, field, quality, and research functions.[12] NIOSH has administered the respirator certification program since 1972 and traces its origins to the early years of the U.S. Bureau of Mines (USBM). The requirements of this activity, which define the process that the PPT Program follows in carrying out its authority, are set forth in 42 CFR Part 84.[13] The PPT Program now has exclusive authority for the testing and certification of respirators with the exception of certain mine emergency devices, which continue to be jointly certified by the PPT Program and the Mine Safety and Health Administration (MSHA).

Under the activity, respirator manufacturers may voluntarily request NIOSH certification for a new product. The PPT Program conducts laboratory testing of sample units, reviews the technical specifications for the product, and evaluates the manufacturer's quality assurance program. If a respirator passes this testing and evaluation, NIOSH grants permission for the device to be labeled as "NIOSH certified." This certification means that, based on the results of the NIOSH testing, the device is expected to perform as it purports to perform, if deployed and used appropriately as part of a formal workplace safety and health program, and in accordance with the manufacturer's instructions.

The respirator certification activities of the PPT Program comprise approximately 30% of the $13.1 million PPT Program budget for fiscal year 2007. This budget allocation demonstrates the commitment of the PPT Program to its respirator certification activity.

Approach

The PPT Program respirator certification activity consists of five distinct sets of functions designed to assure the integrity of the national inventory of respirators: application processing,

respirator testing, quality assurance plan evaluation, product and site audits, and respirator equipment evaluations.

Application Processing

Application processing entails ensuring that manufacturers who submit applications to obtain a respirator certification comply with the requirements described in 42 CFR Part 84.[13] This is assured by first verifying that the application contains all required components, including results of applicant pre-testing of the proposed design, as well as sample units for verification testing in the PPT Program laboratories.

A manufacturer submitting an application for approval must first obtain a manufacturer code to validate the quality assurance of the manufacturing facility. The procedures for registering as a manufacturer and submitting applications to have products certified by the PPT Program are described in Appendix U. If the information submitted by the manufacturer in an application is incomplete, the PPT Program has determined that it is more efficient to work with the manufacturer to document the changes required rather than simply to deny the application. Once the application is complete, accurate, and verified, the manufacturer is issued a manufacturer code. A manufacturer may then submit applications for product certification evaluations.

The type of application received determines how the information is processed through the PPT Program. The eight workflows in Appendix U document PPT Program activities in respirator certification to generate an output of either affirmative certification notification or negative (denial or rejection) certification notification. The PPT certification program currently has approximately 90 active approval holders, with slightly more than 100 manufacturing sites worldwide.

The PPT Program electronically tracks the processing of manufacturers' applications for certification, and monitors the monthly completion of applications. Completed applications for configurations that meet all the applicable requirements result in the certification of new or modified respirator configurations being added to the inventory of NIOSH-certified respirators. Applications with configurations that fail to qualify for approval are denied.

Respirator Testing and Quality Assurance (QA) Plan Evaluation

The PPT Program scientists conduct parallel activities of respirator testing and quality assurance plan evaluation. The respirator testing step is designed to ensure that the submitted respirator meets the performance requirements identified in the Standard Test Procedures (STPs) developed and used by the PPT Program.[14]

To facilitate the application process, the PPT Program maintains an online resource that houses all of the STPs used for its testing of various respirator types. This resource was made available after manufacturers suggested through public and manufacturer meetings that the PPT Program make STPs available to provide the procedures necessary to reproduce the tests prior to their submitting certification applications. A customer satisfaction survey conducted in 2005 in which manufacturers expressed a desire to have the STPs available to them confirmed this need. All

current PPT Program STPs were posted in the spring of 2006. Since the posting of the STPs, the PPT Program has received more than 4,600 website inquiries to the STPs.

In parallel with respirator testing, the PPT Program conducts an evaluation of the manufacturers' QA program to assure the manufacturer has provisions in place to sustain the quality of its manufactured equipment, if and when the PPT Program grants its approval.

Product and Site Audits

To ensure the manufacturers comply with the QA provisions required by 42 CFR 84,[13] the PPT Program monitors the manufacturers through a systematic quality audit program. The quality audit program uses periodic audits to ensure that manufacturers continue to meet their documented manufacturing quality system and product performance requirements as indicated in an approval. An approval issuance authorizes the production and sale of respirators represented as NIOSH-certified. The availability of additional choices of respirators to protect users against the exposures for which the approval is granted and the resultant additional production capacities represent an increase in the national inventory of respirators. The audit program assures the integrity of the NIOSH label by verifying the distributed respirators continue to meet the NIOSH performance standards.

The current program provides on-site quality audits of the manufacturing processes and facilities at each location every 2 years. The only exception to this is that mine escape respirator manufacturers are audited yearly. Generally, 40-50 manufacturing site audits, including follow-up on discrepancy resolutions, are completed per year.

The PPT Program routinely obtains samples of certified respirators from normal sales and distribution sources for product auditing. A sufficient quantity and variety of products are generally obtained to constitute 40 to 60 product audit evaluations per year. The PPT Program uses an audit selection logic to select products for audit. It is designed to include products with a wide range of usage and those demonstrating factors that increase the risk of not meeting the minimum performance for targeted certification tests.

The PPT Program also conducts a mining-specific Long-Term Field Evaluation (LTFE) product auditing program for escape respirators used in mine emergencies. The LTFE evaluations are presented in Section 3.3 with the discussion of the mine emergency respirators.

Respirator Equipment Investigations

Since July 1, 1982, the PPT Program has investigated reports of problems with MSHA/NIOSH- and NIOSH-certified respirators. These reports are from PPT Program audits of certified respirators, regulatory agencies, users and respirator manufacturers.

The source of an investigation can be a complaint from a user (e.g., email, phone, or letter), a problem discovered during evaluation activities in another part of the PPT Program (e.g., LTFE, certification, product audit), or part of an incident investigation in the NIOSH Fire Fighter Fatality Investigation and Prevention Program (FFFIPP).[15] The PPT Program and the

manufacturers work closely to resolve and correct performance failures and other issues associated with a product. The PPT Program is receptive and responsive to user inquiries. Investigations have been systematically tracked since 1994, and over 400 investigations have been conducted as of August 2007.

The primary role of the PPT Program in a problem report investigation on a NIOSH-certified respiratory product is to validate the report through testing, followed by monitoring the manufacturer's corrective actions, if any are required. If the manufacturer cannot appropriately resolve the problem on its own, then the PPT Program will offer technical assistance.

In those rare circumstances where the identified problem has not been resolved, the PPT Program will take appropriate actions contained within its powers. Such actions include requiring the manufacturer to recall or appropriately retrofit its products, or requiring the manufacturer to stop the sale of the product as being NIOSH-certified.

The authority to revoke a certification for cause is provided in 42 CFR Part 84.[13] Revocation or rescission removes the NIOSH-approved status from all respirators produced under that certification, as well as removing authorization for the continued production and distribution as approved respirators.

Recall and retrofit are tools that are not specifically identified in the regulations, but have been developed by the PPT Program. These tools allow a manufacturer to implement an appropriate corrective action to remedy identified problems, thereby avoiding the need for revocation of the approval.

As part of its equipment evaluation function, the PPT Program participates in and contributes to the NIOSH FFFIPP. It participates by evaluating dead or injured fire fighters' SCBA obtained from events under investigation. The PPT Program conducts these activities within the CPIP at the request of the principal NIOSH investigators of the FFFIPP, other investigative authorities, or the affected fire departments. These investigations are normally requested unless the circumstances clearly demonstrate that the performance of the respirator could not have been a factor in the incident under investigation.

Each investigation can involve the evaluation of a single fire fighter's or multiple fire fighters' SCBA, depending on the magnitude of the event under investigation and the number of units whose operational condition has been questioned. The PPT Program submits a written report to the NIOSH FFFIPP at the close of its investigation, which is then appended to the main FFFIPP report. The equipment evaluation for the FFFIPP investigation is videotaped. The videotape is archived in PPT Program files.

Table 3.1.1 - Respirator Certification by Category and Calendar Year (thru Aug 17, 2007)

	13F - Self Contained Breathing Apparatus (SCBA)	CBRN Self-Contained Breathing Apparatus (SCBA) / Sub Category of 13F	14G - Gas Masks	CBRN Air Purifying Respirators (CBRN/APR) / Sub category of 14G	CBRN Air Purifying Respirators (CBRN/APER) / Sub category of 14G	19C - Supplied-Air Respirators (SAR)	21C - Particulate Respirators	23C - Chemical Cartridge Respirator	23C - Chemical Cartridge Respirator (CBRN Loose Fitting PAPR) Sub Category of 23C	84A - Particulate Filter Respirator	Total per Year
1972	0	0	0	0	0	0	4	0	0	0	4
1973	5	0	0	0	0	1	2	10	0	0	18
1974	13	0	4	0	0	10	15	23	0	0	65
1975	20	0	5	0	0	16	20	34	0	0	95
1976	12	0	1	0	0	5	16	33	0	0	67
1977	5	0	3	0	0	7	6	47	0	0	68
1978	6	0	13	0	0	17	11	34	0	0	81
1979	6	0	1	0	0	8	15	47	0	0	77
1980	5	0	2	0	0	10	10	43	0	0	70
1981	10	0	5	0	0	9	19	38	0	0	81
1982	13	0	2	0	0	8	18	100	0	0	141
1983	22	0	7	0	0	9	26	69	0	0	133
1984	36	0	7	0	0	21	30	97	0	0	191
1985	14	0	5	0	0	18	28	55	0	0	120
1986	15	0	6	0	0	7	36	104	0	0	168
1987	17	0	12	0	0	23	50	72	0	0	174
1988	6	0	1	0	0	16	52	60	0	0	135
1989	13	0	14	0	0	16	31	52	0	0	126
1990	13	0	1	0	0	8	24	82	0	0	128
1991	12	0	3	0	0	16	42	165	0	0	238
1992	16	0	1	0	0	8	41	128	0	0	194
1993	28	0	3	0	0	5	17	77	0	0	130
1994	27	0	4	0	0	6	54	185	0	0	276
1995	23	0	11	0	0	21	21	121	0	162	359
1996	33	0	11	0	0	25	4	77	0	1035	1185
1997	18	0	28	0	0	1	11	77	0	1290	1425
1998	34	0	16	0	0	12	4	50	0	358	474
1999	13	0	6	0	0	30	10	95	0	240	394
2000	15	0	6	0	0	6	5	64	0	214	310
2001	5	0	3	0	0	2	6	58	0	362	436
2002	22	3	3	0	0	0	4	33	0	181	246
2003	22	12	0	0	0	1	7	33	0	114	189
2004	1	21	0	2	0	9	4	16	0	137	190
2005	6	0	3	3	3	13	8	48	0	82	166
2006	4	0	2	1	1	5	12	14	0	99	138
2007	10	0	1	3	0	0	2	6	2	66	90
Totals - 081707	520	36	190	9	4	369	665	2247	2	4340	8382
Obsolete	66	0	27	0	0	71	489	370	0	437	1460
Active	454	36	163	9	4	298	176	1877	2	3903	6922
Total Active	490		176			298	176	1879		3903	6922

Output and Transfer Highlights

The number of respirator certifications issued since the inception of NIOSH totals more than 8,000. The distribution by respirator type is provided in Table 3.1.1. In reflecting the level of output from the PPT Program's certification activities, the table shows the output levels based on respirator type SCBA, Supplied Air (SAR or Airline), Particulate Filter (e.g., N95, P100), Particulate (e.g., Dust, Dust/Mist, high-efficiency particulate air (HEPA), etc.).

Certified Product Investigation Procedures are another significant output for the PPT Program. Table 3.1.2 reflects the number of CPIP investigations (including those as part of the NIOSH Fire Fighter Fatality Investigation and Prevention Program) conducted annually since FY01.

The investigations are grouped on the Fiscal Year (FY) basis, and the number of complaints received (opened) and completed (closed) are provided. A total of 33 investigations were carried into the program in 2001 when the Certified Product Investigation Process (CPIP) program was transferred to NPPTL.

Table 3.1.2 - Certified Product Investigation Process (CPIP), including Fire Fighter Fatality Investigation and Prevention Program Investigations conducted by Year (thru Aug 17, 2007).

Fiscal Year	Opened Total	Total Opened Minus FFFIPP	*FFFIPP Opened	Closed Total	Total Closed Minus FFFIPP	*FFFIPP Closed
FY 07	17	9	3	10	9	0
FY 06	32	26	6	37	36	1
FY 05	38	36	2	65	59	6
FY 04	37	33	4	23	19	4
FY 03	39	31	8	31	27	4
FY 02	51	46	5	39	37	2
FY 01	44	39	5	43	37	6
Totals	**258**	**220**	**33**	**248**	**224**	**23**

Over the past year, the PPT Program received more than 4,600 inquiries (including 1,100 to CBRN test procedures) to the PPT Program website where the Standard Test Procedures (STPs) used to conduct the tests for certifying respirators are available http://www.cdc.gov/niosh/npptl/stps/Respirator_Testing.htm. [14]

The Standard Application for the Approval of Respirators is available in downloadable form at http://www.cdc.gov/niosh/npptl/resources/certpgmspt/standardapp.html [16]

Table 3.1.3 - User Notices Distributed by Year (thru Aug 17, 2007)

Fiscal Year	# Issued	Rescind	Recall	Retrofit
FY 07	4	0	2	3
FY 06	16	4	2	11
FY 05	4	2	2	0
FY 04	0	0	0	0
FY 03	2	0	2	1
FY 02	5	2	1	3
FY 01	1	0	1	0
Totals	**32**	**8**	**10**	**18**

NIOSH issues user notices to inform users of a condition or risk that may exist with a NIOSH-certified product. Table 3.1.3 provides a summary of the number of user notices issued per year since FY01.

User notices are outputs of the CPIP activities and are distributed to inform potential users of corrective actions that need to be taken to resolve performance problems with NIOSH-certified respirators. User notices designed to implement corrective actions on identified units may be issued by NIOSH, the affected respirator's manufacturer, the component manufacturer if the problem is from a component from a manufacturer other than the respirator manufacturer, or a combination of the three. Distribution of the PPT Program user notices is through email, Internet postings on the PPT website, and, formerly, by mass mailings. User notices are posted at http://www.cdc.gov/niosh/npptl/usernotices/ .[17]

Generally, respirator and other PPE manufacturers do not have direct and documented seller-buyer relationships with their customers, and therefore are unable to identify customers to notify about problems needing correction. Directed distribution of user notices has been by email or mass mailing through distribution lists generated by the PPT Program. The user notices presented in Appendix O contain examples of the three corrective action possibilities, namely product recall, product retrofit, and certification rescission.

Intermediate Outcomes

Posting the Certified Equipment List (CEL)[18] on the NIOSH website increases users' knowledge about selecting and using appropriate respirators from among the national inventory of approved respirators for particular exposures. It also serves as an input to various PPT components, such as the health hazards evaluations and technical assistance activities and emergency and disaster preparedness that develop respiratory protection strategies and respirator recommendations to guide the appropriate identification and selection of available respirators.

Since 2001, several times annually, the PPT Program has issued a letter to manufacturers or interested parties providing information about the most recent posting of a concept that will affect PPT Program respirator standards and certification activities. A description of these letters is provided at Appendix P. For example, Total Inward Leakage (TIL) Criteria were posted on the

PPT Program website in May 2007. This posting and the letters to manufacturers and interested parties that provide updates regarding ongoing standards development activities can be found here: http://www.cdc.gov/niosh/npptl/resources/pressrel/letters/ .[19]

The PPT Program has a listserv to which it encourages intermediate customers to subscribe. Currently there are over 2,500 PPT Program listserv subscribers (including 286 manufacturers), representing 30 countries. Updates regarding PPT Program research, policy and standards, and respirator certification activities are sent to listserv members approximately monthly or when significant activities warrant announcing to the subscribers.

The Program's policy and standards development and respirator certification activities have led directly to an increase in the national inventory of CBRN capabilities to protect emergency response personnel against the respiratory hazards associated with terrorist events. Neither existing industrial nor military respirators provided protection from the entire range of potential CBRN agents.

Under federal regulations, emergency responders are required to use NIOSH-certified respirators for protection as part of their respiratory protection program.

As of December 2005, NPPTL estimated that at least 46% of career (trained professional) firefighters from fire departments classified as "all career" have CBRN respirators available.

PPT Program CBRN respirator standards were among the first adopted by the Department of Homeland Security (DHS). DHS now uses these standards to award grants for the purchase of PPE for the first responder community.

Use of NIOSH-certified CBRN respirators, as part of a personal protective ensemble, has been incorporated by the National Fire Protection Association (NFPA) into its NFPA 1500, 1991, and 1994 standards.[20-22]

Use of NIOSH-certified CBRN respirators by emergency responders has been endorsed by the InterAgency Board for Equipment Interoperability and Standardization (IAB).

NIOSH reclassification of filters available to the worker as specified in 42 CFR 84 [13] improved the ability of respirator program administrators to select the appropriate respirator to address their particular hazards. Workers are protected from respiratory hazards because of the availability of a wide range of respiratory protective equipment.

The CEL also serves as an intermediate outcome for the NIOSH Respiratory Disease Research Program components that develop respiratory protection strategies as an output to their activities, by making the selection of appropriate respirators available to users which results in reducing exposures. Those users include the investigators, responders and other Respiratory Disease Research Program personnel who are conducting their duties investigating the workplace hazards that are the subject of the research being conducted.

The issuance of NIOSH approvals for respirator configurations increases the national inventory of approved respirators from which selection for particular exposures can be made. It serves as an input to various RDR Program components, such as the health hazards evaluations and technical assistance activities and emergency and disaster preparedness that develop respiratory protection strategies and respirator recommendations as an output to their activities, by making the selection of appropriate respirators available

A selected listing of Internet website links maintained by private sector and public sector entities that reference products and/or services with a direct connection to the NIOSH PPT Program's outputs is provided in Appendix R. This listing demonstrates the impact of the respirator certification program, with an emphasis in the most recent protection, that of CBRN. This information was identified by conducting an internet search on NIOSH-Certified CBRN Respirators as well as by making contact with users at standards development organization committee meetings.

Appendix S provides a listing of responder organizations the PPT Program has been able to identify as purchasers of respiratory protection equipment made available as a result of the Program's certification. The acquisition of this equipment demonstrates a change in the operation for these responders and their organizations as a result of the Program's outputs.

Appendix T includes a selection of entities with Internet links demonstrating that they maintain a respiratory protection program to reduce their employees' exposures to inhalation hazards, or that they provide products and/or services to establish or maintain those programs. The listing is not intended to be comprehensive of all products or services available in the marketplace, but does serve as an indicator of the diversity of customers across the U.S. economy who are potential users of the outputs and outcomes derived from the PPT Program.

The Responder Knowledge Base (RKB)[23] is an independent but government-sponsored online database of first responder PPT and other equipment. The RKB places a heavy emphasis on product compliance with existing standards. It transfers PPT Program standards developments and product evaluations to end users. Products listed in the RKB are aligned with the both the authorized equipment list (AEL) set by Department of Homeland Security (DHS) and the standardized equipment list (SEL) established by the IAB.

The occupational safety and health authorities of Quebec, Canada have a legislative responsibility to publish an annual listing of respirators approved for workplace use in the Province of Quebec. This publication has the same contents as the NIOSH CEL, since NIOSH certified respirators are the required protection. The discontinuance of a printed version of the CEL after the 1992 revision resulted in non-compliance with this legislated requirement. The PPT Program responded to this international need by establishing a licensing agreement with the Canadian authorities. Under this agreement, the PPT Program will supply the database to them as needed, to allow them to fulfill their legislative requirement. In return, the PPT Program will receive the French-translated version of the CEL for distribution by NIOSH.

The framework established under this CEL licensing agreement can be used to establish additional licensing transfer mechanisms with other authorities allowing them to publish the CEL for their needs.

External Factors

The specter of a global pandemic influenza outbreak continues to loom as new avian flu cases are reported around the world. Public anxiety and preparedness activities for a pandemic are expected to grow as governments continue to issue new and updated guidance and recommendations for actions to be undertaken in the case of an outbreak. Since influenza is an airborne infectious disease, the PPT Program has a role in assuring the availability of appropriate means for respiratory protection against possible droplet and aerosol infectious particles. The projected consequences of a pandemic outbreak are expected to increase the PPT program's respirator group efforts in responding to:

- an increased application rate as manufacturers' seek certification of new respirator configurations incorporating innovative and novel PPT into their design, and
- the public's requests for information and guidance on selection and use of NIOSH-certified respirators.

External factors often impact the PPT Program respirator certification activity. Changes to the NFPA 1981 Standard on Open-Circuit SCBA for Emergency Services, 2007 Edition is an example.[24] Implementation of the NFPA standard requires that, after August 31, 2007, new SCBA compliant to NFPA must meet the requirements as contained in its 2007 Edition. NIOSH CBRN SCBA approval is required by the NFPA standard. During the spring and summer of 2007, the PPT Program received written inquiries from Senators Specter and Casey concerning the laboratories' ability to meet the certification timeline. Similarly, in a laboratory visit on April 30 and follow-up telephone conversation on June 13 with Congressman Murphy, certification actions to support the NFPA timeline were discussed. The PPT Program receives inquiries on an average of twice monthly from the media to discuss ongoing certification activities and respiratory protection research and policy and standards initiatives.

Another example of external influence is the August 2, 2007 letter from the U.S. Air Force requesting expedited testing of SCBA and Powered Air-Purifying Respirators (PAPR) to meet a vital need of the USAF war-fighter to provide firefighting and rescue capability.

What's Next?

In 2004, NIOSH initiated a TIL benchmark testing activity. This is designed to evaluate the leakage around the respirator faceseal to identify potential requirements for incorporation of particulate respirator testing in an effort to improve respirator design and fit. TIL is expected to strengthen the scientific basis on which the PPT Program recommendations for respiratory protection depend. The TIL program is establishing inward leakage performance requirements and laboratory test capability for testing of PPE, including all classes of respirators. Initially TIL is addressing half facepiece respirator requirements and testing. Other classes of respirators will be incorporated into the program following completion of the half facepiece project.

The Program is planning to update existing quality assurance requirements under 42 CFR Part 84 for the manufacture of all respirators certified by NIOSH. The proposed new requirements would require respirator manufacturers to be compliant with a widely adopted voluntary consensus standard for quality management systems, would update technical requirements particular to quality assurance for manufacturing of NIOSH-certified respirators, would establish requirements governing the related quality assurance oversight activities of NIOSH, and would allow NIOSH to charge fees for the direct costs for providing quality assurance audits and related testing services to respirator manufacturers.

The TIL program and quality assurance requirements updates are part of the Program's approach to update 42 CFR Part 84 using a modular rulemaking approach. Ultimately, this approach would establish new testing and certification requirements for all classes of respirators, replacing all performance testing and certification requirements of 42 CFR Part 84. Revising Part 84 to incorporate up-to-date requirements for respirator performance is a necessary step to facilitate progress in respirator manufacturing that has been achieved in other manufacturing concerns.

The PPT Program's respirator certification group has begun to experience an increase of applications for NIOSH certification of N95 filtering facepiece respirators (FFRs). This increase is a direct result of the anticipated and growing demand for N95 FFRs as a means of respiratory protection in case of a pandemic influenza outbreak. Many of these applications are from manufacturers who are located in Asia (predominately China) who have no prior experience interacting with the PPT Program. The respirator certification group has realigned resources to increase application processing capacity for FFRs to avoid extended delays. However, as concerns about the potential for an outbreak continue, the increase in applications is expected to accelerate.

The FDA's CDRH has recently finalized the criteria by which a NIOSH-certified N95 respirator can be granted pre-market clearance as a new class of medical devices for use by the general public in the event of an emergency such as a pandemic influenza. The performance and product labeling requirements for this product type require a new and increased level of coordination between the PPT Program's certification group and the FDA CDRH. This coordination will facilitate the simultaneous processing of applications for N95 respirator certification and for pre-market clearance.

Also as a consequence of the potential impacts of a pandemic influenza outbreak, the PPT Program's respirator certification group is preparing to ensure resources are available to accept and process applications for respirator certifications for new respirator designs using innovative technologies. These may include anti-microbial and filtration media based on nanoparticle construction.

Respirator certification within the PPT Program continuously strives to provide efficient processes for manufacturers to expedite availability of NIOSH certified respirators for the respirator user community. The respirator certification staff will continue to conduct manufacturer meetings twice annually to identify program areas for continual process improvement and to disseminate updated procedures to the manufacturer community. These meetings provide the manufacturers the opportunity to meet in person with the certification staff

and obtain clarification regarding procedures and recommendations regarding submission of applications for approval. In addition, these meetings encourage open dialogue between the manufacturers and PPT Program personnel.

Program improvement recommendations revealed at manufacturer meetings and identified through internal managerial self assessment will be explored further through a future Customer Satisfaction Survey (CSS) conducted by the U.S. Office of Personnel Management (OPM) scheduled to be conducted by December 2007. The PPT Program will continue to address the following issues based on manufacturer recommendations:

- Standard test procedures (STPs) will be updated and posted to the PPT Program website as they are completed. The STPs will be available here: http://www.cdc.gov/niosh/npptl/stps/respirator_testing.htm, [14]

- The application process for manufacturers will be continuously improved for efficiency of processing applications, integrity of implementing program requirements by increased test for extensions to approvals, and fairness in applying requirements with avenues for decision review (dispute resolution).

- A second manufacturer focus group will be conducted in FY08 to clarify manufacturer concerns identified in the December 2007 survey. The December 2005 survey is shown here: http://www.cdc.gov/niosh/npptl/pdfs/FinalManufacturerCSSsurvey.pdf, [25]

- Procedure for manufacturers' Dispute Resolution Procedure is expected to be implemented in fall 2007,

- The next survey will be conducted by December 2007 and concerns identified will be assessed and actions considered for improving targeted processes. Survey results from the 2005 survey are summarized in Appendix H. The Interagency Agreement (IA) established between the PPT Program and OPM to conduct the surveys and focus groups is provided in Appendix G.

List of Outputs

Peer Reviewed Publications

Kim, J., Jasper, W., Hinestroza, J. (2007) Probing Solvent-Induced Charge Degradation in Electret Fibers via Electrostatic Force Microscopy, Journal of Microscopy,20,1-8 [26]

Kim, J., Jasper, W. Hinestroza, J. (2006) Charge Characterization Of An Electrically Charged Fiber Via Electrostatic Force Microscopy. Journal of Engineered Fibers and Fabrics, 1,2, 30-46 [27]

Jasper W, Hinestroza J, Mohan A, Kim J, Shiels B, Gunay M, Thompson D, and Barker R: Effect of xylene exposure on the performance of electret filter media. Journal of Aerosol Science 2006, 37:903-911. [28]

Zhuang Z [2006]. Selection and use of NIOSH approved CBRN respirators. The Synergist – The Essential Connection for OEHS Professionals volume 17, No. 3, pages 39-40. [29]

Jasper W, Hinestroza J, Mohan A, Thompson D, and Barker R: Effect of phase of toluene on filtration performance of electret filter media against di-octyl-phthalate aerosols. Journal of the International Society for Respiratory Protection 2005, 22:97-105. [30]

Sinkule E, Turner N. Inhaled Carbon Dioxide and Oxygen Concentrations in Three Escape Hood Respirators During Rest and Exercise. *Medicine & Science in Sports & Exercise 36*: S245, May, 2004 [31]

Internal Investigation Reports

These reports were the results of firefighter investigations involving NIOSH-certified SCBAs. Units were found to be manufactured correctly and problems arose only when the equipment was not properly maintained or used. As part of the NIOSH respirator certification program, NIOSH performs post-certification testing and analysis on respirators that may be involved in injuries or that are suspected of not operating in the same manner as when they were originally certified.

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted By the Houston Fire & Arson Investigation Division Houston, Texas NIOSH Task No. TN-12192 [32]

Status Investigation Report of Two Self-Contained Breathing Apparatus Submitted By the St. Louis Fire Department St. Louis, Missouri NIOSH Task No. TN-12448 [33]

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted By the Anne Arundel County Fire Department Millersville, Maryland NIOSH Task No. TN-12598

Status Investigation Report of Nine Self-Contained Breathing Apparatus Submitted By the U.S. Department of Transportation Maritime Administration Washington, DC NIOSH Task No. TN-12442

Supplemental Status Investigation Report of Three Self-Contained Breathing Apparatus Submitted by the U.S. Department of Transportation Maritime Administration Washington, DC NIOSH Task No. TN-12442

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted By the Jefferson City Fire Department Jefferson City, Tennessee NIOSH Task No. TN-12428

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Greensboro Fire Department Greensboro, North Carolina NIOSH Task No. TN-12534

Status Investigation Report of Four Self-Contained Breathing Apparatus Submitted by the Coos Bay Fire Department Coos Bay, Oregon NIOSH Task No. TN-12789 [34]

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Pennsylvania State Police Dunmore, Pennsylvania NIOSH Task No. TN-12764

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Charlotte Fire Department Charlotte, North Carolina NIOSH Task No. TN-12790

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Sheboygan Fire Department Sheboygan, Wisconsin NIOSH Task No. TN-12588

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Oklahoma City Fire Department Oklahoma City, Oklahoma NIOSH Task No. TN-12410

Status Investigation Report of Three Self-Contained Breathing Apparatus Submitted by the Memphis Division of Fire Services Memphis, Tennessee NIOSH Task No. TN-12993 [35]

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Cincinnati Fire Department Cincinnati, Ohio NIOSH Task No. TN-12892 [36]

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the North Richland Hills Fire Department North Richland Hills, Texas NIOSH Task No. TN-12788

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Mecklenburg County Fire Marshal's Office Charlotte, North Carolina NIOSH Task No. TN-12763

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Ottawa Fire Service Ottawa, Ontario NIOSH Task No. TN-12931

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Broward County Medical Examiner's Office Fort Lauderdale, Florida NIOSH Task No. 13066

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Austin Fire Department Austin, Texas NIOSH Task No. 13074

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Philadelphia Fire Department Philadelphia, Pennsylvania NIOSH Task Number 13161

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the New Jersey Division of Fire Safety Trenton, New Jersey NIOSH Task No. 13458

Status Investigation Report of Two Self-Contained Breathing Apparatus Submitted by the Workers' Compensation Board of British Columbia Richmond, British Columbia NIOSH Task No. 13556

Status Investigation Report of One Self-Contained Breathing Apparatus Submitted by the Houston Fire Department Houston, Texas NIOSH Task No. 13617

Status Investigation Report of Two Self-Contained Breathing Apparatus Submitted by the Philadelphia Fire Department Philadelphia, Pennsylvania NIOSH Task No. 13705

Conferences and Presentations

A PPT scientist attended the American Industrial Hygiene Conference and Exposition in May 2004 in Atlanta, GA to serve as a panelist on the Round Table session 249 "Airflow Requirements for Respirators". A paper entitled "Physiological Aspects of Respiratory Protective Devices" was presented. [37]

Sinkule E, Turner N, Homeland Security – What Does It Take, (Presented at the thematic poster session for the Annual Meeting of the American College of Sports Medicine), Indianapolis, Indiana, June 2004).[38]

Sinkule, E., N. Turner, and S. Hota, Automated breathing and metabolic simulator (ABMS) CO2 test for powered and non-powered air-purifying respirators, airline respirators, and gas mask http://www.aiha.org/aihce03/handouts.htm, in American Industrial Hygiene Conference and Expo. 2003, American Industrial Hygiene Association: Fairfax, VA. p. 54.[39]

Website Postings

The Standard Application for the Approval of Respirators is available in downloadable form at http://www.cdc.gov/niosh/npptl/resources/certpgmspt/standardapp.html [16]

Standard test procedures (STPs) are available and will be updated and posted to the PPT Program website as they are completed. The STPs will be available here: http://www.cdc.gov/niosh/npptl/stps/respirator_testing.htm, [14]

Meetings

PPT scientists and managers provided multiple presentations to National Academies in support of Committee on Personal Protective Equipment (COPPE) activities. Since 2005, more than 10 committee meetings have been supported by at least three PPT Program researchers and managers

Information Regarding NIOSH Certified Respirators

The PPT Program transfers information about the respirator certification program, and makes much of this information on the Program's internet site. This information transfer provides easy access to information regarding NIOSH certified respirators for users, manufacturers and all stakeholders. Notable examples of information included provided to stakeholders in this manner are listed below:

Respirator User Selection and Use Guidance

NIOSH Respirator Selection Logic 2004
DHHS (NIOSH) Pub. No. 2005-100
http://www.cdc.gov/niosh/docs/2005-100/default.html
The RSL provides a process that respirator program administrators can use to select appropriate respirators to protect workers in specific workplaces. Replaces the NIOSH Respirator Decision Logic (NIOSH Publication No. 87-108), and includes information on N-95 through P-100 particulate respirators.[40]

NIOSH-Approved Disposable Particulate Respirators (Filtering Facepieces)
http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/
This link provides a listing of NIOSH-approved disposable particulate respirators that health care workers can use to help protect themselves from diseases potentially spread through the air, such as SARS or Tuberculosis.[41]

Certified Equipment List
http://www.cdc.gov/niosh/npptl/topics/respirators/cel/
The Certified Equipment List (CEL) is a searchable database of all NIOSH-certified respirators. Respirators can be identified through searches on type of respirator, type of protection, facepiece style, manufacturer, etc.[18]

Respirators: Your TB Defense / TB Respiratory Protection: Administrator's Review
DHHS (NIOSH) Publication No. 2002-114d. DVD.
http://www.cdc.gov/niosh/docs/video/tb.html
This guidance includes the programs 'Respirators: Your TB Defense', 'TB Respiratory Protection: Administrator's Review', and written materials in electronic format.[42]

NIOSH Pocket Guide to Chemical Hazards
DHHS (NIOSH) Publication No. 2005-149
http://www.cdc.gov/niosh/npg/default.html

PPT Program personnel served as members of the editorial board and contributed to the development of the pocket guide. The Pocket Guide is a source of general industrial hygiene information on several hundred chemicals/classes found in the work environment. Key data provided for each chemical/substance includes name (including synonyms/trade names), structure/formula, CAS/RTECS Numbers, DOT ID, conversion factors, exposure limits, IDLH, chemical and physical properties, measurement methods, personal protection, respirator recommendations, symptoms, and first aid.[43]

NIOSH Respirator User Notices
http://www.cdc.gov/niosh/npptl/usernotices/
NIOSH issues user notices to inform users of a condition or risk that may exist with a NIOSH-certified product.[17]

Guidance Documents for Respirator Manufacturer Interactions with the Certification Program

Standard Application Procedure, revised July 2005
http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/SAPJul2005.pdf
All information and forms needed for a respirator manufacturer to complete and submit an application for NIOSH approval of a respirator.[44]

Standard Test Procedures
http://www.cdc.gov/niosh/npptl/stps/Respirator_Testing.htm
Test procedures for all performance testing performed by NIOSH in the evaluation of respirators for NIOSH certification.[14]

NIOSH letters to all manufacturers and interested parties
http://www.cdc.gov/niosh/npptl/resources/pressrel/letters/
Since 2001, several times annually, the PPT Program has issued a letter to manufacturers or interested parties providing information about the most recent posting of a concept that will affect PPT Program respirator standards and certification activities.[19]

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3.2 CBRN Respirator Standards Development Back to the Table of Contents

Issue

The means to define the threat levels and identify standards needed to protect against CBRN threats is a clear need of any comprehensive respiratory protection program. Neither industrial nor military respirators provide protection from the entire complement of potential CBRN respiratory hazards.

The hazard to humans from release of a CBRN agent, including those associated with a terrorist incident depends upon the type and quantity of chemical material involved, its method of release, and its portal(s) of entry into the body. Chemicals can enter the body by ingestion, by absorption through the skin, through cuts and abrasions, or by inhalation; many CBRN agents can act through a combination of these portals of entry.

Every chemical has its particular physical, chemical, and toxicological properties and characteristics. Determination of the extent of the hazards must take account of many factors. The type of PPE necessary to ensure that the wearer does not suffer lasting harmful effects from exposure to the chemical compounds must consider all avenues of entry into the body.

Because chemical gas and vapors are considered more reactive than radiological and/or biological particles, the focus of the CBRN respirator testing has been on chemical agent vapor, aerosol, and liquid penetration and permeation effects.

Approach

In 1999, the PPT Program initiated a standards development effort for respirators used to protect against a full range of expected CBRN terrorist threats. It has led this effort by establishing partnerships with a wide range of organizations. Other Federal government agencies have been involved: OSHA, Department of Defense (DoD), FBI, NIJ, National Institute of Standards and Technology (NIST), and DHS. Respirator manufacturers and the International Safety Equipment Association (ISEA) have participated as members of the private sector. Emergency response organizations, including the International Association of Fire Fighters (IAFF), International Association of Fire Chiefs (IAFC), and the NFPA, all have made significant contributions to the effort. DHS has supported the effort by providing funds to support the development of CBRN standards. The PPT Program has collaborated with DoD (through an IA with the U.S. Army Research, Development and Engineering Command [RDECOM]), and with NFPA and the Safety Equipment Institute (SEI) to facilitate testing and certification of devices.

The PPT Program’s respiratory protection standard development for CBRN applications was accomplished using a publicly visible process that included seven major steps:

- Hazard analysis
- Operational requirements (including human and environmental factors)
- Protection requirements (use of air-purifying or supplied-air technologies)
- Standards requirements definition (standard concept)

- Federal Register Notices (FRN) announced the availability of draft concept requirements and standards for public comments
- Information was published on the NIOSH website and a docket established for comment submission. The PPT Program responded to public comments submitted through the docket by providing information to the public regarding the PPT Program approach for addressing the docket comments
- Public meetings were conducted an average of twice annually
- Test procedure and validation, including reliability and quality assurance requirement development

Specific actions taken by the PPT Program as it developed the CBRN standards are discussed below.

A NIOSH-DoD-OSHA-Sponsored Chemical and Biological Respiratory Protection Workshop planned and run by the PPT Program was held from March 10-12, 1999 in Morgantown, West Virginia.[45] At this workshop, attendees expressed the need for NIOSH-certified respirators that would provide adequate protection against chemicals released in a terrorist attack. The meeting clearly revealed that both chemical warfare agents (CWA) and toxic industrial chemicals (TIC) were of concern, particularly to first responders to such emergencies. It was expressed that military CWA would less likely be used in a terrorist event because CWA are tightly controlled and difficult to produce. It was concluded that TIC would more likely be used as a weapon because of their availability.

Based in part on the findings from the workshop, research, guidelines and standards were identified as needs for assessing chemical and/or biological concentration levels of response scenarios. Further, NIOSH certification of various respirators and PPE for use against these threats were addressed as requirements. Respiratory protection standards and certifications for SCBA, APR and PAPR, as well as for PPE were listed as immediate responder needs.

At the time, respirator standards to protect specifically against both military CWA and many TIC did not exist. The PPT Program and the Army's Soldier Biological and Chemical Command (SBCCOM, now the Army's RDECOM felt the initial step to developing respirator and other PPE standards was to identify the hazards posed to first responders in a nuclear, biological, and chemical (NBC) terrorist incident for both CWA and TIC and to estimate typical concentrations in selected venues. An Interagency Agreement (IA) between the two organizations established test procedures for various classes of respirators for use by first responders to incidents of terrorism.

Further in 1999 and 2000, The Office of Law Enforcement Standards (OLES) provided funding to the National Institute of Justice and Memorial Institute for the Prevention of Terrorism for parallel IAs with NIOSH (PPT Program) and SBCCOM. The purpose of the agreements was to support the joint development of CBRN respiratory device certification standards that would protect law enforcement and public safety emergency response personnel.

The PPT Program determined that to support this CBRN respirator standards development effort fully, it was important to also involve OSHA, NFPA, and NIST. This was to ensure that all

appropriate expertise within each of these additional organizations would contribute to the standards development activity. The result was a memorandum of understanding that defines each agency's role in developing, establishing, and enforcing standards or publishing guidelines for responder respiratory protective devices.

Additionally, the PPT Program funded the Rand Corporation to conduct focus groups with experts to identify emerging issues and research needs in respiratory protection. Recommendations were in three general areas. Participants recommended more research and development for identifying selection and use guidelines for PPE used in sustained, disaster and bio-terrorism responses. Equipment standardization and interoperability were recommended as a way to facilitate the use of the myriad of PPE among responder organizations and manufacturers. Safety management recommendations included the development of guidelines to require the use of PPE at large-scale disaster sites, the establishment of site management as early as possible, and the identification of ways to provide real-time safety and health information to responders at incident sites.

The PPT Program responded to the need for interoperability among air purifying cylinders for APRs to enable canisters and facepiece components from different manufacturers to be interchanged at the time of supply shortages during an emergency response. Since the CBRN SCBA standard was finalized in December 2001, this emerging need was not identified early enough to be incorporated in the CBRN SCBA standard.

Through participation in NFPA consensus standards the PPT Program supported the need to develop a technical proposal to incorporate the requirement for interoperable cylinders in the NFPA 1981 standard for open-circuit SCBA for emergency services. The PPT Program research supported the requirement; however, the NFPA technical committee rejected the recommendation. PPT Program incorporated the requirement in the NIOSH CBRN APR standard and presented the concept at PPT Program public meetings to obtain stakeholder input. This became a requirement in the NIOSH CBRN APR standard finalized in 2003.

To meet the emerging needs of emergency responders in the post 9/11 era, the PPT Program fast-tracked an exploratory SCBA benchmark test to assess the performance of commercially available SCBA against CWA. A U.S. Army hazard analysis of CWA using venues in multiple open air situations or confined spaces was adopted. Existing U.S. Army chemical warfare agent test methods were adapted for the benchmark tests. The PPT Program then conducted benchmark testing on available NIOSH-approved, European (EN)-approved, U.S. military-specified (MILSPEC), and NFPA-compliant SCBA that were available to emergency responders in the United States.

In a parallel effort, a PPT Program team evaluated the applicability of industrial respirator certification standards and the NIOSH authority to implement new CBRN SCBA certification testing through existing authorities in 42 CFR Part 84.[13] More than 340 standards for respiratory protection equipment from 32 countries and standards organizations were evaluated for provisions specifically related to protection from CBRN agents that potentially could be used for terrorism. The PPT Program identified those standards related to CBRN environments, and adopted those standards meeting the requirements identified in the hazard assessment into the

NIOSH CBRN standards. In most cases, existing standards were adopted by the PPT Program. However, the TIC and toxic industrial material (TIM) requirements were researched and developed by the PPT Program scientists. These concepts were presented at public meetings

From these existing regulations and standards a list of human factors and environmental performance characteristics appropriate for CBRN respiratory equipment were identified to define a more comprehensive list of factors addressing both physiological and environmental issues. Minimum CBRN respirator performance requirements then were established to protect emergency responders; they were designed to address operational and environmental conditions of use. These considerations were incorporated in the NIOSH CBRN standards for respiratory protection devices.

The PPT Program recognized the knowledge gap in material performance against CWA and established a research program for manufacturers to obtain expedited testing of PPT to ascertain material capabilities to withstand exposures to CWA. Manufacturers tested both PPT (e.g. material swatches) and PPE (e.g. SCBA) to discover PPT and PPE capabilities. This program expedited the availability of improved CBRN respirators for emergency responders and receivers as the CBRN standards were being developed. The PPT Program expedited availability of NIOSH CBRN certified respirator protective device (RPD) by initiating certification processes for CBRN protection as the standard for each respirator class was completed. This program was in place for Open-Circuit SCBA, APER, APR, Self-Contained Escape Respirators, and PAPR. The research program established in 2001 is still in place today.

Through the collaborative approach with multiple partnerships, applicable industrial and military technologies were integrated by the PPT Program to provide the full range of protection needed by emergency responders. Working with this diverse group of Federal government and private sector partners, the PPT Program expedited development and publication of stringent new testing and respirator certification standards for voluntary use by emergency responders in CBRN terrorist attacks.

Output and Transfer Highlights

Letters were issued in 2001, 2003, and 2006 to inform manufacturers' that the PPT Program would begin processing applications for different classes of CBRN Respirators.[25-28]

The collaborative standards development and research efforts of the IAA resulted in the publication of the first NIOSH CBRN SCBA certification standard, dated December 2001.

Development and subsequent website posting of 5 Statements of Standard for CBRN protection [46]

Through FY 2007, NIOSH certified additional commercial respirators which increased the number of CBRN approved respirators to 68, 48 CBRN approvals and 20 retrofits. A retrofit is a respirator that has an industrial respirator approval and has been upgraded to incorporate CBRN protections. This output increases the national inventory of approved respirators from which selection for particular protections can be made. It serves as an input to various Respiratory

Disease Research Program components, such as the health hazards evaluations and technical assistance activities and emergency and disaster preparedness that develop respiratory protection strategies and respirator recommendations as an output to their activities, by making the selection of appropriate respirators available.

Listserv notification of issuance of Statement of Standard for CBRN protection

Mailing of letter issuing Statements of Standard for CBRN protection

IAs between NIOSH and SBCCOM, 1999/2000

Copies of the public meeting presentations, as well as concept papers that explain the evolution of the different standards, and the standards themselves, are available through the PPT Program web site.

A final report was issued to the PPT Program in May 2003 from Pennsylvania State University providing a compilation of PPE Guidelines for Emergency Responders.[47]

A final report was issued to the PPT Program in May 2003 from RAND providing a compilation of PPE Guidelines for Emergency Responders.[48]

Firefighters and emergency response personnel have enhanced protection available and use CBRN certified devices in their daily operations.

The PPT Program updates stakeholders on stakeholder development activities at least twice monthly. Several examples of these outreach activities are listed below.

Boord L, Dower JM [2002]. NIOSH CBRN respiratory protection standards update. International Society for Respiratory Protection 11th International Conference, Edinburgh, Scotland, September 29 - October 3, 2002. [49]

Dower J, Boord L [2003]. NIOSH CBRN respiratory protection standards update. American Industrial Hygiene Conference and Expo. Fairfax, VA: American Industrial Hygiene Association, 2003 May. [50]

NIOSH [2005]. Join us in moving science to solutions for... emergency preparedness. DHHS (NIOSH) 2005-157. [51]

Presentation covering a literature review on the effects of CO_2 and O_2 (now a numbered document - ISO/TC 94/SC/15/WG1/PG5/N022) on human respiration to the PG5 which included information on the physiological limits of inhaled CO_2 and O_2 (hypercapnia, hyperoxia, and hypoxia) and respirator use, ISO TC94 SC15 WG1 PG5 Human Factors meeting, March 2-5, 2006, Presenter: Dr. Jon Williams.

Presentation on the developments in defining standard test head forms, ISO TC94 SC15 WG1/PG4 meeting, February 15-17, 2006, Presenter: Dr. Ziqing Zhuang

Untitled PowerPoint presentation on the effects of CO_2 in the breathing space of respirators and the challenges of controlling CO_2, meeting with Dr. David Caretti of RDECOM and members of the Israeli Military Medical Corp., February 8, 2006

Untitled presentations on the status of NIOSH CBRN respirator standards development and NFPA protective clothing and equipment standards, American Society for Testing and Materials (ASTM) E54.04 Personal Protective Equipment (PPE) subcommittee meeting, February 7 - 9, 2006

"An overview of oxygen and carbon dioxide in the breathing environment: physiological responses and limitations" (now a numbered document - ISO/TC94/SC15/WG1/PG5/N022), ISO/ American National Standards Institute (ANSI) TC94/SC15/WG1/PG5 Human Factors Committee, January 16-20, 2006

Intermediate Outcomes

NIOSH developed CBRN respirator standards were among the first adopted by the DHS. DHS now uses these standards to award grants for the purchase of PPE for the first responder community.

Use of NIOSH Certified CBRN Respirators, as part of a personal protective ensemble, has been incorporated by the NFPA into its NFPA 1500, 1991, and 1994 standards.[20-22]

The British Standards Institution (BSI) has included NIOSH CBRN Respirator standards performance requirements and test methods into the British standards for SCBA, APR, PAPR, and escape hoods.

Use of CBRN respirators by emergency responders has been endorsed by the InterAgency Board for Equipment Interoperability and Standardization.

A 2-hour Internet search identified 70 website links maintained by private and public sector entities that reference PPT Program products and/or services having a direct connection to the PPT Program outputs and outcomes. This search focused on CBRN respirator standards which are exclusive outputs of the PPT Program. Appendix R contains a selected listing of Internet website links maintained by private sector and public sector entities that reference products and/or services having a direct connection to the PPT Program.

A 2-hour Internet search provided confirmation that more than 23,000 NIOSH Certified CBRN respirators have been purchased. The organization, date of purchase, manufacturer, and number purchased were identified. Appendix S provides a listing of Responder organizations the PPT Program has been able to identify as purchasers of respiratory protection equipment made available as a result of the PPT Program's certifications.

A 2-hour Internet search revealed evidence of 68 organizations that have implemented a respiratory protection program that requires the use of NIOSH Certified respirators. These organizations include chemical companies and laboratories, educational consultants, universities,

manufacturing and labor organizations, healthcare organizations, and construction organizations. Appendix T provides the details for these organizations. The listing is not intended to be comprehensive of all products or services available in the marketplace, but it does indicate the diversity of customers across the U.S. economy who support or participate in the use of outputs and outcomes derived from the PPT Program.

Through the development and implementation of the CBRN respirator performance criteria, respirators are more protective for user safety and health in a variety of emergency response situations when the respirator is certified to NIOSH chemical, biological, radiological, and nuclear (CBRN) protections. Implementation of these criteria through the use of regulations and standards results in overall improvements for performance, reliability, and safety of respirators.

NFPA 1981 Technical Committee on the Open Circuit SCBA for Emergency Services (2007 edition) requires that all new SCBA produced in accordance with this standard be NIOSH CBRN certified.[24]

The NIOSH standards development and respirator certification programs have led to an increase in the national inventory of CBRN capabilities to protect emergency response personnel against the respiratory hazards associated with a terrorist event. Neither industrial nor military respirators provided protection from the range of known or projected CBRN terrorist threats entire compliment of potential CBRN agents. Under federal regulations, emergency responders are required to use NIOSH-certified respirators for respiratory protection as part of their respiratory protection program.

General workers and other non-emergency response personnel in areas of high threat for a terrorist event (such as major metropolitan areas) have access to NIOSH CBRN Escape Respirators.

As of December, 2005, the PPT Program estimates that at least 46% of career (trained professional) firefighters from fire departments classified as all career have CBRN respirators available. This estimate is based on a preliminary survey of the nine largest fire services.

NIOSH CBRN respirator statements of standard have been adopted by the InterAgency Board (IAB) in its Equipment Interoperability and Standardization's 2006 Annual Report with 2007 Standardized Equipment List.[52]

External factors

In May 1998, President Clinton issued Presidential Decision Directive 62 (PDD-62), *Combating Terrorism* [53] and made the fight against terrorism a national domestic security issue. The issuance of PDD-62 was an external factor of major impact on the PPT Program. Municipal, state, and National Guard responder groups began developing response plans and establishing the procedural and equipment infrastructures to respond to chemical and/or biological terrorism and other crisis situations.

The threat of terrorism has created an immense concern about the protective capability of PPE used by the nation's first responders, first receivers and other personnel in high-threat areas. To address the concern, the PPT program partnered with the U.S. Army to:

- Leverage knowledge of chemical warfare agents
- Use military capability to perform chemical warfare agent tests
- Define level chemical warfare agents hazard likely for terrorist events, and
- Define acceptable exposure limits for chemical warfare agents.

The terrorist attacks of 911 were instrumental in expediting the CBRN standard development effort. Less than two months after the attacks, the PPT Program contracted RAND to organize a conference to assemble PPE experts to assess PPE use and practices and make recommendations for improvement.

What's Next?

NIOSH is continuing to test and evaluate CBRN respirators submitted by manufacturers for certification under the NIOSH respirator certification program. It also is developing similar CBRN certification criteria for certifying other types of respirators, such as closed circuit SCBA and supplied air respirators, for use by responders. Due to the increased use of CBRN respirators in emergency response, new challenges exist in training users to recognize a CBRN-certified respirator. The PPT Program is developing user guidance products for all the classes of certified CBRN respirators to assist the emergency responder community with their use.

The partnerships established as part of the standards development program have enabled the PPT Program to gain a broad base of support for its standards. The CBRN respirator standards have defined performance criteria in response to terrorism incidents based on the continuing threats. The Program is continuing to test and evaluate other escape respirators submitted by manufacturers for certification. It also is developing similar criteria for approving other types of respirators, such as powered, air-purifying devices, for use by emergency responders. The U.S. military services (Army and Navy) are working with the PPT Program to facilitate military specified respirator compliance with the NIOSH CBRN APR standard.

Several research efforts initiated by the PPT Program will support future CBRN requirements. The PPT Program initiated a research program in response to the IOM Committee Reusability Report recommendations by developing a research proposal to support respiratory protection issues during an influenza pandemic. PPT Program scientists proposed, peer reviewed, and initiated research studies to measure the CO2 and O2 concentrations in the breathing space of N95 respirators with surgical mask overlays. The physiological responses of medical personnel wearing the N95 with surgical overlay will be measured to determine if there are significant detrimental physiological effects that would preclude the use of the N95 with surgical mask overlay. The research in this area also supports the CBRN respirator evaluation process since the techniques used to measure CO2/O2 in the breathing space may be adapted for the CBRN respirator evaluation.

In addition, PPT researchers are writing guidance documents for the International Organization for Standardization (ISO) Human Factors committee (ISO TC94 SC15 WG1 PG5) that will be used to develop standards for future CBRN respirator certification. The information on the physiological responses to changes in CO2 and O2 in the breathing atmosphere also will be used in the evaluation of portable mine refuge chamber habitability in response to the MINER Act of 2006.[54] The use of test representative agents to represent chemical families for respirator gas and vapor certification testing is being considered by the ISO TC94 SC15 to mirror the CBRN respirator standards approach for such testing.

List of Outputs

Peer Reviewed Publications

Kim, J., Jasper, W., Hinestroza, J. (2007) Probing Solvent-Induced Charge Degradation in Electret Fibers via Electrostatic Force Microscopy, Journal of Microscopy,20,1-8 [26]

Kim, J., Jasper, W. Hinestroza, J. (2006) Charge Characterization Of An Electrically Charged Fiber Via Electrostatic Force Microscopy. Journal of Engineered Fibers and Fabrics, 1,2, 30-46 [27]

Jasper W, Hinestroza J, Mohan A, Kim J, Shiels B, Gunay M, Thompson D, and Barker R: Effect of xylene exposure on the performance of electret filter media. Journal of Aerosol Science 2006, 37:903-911. [28]

Zhuang Z [2006]. Selection and use of NIOSH approved CBRN respirators. The Synergist – The Essential Connection for OEHS Professionals volume 17, No. 3, pages 39-40. [29]

Jasper W, Hinestroza J, Mohan A, Thompson D, and Barker R: Effect of phase of toluene on filtration performance of electret filter media against di-octyl-phthalate aerosols. Journal of the International Society for Respiratory Protection 2005, 22:97-105. [30]

Sinkule E, Turner N. Inhaled Carbon Dioxide and Oxygen Concentrations in Three Escape Hood Respirators During Rest and Exercise. *Medicine & Science in Sports & Exercise 36*: S245, May, 2004 [31]

Conferences and Presentations

A PPT scientist attended the American Industrial Hygiene Conference and Exposition in May 2004 in Atlanta, GA to serve as a panelist on the Round Table session 249 “Airflow Requirements for Respirators”. A paper entitled “Physiological Aspects of Respiratory Protective Devices” was presented. [37]

Sinkule E, Turner N, Homeland Security – What Does It Take, (Presented at the thematic poster session for the Annual Meeting of the American College of Sports Medicine), Indianapolis, Indiana, June 2004).[38]

Sinkule, E., N. Turner, and S. Hota, Automated breathing and metabolic simulator (ABMS) CO2 test for powered and non-powered air-purifying respirators, airline respirators, and gas mask http://www.aiha.org/aihce03/handouts.htm, in American Industrial Hygiene Conference and Expo. 2003, American Industrial Hygiene Association: Fairfax, VA. p. 54.[39]

Statements of Standard

Current CBRN certifications are posted on the NIOSH website at www.cdc.gov/niosh/npptl/. Certifications are posted as they occur.

Formal letters were issued in 2001, 2003, and 2006 to inform manufacturers that the PPT Program would begin processing applications for different classes of CBRN respirators. [25-28]

The collaborative standards development and research efforts of the IAA between the PPT Program and ECBC resulted in the publication of the first NIOSH CBRN SCBA certification standard in 2001.

Subsequently, we posted five website Statements of Standard for CBRN protection between 2001 and 2006. The statements were also distributed by mail and on a listserv that reaches about 4000 stakeholders. [46]

NIOSH has certified 68 CBRN commercial respirators, including 48 approvals and 20 retrofit approvals. A retrofit is a respirator that has an industrial respirator approval and has been upgraded to incorporate CBRN protections.

Copies of the public meeting presentations, as well as concept papers that explain the evolution of the different standards, and the standards themselves, are available through the PPT Program website. Three public meetings, on average, are held annually to discuss CBRN Standards.

The final report from Pennsylvania State University [47] provided a compilation of PPE guidelines for emergency responders and the Rand Corporation report [48] summarized the focus group findings.

Guidance and Recommendations

Interim Guidance on Using CBRN Canisters for activities other than response to terrorist events
September 15, 2005
http://www.cdc.gov/niosh/npptl/guidancedocs/intercbrn091505.html [55]

Air-Purifying Escape Hood Respirators (Escape Hoods): Interim Findings and Guidance for Models Put Into Use Prior to NIOSH CBRN Certification Standards April 2004
http://www.cdc.gov/niosh/npptl/guidancedocs/interesc0404.html [56]

OSHA/NIOSH Interim Guidance - April 1, 2005
Chemical - Biological - Radiological - Nuclear (CBRN)
Personal Protective Equipment Selection Matrix for Emergency Responders
External Link: (OSHA Web Site)
http://www.osha.gov/SLTC/emergencypreparedness/cbrnmatrix/index.html [57]

Respirator Fact Sheet: What You Should Know in Deciding Whether to Buy Escape Hoods, Gas Masks, or Other Respirators for Preparedness at Home and Work
06-22-2004
http://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respfact.html [58]

Respirator Usage in Private Sector Firms, 2001 [3]

NIOSH and the Bureau of Labor Statistics conducted a voluntary survey of U.S. employers regarding the use of respirators. The findings are intended to provide information to develop interventions and to increase the frequency and effectiveness of respirator use in the workplace.

Szalajda J [2003]. Chemical/biological/radioactive/nuclear (CBRN) respirator standards development. Abstr Pap - Am Chem Soc 2003 Sep; 226(Part 1):U217 011-CHAS. [59]

Szalajda J [2005]. CBRN respirator standards developmental processes. American Industrial Hygiene Conference and Expo, May 21-26, 2005, Anaheim, California. Fairfax, VA: American Industrial Hygiene Association. [60]

Sponsored Workshops

NIOSH-DoD-OSHA Sponsored Chemical and Biological Respiratory Protection Workshop Report DHHS (NIOSH) Pub. No. 2000-122
Covers hazards associated with chemical and/or biological incidents, responders and their respiratory protection needs, respirator standards for chemical and/or biological incident responses, public health and medical community concerns
February 2000 http://www.cdc.gov/niosh/2000-122.html [45]

Website Inquiries

Over the past year, the PPT Program received more than 4,600 inquiries (including 1,100 to CBRN test procedures) to the PPT Program website URL where the Standard Test Procedures (STPs) used to conduct the tests for certifying respirators. The STPs are available at http://www.cdc.gov/niosh/npptl/stps/Respirator_Testing.htm [14]

The Standard Application for the Approval of Respirators is available in downloadable form at http://www.cdc.gov/niosh/npptl/resources/certpgmspt/standardapp.html [16]

NIOSH issues user notices to inform users of a condition or risk that may exist with a NIOSH-certified product. Table3.3 provides a summary of the number of user notices issued per year since 1995. [17]

3.3 Mine Emergency Respirators/Self Contained Self Rescuers Back to the Table of Contents

Issue

As a workplace underground mines present many occupational safety and health challenges. Typical miner gear may include hard hats, goggles, and respirators. The absence of light and the limited space of working, in “low coal” present work in conditions that are difficult and challenging. Further complicating the occupational safety and health issues are the infrequent fires or explosions in an underground mine can occur at any time without warning. They can cause the atmosphere inside the mine to become oxygen-deficient or filled with smoke and toxic gases. Readily available and reliable respiratory protection for these inhalation hazards is essential for miners to successfully escape through these hazardous types of atmospheres.

When a disaster occurs, mine rescue workers in underground mines use long-duration, closed-circuit self-contained breathing apparatus (CCBA) to complete their mission of bringing trapped miners out of the mine alive. They do this by careful and calculated re-entry into a mine where the atmosphere has been affected with hazardous concentrations of contaminants, and making it safe for the trapped survivors to be brought to the surface. When used by working miners and rescue workers during mine disasters and the associated rescue and recovery operations, the PPT must have survived the rigors of the mining environment to provide a reliable level of respiratory protection from any highly toxic atmosphere.

Rescuers must deal with the heavy physiological burden from wear and use of the CCBA, as they reestablish safe conditions and progress in their search for the victims. They also carry the psychological burden of knowing the trapped miners’ lives are sustained by a limited supply of breathable air, food and water.

Background

A reported 32,311 coal miners regularly working underground are required to be supplied with a self-contained self rescuer (SCSR). Other federal regulations (30 CFR 49) [61] require the use of longer duration CCBA by mine rescue teams. Between 1984 and 2006, 12 mine fires or explosions resulted in forced evacuation or fatalities. Most incident reports indicate that miners donned their SCSRs and were able to escape.

Since 1981, federal regulations (30 CFR 75.1714) [62] require that every person entering an underground coal mine in the U. S. must be supplied with a one-hour-rated CCBA, called an SCSR. The regulations further require that every such person must be trained in the use of the device.

MSHA is a co-approver with the PPT Program of the respirators used for mine emergencies. The PPT Program and MSHA maintain a Memorandum of Understanding (MOU) defining their respective roles in respirator certification and related activities. As part of its role, MSHA reviews the PPT Program’s results of the certification tests for submitted devices, prior to the issuance of a certification.

Because the first generation SCSRs were large and bulky, miners found it difficult to carry them continuously during their normal work. This, to some degree, compromised miner safety. In 1984, an interagency task force composed of representatives from the USBM, MSHA and NIOSH (including the PPT Program) worked with industry and labor to define the concept of a second generation SCSR. This device was called a Person Wearable Self-Contained Self-Rescuer (PW-SCSR) and the joint effort was designed to determine its technical feasibility.

SCSRs are enclosed in sealed cases thereby preventing a thorough inspection and operational check prior to use in escape from a hazardous atmosphere. These operational conditions require that they be certified with a service life plan defining the conditions under which they can remain deployed for possible use.

The SCSR models certified by the USBM or PPT Program currently available for use as escape devices in underground mines include the CSE SR-100 (certified in 1989), OCENCO EBA 6.5 (certified in 1981), OCENCO M20 (certified in 1991), and the DRAEGER OXY-K Plus (certified in 1993).[63]

Approach

Escape Respirator Performance Standard

The PPT program has identified the reduction of exposure to inhalation hazards during a mine emergency, e.g., fires, explosions as a program priority area. In this effort, the PPT program collaborates routinely with respirator manufacturers, MSHA, mining companies, the United Mine Workers of America (UMWA), the United Steel Workers of America (USWA), the Bituminous Coal Operators of America (BCOA), and the National Mining Association (NMA). Discussions and exchange of ideas occur during public and individual stakeholder meetings, symposiums and conferences. These collaborations ensure the PPT Program is aware of user needs and ensures stakeholder concerns are incorporated in the research, policy and standards development, and respirator certification activities.

In 2003, NIOSH began holding public meetings to engage stakeholders to identify and pursue actions to improve SCSR performance and reliability. The Program held two public meetings in April 2003 (in Arlington, Virginia and Denver, Colorado) to share concepts and solicit input on developing standards to update current SCSR certification requirements.

The PPT Program expanded the opportunity for public comment in early 2006 after the Sago, Darby, and Alma mine disasters. Public meetings to discuss the revised requirements under development were conducted in September 2006 in Arlington, Virginia, and Denver, Colorado.[64] In December 2006 MSHA instituted a rule on emergency evacuation that requires inserting the mouthpiece during training and refresher training every 90 days. The Mine Improvement and New Emergency Response Act of 2006 (MINER Act) [54] requires additional supplies of breathable air for individuals trapped underground during mine evacuation. It also requires that additional devices be made available during training that are comparable to devices used during an actual emergency.

The PPT Program keeps stakeholders fully informed of its actions throughout the standards development process. It does this through listserv notices, public meetings, formal scientific peer review of program concepts, protocols, and scientific information products, and through routine website postings of these products. The time and place of those meetings are announced via listserv, Internet posting, and FRN announcement. Stakeholders and partners were invited to provide input and recommendations by submitting comments to the NIOSH Docket.

The PPT Program gathered and reviewed input from meetings in which concepts for changes in requirements for evaluating and testing SCSRs for NIOSH certification were presented. The changes are based on advancements in technologies for testing respirators and in the understanding of interactions between SCSRs and human physiology. The changes have been incorporated into a new proposed standard that is being processed through rulemaking procedures as a revision to 42 CFR Part 84.[13]

Long-Term Field Evaluation (LTFE) Program

The LTFE program is a product auditing program for SCSRs used in the mining environment. The objective of the LTFE program is to determine how well SCSRs endure the underground coal mining environment with regard to both physical damage and aging when they are deployed in accordance with Federal regulations (30 CFR 75.1714).[62] The LTFE Program compares the performance of deployed SCSRs to new SCSRs using a series of selected tests.

Findings from 1986, the first year of the initial 5-year LTFE Program,[65] included recommendations for improved training in inspection procedures because equipment damage that may not be detected by the miners or the mine operators posed a danger to a user in an emergency. Subsequent results from other phases of the LTFE Program have found that SCSRs carried in and out of the mine daily and stored at the working section may also suffer damage.

Results of the combined eighth and ninth phases of the LTFE Program (December 2000 - April 2004),[66] indicated that all SCSRs experience some performance degradation due to the mining environment. Observed degradation included elevated levels of carbon dioxide, high breathing resistance, and reduced capacity. Mechanical degradation to the SCSR components included breathing hoses, chemical beds, outer cases and seals.

The suspected problems and nonconformities identified in the LTFE Program are reported for investigation under the CPIP.

Research Next Generation SCSRs

A need for new engineering designs of SCSR respirators was identified by the PPT Program in 2001. Consequently, incremental improvements in design, size and weight, and overall reliability of SCSRs were made part of the PPT Program research agenda. In 2005, the PPT Program collaborated with the National Technology Transfer Center (NTTC) to conduct workshops seeking new SCSR technologies. By reducing the size and weight of SCSRs, the PPT Program anticipated that more miners would wear the devices, providing them with immediate access to respiratory protection in the event of an emergency. In the NTTC workshops, two promising concepts, hybrid technology and docking

technology, emerged in discussions with stakeholders in national workshops sponsored by the PPT Program convened in 2005 and 2006. [67]

One new approach to SCSR design involves a modular device where additional units of oxygen supply could be “plugged” into the device without exposing the wearer to the surrounding air. The second new approach combined a self-contained unit with a carbon monoxide filtering device, much like but improved over the earlier filter self-rescuers (FSR) still being used.

A contract was awarded in February 2007 to Technology Products Inc. to design and produce a person wearable dockable and hybrid SCSR that will meet the requirements of 42 CFR Part 84 [13] and Federal Mining Regulations, including the newly enacted MINER Act.[54] A design has been completed and prototypes were delivered in June 2007. The prototype SCSRs combined new engineered materials technology with innovative design to accomplish the hybrid and dockable features. These prototypes are being tested to determine their performance relative to certification requirements. The testing is being performed with an ABMS to demonstrate operational performance of the system, including the docking operation connecting two SCSRs without interrupting the breathing circuit. In August 2007 a meeting with PPT Program stakeholders was held to demonstrate and discuss these developments to extend the protective capacity of the respirator.

The PPT Program also is focusing its research on the application of new technologies for oxygen generation, carbon dioxide removal, and carbon monoxide purification, and for respirator components, service, maintenance and inspection. The Program is interested in new technologies (methods and materials) for training that simulate actual respirator use. Realistic training that can be done frequently and efficiently will improve miners’ ability to escape.

MSHA and the PPT Program continue to update current training modules for donning SCSRs. Updates incorporate guidance on the donning of multiple SCSRs during an emergency escape, reflecting new requirements under the MINER Act. Those provisions require mine operators to provide individual miners with immediate access to at least two SCSRs, and to store extra units along escapeways.

Other research is being conducted through the PPT Program to assess 1) the effectiveness of realistic smoke training for escaping miners and 2) technologies such as handheld lasers, chemical light sticks, and directional lifelines that can be used to aid miners during escape. Findings are being translated into training modules to help mine operators’ conduct realistic evacuation training.

Output and Transfer Highlights

NIOSH published rulemaking priorities in the Federal Register in 1999 that represented a re-evaluation due to serious field problems with deployed SCSRs, and with a focus on three rulemaking modules; administrative/quality assurance, SCSR, and PAPR. In addition, NIOSH set priorities on the evaluation and approval of respirators for use by responders to terrorist events. [68]

In a 1999 study, the PPT program developed a scientific definition of a mine escape, providing both the content and context for designing new testing and approval standards for SCSRs used in mine emergencies. [69]

Investigative reports for nine phases of LTFE have been published and posted on the Internet and the reports have been presented at two conferences.[47-51, 55]

Problems identified in the SCSR evaluations of the LTFE program are referred to the CPIP for resolution. PPT program staff working in the CPIP interact with the SCSR manufacturer to define appropriate corrective actions to eliminate the identified actions. Corrective actions affecting product configurations can include product recall from the field, retrofit of deployed product, or processes changes in the manufacture of new SCSRs. Problems unresolved by configuration changes can result in the revocation of the approval for that SCSR model. The PPT program issues public notifications (user notices) to inform the users of significant corrective actions undertaken in the CPIP program. User notices and LTFE investigative reports are posted regularly and listserv notices are sent to PPT Program listserv subscribers when issues are identified in the investigative reports.

Nine Respirator User Notices related to Mine Escape Respirators were posted to the PPT Program website. One SCSR model that was NIOSH-certified, the MSA LifeSaver 60, has been made obsolete by the manufacturer in 2007. MSA LifeSaver 60 SCSR models have been recalled from use by the manufacturer. This recall followed two user notices issued by NIOSH in 2002. [70, 71] Other user notices associated with SCSRs are listed in Appendix O (List of User Notices).

New SCSR hybrid respirator designs for combination air-purifying and self-contained escape respirators for emergency use in escape from mines, development of scientifically sound redesigned LTFE program, and a NTTC 2005-2006 Workshop notes posted at http://www.nttc.edu/clients/nioshworkshop/workshopnotes.asp.[67]

Ten public presentations, three briefings to MSHA leadership and two briefings to NIOSH leadership were conducted between 2001 - 2006 to introduce the closed circuit escape respirator (CCER) standard that incorporates most recent research and evaluation findings to maintain state-of-the-art knowledge. The PPT Program outreach activities are highlighted in Appendix Q. These activities outline the requests for PPT Program leadership and researchers to provide updates regarding the PPT Program activities. The PPT Program-sponsored workshops and presentations are highlighted in Appendix M to provide an overview of the PPT Program commitment to addressing stakeholder needs in addition to conducting sound research.

Intermediate Outcomes

SCSR Training Modules were distributed to more than 75 stakeholders to include SCSR manufacturers, MSHA, mining companies, the United Mine Workers of America (UMWA), United Steel Workers of America (USWA), Bituminous Coal Operators of America (BCOA), and the National Mining Association (NMA). Training modules also were distributed to 1,850 mines in Jun 2006 and 1,100 mines in late 2006.[63]

Final customers of the SCSR program are underground miners, mine operators, and MSHA Mine inspectors. A total of 8,396 mining establishments use NIOSH-certified respirators with the majority (4,978) in nonmetallic mineral (except fuels) establishments. Correction of or removal of problematic deployed SCSRs from underground mines is the principal action taken by NIOSH to protect the miners in the event of an emergency.

End Outcome

NIOSH-approved self-contained self-rescuers saved the lives of 10 Aracoma Mine workers as they escaped the inhalation hazard exposure to carbon monoxide (CO). On the evening of January 19, 2006, the 12-member crew of the #2 section of the Aracoma Alma Mine #1 used NIOSH-approved escape respirators that chemically generate breathing oxygen (self-contained self-rescuers) to escape from the hazardous atmosphere of dense smoke and deadly concentrations of CO resulting from a mine fire.

Although training and escape procedures would have the miners begin using the respirators as soon as they began their escape, no crew member attempted to begin respirator use until after they had progressed into smoke so dense and black that one crew member estimated visibility at no more than 2 inches. They described difficulties in opening the respirators, losing goggles packed within the respirator case and finding the components to initiate their operation properly because of the growing confusion and panic from the inability to see and the choking effects of the smoke.

Two crew members, who unfortunately died from the toxic atmosphere, became separated from the rest of the crew during this time. The surviving crew members reportedly measured the concentration of CO in the smoky mine atmosphere to be about 650 parts per million above the lethal concentration threshold. This crew successfully used the SCSRs to escape a hazardous atmosphere of deadly CO, despite their documented accounts that they did not begin use of the respirators until they were already into a hazardous atmosphere and they inappropriately removed them in that atmosphere to communicate with each other during their escape. This information is described in detail in the State of West Virginia report released in May 2007.[72]

External Factors

Due to the high incidence of mine accident fatalities in West Virginia, in spring 2001 Governor Bob Wise requested that efforts be undertaken to halt the accidents, to study their causes, and to develop a plan for reducing and eliminating fatal accidents involving its miners. During the first 10 months of 2001, 13 miners were killed, making West Virginia mines the most dangerous in the nation. Later that year a report from Davitt McAteer to Governor Wise outlined a strategy to make West Virginia mines the safest in the nation. The West Virginia program was instrumental in the PPT Program decision to explore approaches for improving existing mine escape respirator strategies.[72]

In the disasters at Sago, Alma No.1 and Darby mines, all the miners who perished after the initial impact of the explosion died of carbon monoxide poisoning.[73-75] For example, in the mine

explosion at the International Coal Group, Inc (ICG) Sago Mine, near Buckhannon, West Virginia, the potential usefulness of greater life support capacity (duration) was highlighted. Miners perished there due to carbon monoxide poisoning after barricading for a length of time far greater than the oxygen producing life support capacity of their SCSRs. Additional oxygen supplies may have allowed the miners to remain in the barricaded section for a longer period of time or to escape after the dust and smoke had cleared.

The recently enacted MINER Act [54] addresses this problem by requiring additional supplies of breathable air for individuals trapped underground during mine evacuation. With additional supplies of SCSRs miners could transfer from one device to another, thus extending the amount of protection available. However, the current technology does not permit the miner to successfully make transfers from one SCSR to the next while in a hazardous atmosphere. Also, transferring from one SCSR to another could be very difficult in the high stress situation of a mine fire or explosion. The hybrid and dockable technologies are expected to address the current challenges.

What's Next?

The PPT Program is continuing initiatives to update the respirator standards related to SCSRs, improve the LTFE program, and develop an SCSR using state of the art technology.

Expansion of the LTFE program to collect and test a larger sample of SCSRs under a standard procedure, to achieve statistical significance, document corrective and follow-up actions as needed, and report evaluation results annually has been drafted. The future program concept was announced by FRN in spring 2007, posted on the Internet for public comment, described at a stakeholder meeting, and peer reviewed by a group of scientific experts. The peer-review reports are being evaluated and a response is being prepared.

PPT Program researchers and their partners have proposed strategic research to develop a new generation of mine escape respirators that will include state of the art technology. They have determined that the focus should be on:

- greater durability to withstand the rigors of daily mine use,
- greater life support capacity (duration) to increase the amount of protection available for miner escape,
- reduced physiological burden including lower breathing resistance and inhalation temperatures.

As noted earlier, reduced physiological burden is a desirable trait for future escape devices. An FY08 new project has been proposed that has the objective of obtaining a better understanding of the burden of current devices to develop a baseline from which future improvements can be based. This investigation will explore the work rate variability among four NIOSH-approved SCSRs using human subjects. The subjects will wear the same types of clothes and weighted vests to mimic the additional burden from the weight of personal protection. In addition to work rate variability, circulatory, thermoregulatory, and metabolic responses will be measured.

The PPT Program will continuously work to explore opportunities to introduce new technology for mine escape respirators. New technology not only for the life support feature, O2 supply and CO2 removal, but the application of new materials, test technology, inspection technology, packaging, and training.

List of Outputs

Long-Term Field Evaluation Reports

NIOSH. [2006] Self-Contained Self-Rescuer Long Term Field Evaluation: Combined Eighth and Ninth Phase Results. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2007-103, Report of Investigations 9671, 2006 Oct :1-51. http://wwwlink.cdc.gov/niosh/mining/pubs/pdfs/2007-103.pdf [66]

Kyriazi-N, Shubilla-JP. [2002] Self-Contained Self-Rescuer Field Evaluation: Seventh-Phase Results. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2001-127, Report of Investigations 9656, 2002 Mar :1-13. http://www.cdc.gov/niosh/mining/pubs/pdfs/2002-127.pdf [76]

Kyriazi-N, Shubilla-JP. [] Self-Contained Self-Rescuer Field Evaluation: Sixth-Phase Results. Pittsburgh, PA: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, NIOSH, DHHS (NIOSH) Publication No. 98-1998, Information Circular 9451, 2000 Jul; :1-13. http://www.cdc.gov/niosh/mining/pubs/pdfs/ic9451.pdf [77]

Kyriazi-N; Shubilla-JP. 1996. Self-contained self-rescuer field evaluation: fifth-phase results. NIOSH,1996 Dec; :1-22. http://www.cdc.gov/niosh/mining/pubs/pdfs/ri9635.pdf [78]

Kyriazi-N; Shubil-JP. 1994. Self-Contained Self-rescuer Field Evaluation: Fourth-phase. BoM, 1994 :10 pages. [79]

Kyriazi-N; Kovac-JG; Shubilla-JP; Duerr-W; Kravitz-J. 1986. Self-Contained Self-Rescuer Field Evaluation: First Year Results of 5-Year Study. BoM, 1986 :12 pages. [65]

User Notices Associated with SCSRs.
(Examples of PPT Program User Notices are listed in Appendix O)

Nov. 14, 2002 - Potential for the Quick Start Candle on MSA Life-Saver 60 Self-Contained Self-Rescuer (SCSR) to Overheat or Catch fire on Units Manufactured from October 2000 to July 2002 [71]

Nov. 5, 2002 - Potential Deterioration of Exhalation Breathing Hose on Ocenco EBA 6.5 Self-Contained, Self-Rescuer Manufactured or Refurbished in the Calendar Year 1992 [80]

March 4, 2002 - Potential Reduction to Service Life for MSA Life-Saver 60 SCSRs [70]

Oct. 4, 2001 - Improperly Assembled Relief Valves on Certain Drager OXY K Plus SCSRs [81]

Dec. 22, 1999 - CSE SR-100 Breathing Tube [82]

Aug. 11, 1998 - Ocenco, Incorporated EBA 6.5 Non-conformance [83]

Nov. 14, 1997 - NIOSH/MSHA Respirator Notice [84]

Aug. 25, 1995 - CSE Corporation Self-Contained Self-Rescuer (SCSR) Model AU-9A1 (TC-13F-101) Retrofit and Service Life Updates [85]

Aug. 25, 1995 - Retrofit and Service Life Update: CSE Corporation SR-100 SCSR [86]

Peer Reviewed Publications

Sinkule, E., N. Turner, and W. Eschenbacher, Metabolic and Respiratory Responses During the Performance of a One-Hour Man Test 4. J Int Soc Respir Prot, Spring/Summer, 2002. 19(1-2): p. 49-57.[87]

Kyriazi-N; Shubilla-JP. 2000b. Self-contained self-rescuer field evaluation: sixth-phase results. J Int Soc Respir Prot 2000 Jan; 18(1):6-21. http://www.isrp.com.au/ [88]

Kyriazi-N. [1999] Proposal for Certification Tests and Standards for Closed-Circuit Breathing Apparatus. Pittsburgh, PA: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, NIOSH, DHHS (NIOSH) Pub No. 99-144, Information Circular 9449, 1999; :1-12. [89]

Kovac-JG; Vaught-C; Brnich-MJ. 1992. Probability of making a successful mine escape while wearing a self-contained self-rescuer. J Int Soc Respir Prot, 1992 Winter 10(4):18-30 pages. [90]

Kovac-JG; Kravitz-JH. 1991. Person Wearable Self-contained Self-rescuer (Pw-SCSR). Gluckauf 1991 Aug; 15/16:682-684(In German). [91]

Kovac-JG; Kravitz-JH. 1990. Person Wearable Self-contained Self-rescuer (Pw-SCSR). Issa-aiss-ivss Bull 7 1990 :49-55. [92]

Kovac-JG; Vaught-C; Brnich-MJ, Jr. 1990. Probability of making a successful mine escape while wearing a self-contained self-rescuer--a computer simulation USBM 1990 Jan; 1-11. [93]

Kovac-JG; Kravitz-JH. 1989. Person Wearable Self-contained Self-rescuer (Pw-SCSR). Paper in Tram XV & XVI Training Res Applied to Mng Comb Proc West Virginia, & Pennsylvania State Univ '89 pp 79-86 [94]

Conferences and Presentations

Turner-N; Sinkule-E; Hota-S. 2002. Performance of Self-Contained Self-Rescuers During a Man Test 4 Protocol for the Automated Breathing and Metabolic Simulator. Am Ind Hyg Conf Expo, 2002 Jun AIHA :47. http://www.aiha.org/aihce02/handouts.htm [95]

Kovac-JG; Kravitz-JH. 2000. Chemical Bed Degradation in Self-Contained Self-Rescuers Deployed in U.S. Coal Mines. ISRP International Conference, 2000 Nov :1. http://www.isrp.com.au/isrpcom/journal/syd_abstracts/abstract__kovac.htm [96]

Sinkule, E., N. Turner, and W. Eschenbacher, Metabolic and Respiratory Responses during the Performance of a 60-Minute Man Test 4, http://www.isrp.com.au/isrpcom/journal/pa_abstracts/abstract__turner.htm, in ISRP International Conference, Oct 1. 1999.[97]

Kovac-JG; Kravitz-JH; Rehak-TR. 1999. The Oxygen Cost of a Mine Escape. ISRP International Conference, 1999 Oct :1. http://www.isrp.com.au/isrpcom/journal/pa_abstracts/abstract__kovac.htm [69]

Berry Ann-R; Metzler-RW. 1999. Update on NIOSH Standards Development Activities AU: SO: ISRP International Conference, 1999 Oct :1. http://www.isrp.com.au/isrpcom/journal/pa_abstracts/abstract__berrymetzler.htm [68]

Kyriazi-N; Shubilla-JP. 1999. Self-Contained Self-Rescuer Field Evaluation: Sixth-Phase Results. ISRP International Conference, 1999 Oct :1. http://www.isrp.com.au [88]

Kovac-JG; Vaught-C. 1989. Self-contained Self-rescuers: New Developments in Technology and Training Proc 23rd Int'l Conf Safety in Mines Research Inst Wash DC 9/11-15/89, pp 417-424. [98]

Kyriazi-N; Kovac-JG; Shubilla-JP; et al. 1987. Five-year Self-Contained Self-Rescuer Field Evaluation: First Year Results. Proc Int'l Symp on Rescue Service in Svc of Mine Workmen Bytom Poland 9/8-10/87 Pp 371-388 :371-388. [99]

Website Postings

A website posting the certified equipment list http://www.cdc.gov/niosh/npptl/topics/respirators/CEL/default.html.[18]

A website posting of investigative reports http://www.cdc.gov/niosh/mining/pubs/pubreference/outputid2120.htm [66]

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3.4 Facial Anthropometrics and Respirator Fit

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Issue

A criterion for performance that influences PPE design to better fit a range of facial dimensions of respirator users in the U.S. workforce is needed to improve the reliability and level of protection provided by respirators.

Background

Face-fitting characteristics are an important characteristic of negative pressure respirators to ensure the reliability and level of the protection they offer. Yet, the database of facial dimensions used for sizing respirators to fit workers' faces is more than 30 years old. Further, the fit test procedures used in assessing the level of protection were developed without determination of their correlation to actual exposure. Validated test protocols and an up-to-date knowledge base on workers' facial characteristics are necessary to improve the ability of PPT developers, PPT manufacturers, and the PPT Program's certification activity to assess the fitting characteristics of respirators.

The face seal is the weak point in the level of provided respiratory protection for the most commonly used class of tight-fitting, negative-pressure respirators. First and foremost, the respiratory protection must be reliable. In addition, the protection afforded to individual workers should be able to be determinable in a reliable way. Ideally, the expected level of protection should be routinely achieved with minimal dependence on the wearer's consistency in putting on the respirator.

The PPT Program did not include certification fit testing for particulate filter respirators in the 1995 revision to the certification regulations. This was because the test previously used was inappropriate for assessing the fit of respirators using only particulate filters and there were no alternate validated fit tests for replacement. As filtering facepiece respirators approved under 42 CFR Part 84 [13] became more widely used, there were reports of difficulty in obtaining a good fit during testing.

Proper fit is highly dependent on the wearer achieving proper adjustment to the face when putting the respirator on and wearing it. It is the source of most respirator leakage and, therefore, is the single most important feature in determining the respirator's ability to control the exposure to inhalation hazards.

Approach

The NIOSH Control of Workplace Hazards for the 21st Century Conference [100] conducted with more than 250 researchers, manufacturers, and stakeholders in 1998 guided the facial anthropometrics and respirator fit PPT Program initiatives over the past 10 years. The workshop served as an input to program planning and validated the need to update the outdated respirator panel and to conduct research studies with an emphasis on respirator fit.

The PPT Program initiated coordinated and systematic research activities to provide a scientific basis for the better design and assessment of respirator fitting characteristics. To include performance tests as a condition of certification for all respirator classes, the PPT Program realized that such tests must be validated to accurate measures of inhalation exposures in laboratory settings and/or actual workplace conditions.

The PPT Program conducted a study to compare six respirator fit test methods with a biological measurement of exposure using Freon-113 while subjects were wearing negative pressure, air-purifying, half facepiece respirators.[101, 102] Fit factors of the corn oil and ambient aerosol (TSI PortaCount® Plus) fit test methods were found to be correlated with wearers' measured exposure doses. These two common methods have the potential to be useful tests for screening out respirator/wearer combinations with excessive leakage. The laboratories used for these studies are described in Appendix K.

Another separate PPT Program study demonstrated that protection factors for negative-pressure, air-purifying, half facepiece respirators measured under actual workplace environment are significantly correlated with quantitative fit factors.[103]

The PPT Program initiated the second aspect of this research effort in 2001. This effort was aimed at obtaining current anthropometric data on respirator users in the U.S. workforce to update the respirator fit test panels. The PPT Program recognized the difficulties inherent in using anthropometric data collected in the early 1970s.

A contractor (Anthrotech) was identified and funded to develop an anthropometric database of the heads and faces of civilian respirator users that would be used to update the PPT Program respirator test panel. The requirement was that the database should be representative of the demographic variability in the U. S. The sampling was to include respirator users from all segments of the user population, including those in various types of industrial, health care, and emergency response jobs. Subjects from survey databases representative of the general population were selected to match the proportions of race and age in the year 2000 population.

A total of 4,026 subjects were recruited from industries and public services in which workers routinely or occasionally use respirators. Although the sampling plan did not call for sampling specific geographic regions, subjects were obtained at 41 separate sites located in eight states from the East to West coasts of the United States. Subjects were measured for 21 dimensions and 1,045 of the total were scanned with a 3D scanner. [104]

The researchers established a database containing anthropometric measures that are representative of nationwide populations who rely on respirators to prevent work-related respiratory illnesses, injuries, and death. The measurements of the human subjects surveyed were obtained through the use of traditional measurement tools and a state of the art 3D laser scanning system. The 3D data were analyzed and shape statistics were used to capture the variability in the actual shape of the faces.

Based on the data collected, PPT Program researchers developed two new panels for half- and full-face respirator fit testing. [105] One of the new panels (NPPTL panel) included the same linear measurements used for the presently-used panel developed for the respirator certification program by the Los Alamos National Laboratory (LANL panel). The other panel recommended was based on establishing the appropriate facial features by using principal component analysis (PCA) to identify the combination of facial dimensions that best represented the variation among the faces in the data set. A PCA panel was designed by PPT Program researchers.

The PPT Program identified the importance of validating the quality, relevance, and potential impact of the survey conducted and the recommendations being made prior to incorporating the recommended panel updates into the respirator certification program. Because of the potential implications on the respirator users, manufacturers, and respirator market, the PPT Program commissioned the Institute of Medicine (IOM) to review the 2004 NIOSH report, Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users.[106]

The IOM completed the study and issued its final report in April 2007.[106] The IOM provided three overarching conclusions and a series of recommendations for maximizing the opportunity to incorporate the panel in current respirator certification. The committee also provided recommendations regarding future research opportunities. The three overarching conclusions are quoted here:

- The results of the PPT Program sponsored Anthrotech study represented a clear improvement over the anthropometric data and corresponding LANL fit test face panels that have been used since the 1970s;
- nonetheless, the Anthrotech study had a number of weaknesses that limit its effectiveness and reliability; and,
- certain steps should be taken to address the weaknesses, in order to move toward more effective testing and certification of respirators in the future.

The program has developed an action plan to address the conclusions and recommendations. The action plan is discussed in the What’s Next section.

In another effort toward improving current respirator certification procedures to assess respirator fitting characteristics, the TIL initiative was started in 2003. The objective of the TIL project is to establish a laboratory test capability and performance requirements for respirator certification. Although TIL testing is intended to quantify the ability of respirators to fit a range of individuals, it is not intended to replace individual fit testing as mandated by OSHA.

The inward leakage of a respirator is determined by measuring the concentration of a challenge aerosol outside of the respirator as well as the concentration within the breathing zone. The TIL is defined as the ratio of the external concentration to the breathing-zone concentration. Total inward leakage defines a protective level achieved by a respirator when the contributions of all leakage paths, including face seal leakage, are considered. While the total inward leakage testing performed under laboratory conditions

is not expected to reflect expected actual field level PPE performance, it does represent a criterion for performance that will influence PPE design and performance.

In July 2004, a public meeting was held to introduce the TIL concept to stakeholders and obtain feedback on the initial concept and plan to test half facepiece respirators. A FRN was posted to solicit public comment on the protocol. The FRN generated one input from one stakeholder. The stakeholder comments were considered in the revised protocol and test plan. As a result, several changes were incorporated in the test plan to improve the benchmark testing and protocol.

The TIL protocol, developed in 2004, was designed to improve the initial study design of half facepiece respirators. A peer review team composed of manufacturers and users, as well as scientific experts from academia and government was identified and formally requested to review the protocol. The peer reviewers evaluated the initial TIL concept for the performance requirements and test protocol. Their comments were incorporated in a revised protocol. Benchmark testing began in 2005 using the respirator panel developed as part of the anthropometrics research.

In 2006, the PPT Program completed testing of 101 models of half facepiece respirators on the panel of test subjects to establish a database of half facepiece performance capabilities in a laboratory test protocol. The tests were conducted using a panel of test subjects defined by the PPT Program anthropometric study and the ambient aerosol test protocol using the TSI PortaCount® Plus instruments. Results of these tests were analyzed and used to determine the state of the art performance capabilities of the half facepiece class of respirators. The proposed performance criterion for half facepiece respirators was posted on the PPT website for comment by the general public in May 2007. On May 29, 2007 a Federal Register notice was posted announcing a June 2007 public meeting and soliciting input on the TIL concept. The TIL concept was presented at a public meeting held on the June 26, 2007, where approximately 50 stakeholders and interested parties participated.[107]

Output and Transfer Highlights

These studies have created several new approaches for updating the current respirator panel for certifying respirators. An updated panel using traditional facial measurements has been proposed for half- and full-face respirators. The revised bivariate panel was used to identify human subjects for the total inward leakage benchmark testing. An alternate PCA panel was developed and has demonstrated potential for eliminating outliers (subjects with atypical facial features) from having undue influence on respirator facepiece design. The software for the PCA panel has been developed and is available for PPT Program use. It has been shared with research partners and has received favorable reviews.

These approaches have been incorporated in the current initiative to introduce TIL in the respirator certification process.

The anthropometrics study and results have been presented to ISO committees and are being used to establish standardized headforms for respirator testing. A training video demonstrating how to make the anthropometric measurements necessary to support the PCA panel was produced by the PPT Program. This video, developed for PPT Program researcher use as a Windows media player file, has been shared with research partners and has received favorable reviews. The next step is to initiate action to make the training video available on the PPT Program website.

The Technical Reports and Technical Specifications are being used by the ISO Respiratory Protective Device Standards writing committees as the basis for the future performance requirements. The standards will be used to provide a criterion for improving the reliability and level of protection of respirators by respirator designers and manufacturers, respirator users, respirator wearers, regulators, test facilities and third party certifiers worldwide.

In summary, PPT Program researchers authored a total of 22 peer-reviewed journal articles on this topic, provided 22 presentations, and created two miscellaneous documents such as reports, patents, and book chapters.

Intermediate Outcomes

The Food and Drug Administration (FDA) issued a guidance document for pre-marketing clearance of products for use of the general public during a public health emergency that requires the use of a NIOSH-certified respirator and accepts the use of the updated NPPTL panel to demonstrate adequate fitting characteristics prior to obtaining FDA clearance.

Several respirator manufacturers have reported through informal communications that they have begun using the NPPTL panel as a tool in designing and sizing new respirator facepieces.

The NPPTL panel will serve as the foundation for the TIL respirator certification requirement. The PCA panel will be used in the respirator certification program as a screening criterion for human subject testing in research and certification. Use of this screening tool will eliminate outliers from normal face dimension combinations from having undue influence on respirator facepiece designs.

Results from this research have, to date, impacted one respirator standard developed by PPT Program scientists. Head circumference and neck circumference data have been used in the new NIOSH standard for CBRN escape respirators/hoods.

The data lead to establishment of new fit test panels for today’s workers, which will improve the facepiece design and face fit of respirators and thus the health and safety of the nation’s workers. The new panels, after going through the peer-review process, will be incorporated into the new NPPTL total inward leakage test standard for half facepiece respirators which is anticipated to be promulgated in 2008.

Results from anthropometrics research have been incorporated into a technical specification standard for ISO TC94 SC15 WG1 PG5. That standard is titled “ISO 16976-2 Respiratory Protective Devices — Human Factors — Part 2: Anthropometrics.” [108]

ISO TC94 SC 6 is also waiting for the results of NIOSH PPT research results to be incorporated into the ISO eye and face protection standards. [109]

What’s Next?

Recent trends in the field of PPE testing have focused on the need to effectively evaluate the performance for TIL under laboratory conditions. The PPT Program is moving forward with plans to implement TIL testing as part of its respirator certification activity. TIL requirements will initially be required for half-facepiece air-purifying filtering respirator certification and filtering facepiece respirator certification, with plans to later include appropriate requirements for all respirator certifications.

Since face seal leakage is an important detriment to adequate respirator performance, it is widely accepted that every respirator wearer must be fit tested (typically once a year) to verify that the respirator model and size have been properly selected. In 2007, the PPT Program initiated research to assess the causative factors affecting temporal changes in filtering-facepiece respirator fit. The goals of this study are to (a) assess the rate at which respirator fit changes as a function of time for a representative sample of subjects wearing filtering-facepiece respirators and (b) investigate the factors that affect such change.

The PPT Program is responding to the IOM report by developing an action plan for addressing the IOM recommendations. The action plan strategy was presented at the most recent PPT Program public meeting in June 2007. The action plan will be posted to the PPT Program website for public comment and discussed in detail at a public meeting in fall 2007.

A study was undertaken to investigate any possible effect of overweight or obese states on facial dimensions, and to compare prior anthropometric surveys for the purpose of analyzing study population differences that might affect facial dimensions utilizing the NPPTL respirator fit test panel.[110, 111]

List of Outputs

Peer Reviewed Publications

Zhuang Z, Bradtmiller B, and Shaffer RE [2007]. New respirator fit test panels representing the current U.S. civilian workforce. J Occup Environ Hyg. 4: 647-659. [105]

Duling MG, Lawrence RB, Slaven JE, Coffey CC [2007]. Simulated workplace protection factors for half-facepiece respiratory protective devices. J Occup Environ Hyg. 4(6):420-31. [112]

Coffey CC, Lawrence RB, Zhuang Z, Duling MG, Campbell DL [2006]. Errors associated with three methods of assessing respirator fit. J Occup Environ Hyg. 3(1):44-52. [95]

Lawrence RB, Duling MG, Calvert CA, Coffey CC [2006]. Comparison of performance of three different types of respiratory protection devices. J Occup Environ Hyg. 3(9):465-74. [113]

Martin S, Moyer E, Jensen P [2006]. Integrated unit performance testing of powered, air-purifying particulate respirators using a DOP challenge aerosol. J Occup Environ Hyg. 3(11):631-41. [114]

Martin S, Moyer E, Jensen P [2006]. Powered, air-purifying particulate respirator filter penetration by a DOP aerosol. J Occup Environ Hyg. 3(11):620-30. [115]

Roberge RJ, Zhuang Z, and Stein LM [2006]. Association of body mass index with facial dimensions for defining respirator fit test panels. Journal of the International Society for Respiratory Protection, 23(I-II):44-52. [110]

Campbell DL, Coffey CC, Zhuang Z**,** and Jensen PA [2005]. Reducing respirator fit test errors: a multi-donning approach. Journal of Occupational and Environmental Hygiene, 2:391-399. [116]

Doney BC, Groce DW, Campbell DL, Greskevitch MF, Hoffman WA, Middendorf PJ, Syamlal G, Bang KM [2005]. A survey of private sector respirator use in the United States: an overview of findings. J Occup Environ Hyg. 2(5):267-276. [117]

Maciejczyk P, Zhong M, Li Q, Xiong J, Nadziejko C, Chen LC [2005]. Effects of subchronic exposures to concentrated ambient particles (CAPs) in mice. II. The design of a CAPs exposure system for biometric telemetry monitoring. Inhal Toxicol. 2005 Apr;17(4-5):189-197. [118]

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3.5 Pandemic Influenza Preparedness Back to the Table of Contents

Issue

The human-to-human spread of avian influenza (H5N1) during a public health emergency is a hazard to workers and the general public. During a pandemic, transmission can be anticipated in the workplace, not only from patient to workers in healthcare settings, but also among co-workers in general work settings. Close interpersonal activities, whether interaction among co-workers or with customers and the general public, present a higher risk possibility for transmission to occur.

A pandemic would cause high levels of illness, death, social disruption, and economic loss. Everyday life would be disrupted because many people in many places would become seriously ill at the same time.

Effective vaccines for a novel influenza strain causing a pandemic will probably not be available for an extended period of time. Use of respirators and surgical masks is expected to be an important intervention available, at least at the onset, to healthcare and other workers to help avoid infection and stem the spread of a pandemic. The potential for respirators and surgical masks to be used in unprecedented numbers for an extended duration raises issues of availability of supply and adequacy of protection in their use. It has been estimated that demand for N95 respirators by the healthcare sector alone could exceed 90 million for a 42 day outbreak.

Background

In January 2006, the Department of Health and Human Services (DHHS) Office of the Assistant Secretary for Public Health preparedness, through the PPT Program, engaged the IOM to address issues regarding the availability of surgical masks and N95 respirators in the event of a pandemic influenza event. Issues of concern included availability and public use of respirators, reusability of respirators and surgical masks, duration of wearing current filtering facepieces, and the potential for new design types for N95. The IOM panel's report on reusability of facemasks during an influenza pandemic was completed in 2006. The PPT Program was integrally involved in the activities of this IOM committee. The output from this effort served as an input to the ongoing PPT Program's research activity.

Approach

The IOM report, *Reusability of Facemasks During An Influenza Pandemic*, [152] provided recommendations to address the charge to the committee. The PPT Program acted upon the following PPT specific findings and recommendations:

- Cover a respirator worn by an individual who needs to reuse it with a medical mask to protect the respirator from contamination,
- Conduct research that will lead to better understanding of the efficacy of decontamination methods,
- Conduct research on the risks associated with handling a respirator that has been used to protect against a viral threat.

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) consulted the PPT Program in spring 2006 to discuss a new classification of medical device. The new classification was intended to reduce the general public risk of exposure to pandemic influenza. Collaborative discussions about program Anthropometrics, fit testing research and respirator certification were conducted. Acting on program technical support the FDA announced establishment of criteria for evaluating the new device that includes respirator fit testing requirements based on program research outputs for Anthropometrics and fit testing. The FDA criteria also specifies the medical device must be a NIOSH certified N95 respirator.

In another effort to increase pandemic influenza preparedness, the PPT Program is actively working with other government agencies and stakeholders to develop and prepare an influenza response. Given its unique expertise within CDC, PPT Program researchers are taking the lead on workplace and industrial hygiene issues.

Public and worker demand for N95 FFRs and surgical masks is expected to be extremely high during a pandemic influenza outbreak, particularly at the outset. Manufacturers have begun submitting applications for certification of filtering facepiece designs. The PPT Program has aligned resources in its respirator certification activity to ensure the timely processing of all received applications. The PPT Program maintains specific FFR information on the NPPTL website.

Output and Transfer Highlights

PPT Program scientists have contributed to the development of documents, publications and websites for knowledge dissemination. They have organized and participated in meetings and other communications, and they have provided technical reviews and assistance:

Extramural PPT Program research on the efficacy of N95 respirators against virus size particles was presented at a national conference in 2005. [153]

Standards Development

A PPT Program researcher proposed a new work item for a standard titled “Test Method for Evaluation of the Effectiveness of Biological Decontamination Procedures on Viral Contaminated Air Permeable Material” to the ASTM F23.40 Subcommittee. The sub-committee approved the creation of a work item and the submission of a draft for the next subcommittee ballot.

Technical Presentations

PPT Program scientists have provided presentations on avian influenza and PPT prevention response efforts at professional meetings, including:

American Industrial Hygiene Association (AIHA) (2006) www.aiha.org/Content/CE/aihce/aihce-iaqsymp.htm

At least monthly information briefings are provided to CDC and HHS leadership regarding respiratory protection issues for pandemic flu.

Meeting Disseminations

A meeting on Public Use of Respiratory Protection was held in January 2006. The meeting was called by the NIOSH OD and PPT Program scientific experts served as PPT consultants for the meeting. The impetus for the meeting was that in the event of an influenza pandemic, utilization of N-95 surgical masks, and other types of mouth/nose protection will likely become increasingly popular, thereby affecting availability and likely requiring prioritization or rationing of use. The public and other branches of government will need consistent, clear, and timely guidance. Issues related to prioritization and rationing were discussed. A range of participants attended the meetings, including: participants from across CDC, the International Safety Equipment Association, and respirator manufacturers.

Personal Protective Equipment on the Strategic National Stockpile: A series of meetings were held with DHHS, DHQP, DSNS, and NCID to discuss and determine the appropriate type and balance of PPE to place in the Strategic National Stockpile in the event of an influenza pandemic. Surgical N-95 respirators were recommended as a first priority to be purchased with the $65 million appropriation.

PPT Program scientists organized and participated in a workshop on “Respiratory protection for infectious agents” in Atlanta, Georgia, in November 2004. The aim of this workshop was to understand the research gaps in respiratory protection against infectious aerosols and to explore research needs. Scientists from various branches of CDC, universities, respirator manufacturers and stakeholders participated and shared information on respiratory protection for infectious aerosols. Information from this workshop is posted on the PPT Program website and has been incorporated in PPT Program project plans and research proposals.
http://www.cdc.gov/niosh/npptl/resources/pressrel/announcements/113004wkshp/questions.html

NIOSH Interagency Workgroup Meetings

A working group has been formed for avian influenza issues to provide recommendations for various work sectors regarding PPE, work practices, and surveillance. The workgroup meets regularly to address technical issues related to avian influenza prevention; the group has USDA and FDA representation.

Food and Drug Administration

PPT Program scientists provide technical assistance to the U.S. FDA through participation in weekly meetings. They offer a resource to address occupational health and safety issues in the context of food safety.

Technical Reviews/Assistance

Respirator use for pandemic influenza: The DHHS Office of the Assistant Secretary for Public Health preparedness, through a NIOSH/PPT Program Interagency Agreement , engaged the IOM

to address issues regarding the availability of surgical masks and N95 respirators in the event of a pandemic influenza event. Issues of concern included availability and public use of respirators, reusability of respirators and surgical masks, how long current filtering facepieces may be worn, and the potential for new design types for N95. An IOM panel studied these issues. Their report on reusability of facemasks during an influenza pandemic, was completed in 2006. [152]

In a related effort PPT Program scientists were invited to participate as subject matter experts (SME) and Peer Review panelists at a meeting at Tyndall Air Force Base, Florida. The purpose of the panel was to review historical and current studies concerning the penetration of viral particles through HEPA (high efficiency particulate air) filters used by the military for collective (COLPRO) and individual (IPE) protection; exchange data on bioaerosol removal efficacy of HEPA filters; and to summarize findings and identify technical gaps for briefings with military leadership.

DHS Pandemic Flu Plan Review

The Department of Homeland Security (Coast Guard) has requested NIOSH/PPT Program review and comment on their internal Pandemic Flu Plan (addressing protection of Department of Homeland Security (DHS) Personnel). The plan is under the direction of the Department of Homeland Security Medical Director. The NIOSH Coordinating Office of Emergency Response is working with DHS on this project.

Homeland Security Council National Implementation Plan Review: The Homeland Security Council has requested PPT Program review of the PPE sections of the national pandemic flu implementation plan. [154]

Intermediate Outcomes

As revised recommendations for respiratory protection are an important means of protecting worker health against infection, PPT Program scientists met with respirator manufacturers to address concerns that the demand for NIOSH-certified N95 disposable respirators might outrun supply. As a practical solution to this international problem, PPT Program scientists played an integral role in convincing the World Health Organization (WHO) to revise its posted recommendations for respiratory protection by emphasizing that some respirators certified by governments of other countries provide protection similar to NIOSH-certified N-95s and thus are acceptable for use to protect against influenza

Program Activities Requiring Response for Pandemic

FDA established a new device class, 21 CFR 880.6260 [155] for use by the general public. The device is required to first be certified by NIOSH prior to being classified as an FDA device for use by the general public in public health emergencies. Information regarding this device is available at: http://www.fda.gov/cdrh/pdf6/K062070.pdf

In addition to the general controls of the act, the FDA CDRH determined that Respirators for Use by the General Public in Public Health Medical Emergencies are subject to the following

special controls: (1) Certification by NIOSH as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84 and (2) The FDA guidance document entitled: *Guidance for Industry and Food and Drug Administration Staff; Class I1 Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies*.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=2266 [156]

What's Next?

A NIOSH Alert to help prevent avian influenza transmission to poultry workers will be released in the near future. PPT Program scientists will continue to work with its partners in labor, industry, and other government agencies to coordinate prevention efforts for avian influenza. The completion of draft and new guidance is a priority.

The PPT Program has been actively engaged in identifying and addressing issues relevant to a pandemic influenza outbreak. These efforts include research to fill knowledge gaps, prepare for evaluation of novel and innovative technologies for respiratory protection, as well as evaluation measures to address anticipated supply problems and inventory depletion of respirators during a pandemic emergency. Several research initiatives are underway in response to the 2006 IOM report, *Reusability of Facemask during an Influenza Pandemic.* [152] A key focus of the research is to assess strategies to prevent a respirator shortage during a pandemic. The PPT Program has initiated the study using six commercially available or prototype respirators in collaboration with the manufacturers.

In 2006, PPT Program scientists prepared a research proposal to assess the reusability of disposable filtering facepiece respirators used for protection against infectious aerosols. Laboratory studies are being conducted to achieve two objectives: (1) to understand the efficacy and impact of decontamination methods on respirator performance and (2) to understand the risks associated with handling a respirator exposed to virus particles.

In this project, studies will continue to assess the effects of decontamination on the filtration performance of FFRs. Preliminary studies [150] have shown that decontamination using an autoclave, 160 ºC dry heat, 70% isopropyl alcohol, and soap and water (20 minute soak) caused significant filter degradation to the N95 and P100 FFR models tested. The particle penetration levels were larger than allowed for NIOSH certification. Filtration performance after decontamination using bleach, ethylene oxide, and a microwave oven was degraded for both respirator models, although particle penetration levels were still less than the NIOSH certification criteria. The decontamination methods that had the least affect on particle penetration were vaporized and liquid hydrogen peroxide and UV radiation. Future research should consider low-temperature decontamination methods such as vaporized and liquid hydrogen peroxide, ethylene oxide, microwave radiation for two minutes or less, UV radiation, and 10% diluted household bleach for further study.

In another aspect of this project, the PPT Program will also continue to refine the new ASTM work item accepted for addressing the effectiveness of techniques used to biologically

decontaminate filter materials. This work is significant as it represents the first respirator-related work to be undertaken by ASTM Committee F23;[157] and addresses an urgent national need in the likelihood of a pandemic event that exhausts the national supply of disposable respirators.

Another aspect of the research that will continue is laboratory studies to assess the performance of new biocide technology that can be incorporated into respirator filter media. The issue of disinfecting respirators for reuse has resulted in several manufacturers developing new products using technologies intended to offer biocidal and antimicrobial protection as a design feature of the respirator. Using a federal register notice published in 2006, the PPT Program initiated collaborations with six manufacturers to assess commercially available and prototype respirators incorporating biocidal technologies. The research will evaluate the ability of each mechanism to neutralize viruses, and any reaction by-products or off-gassing that result. The PPT Program respirator certification and research activities also are partnering with the FDA CDRH under an existing CDC/FDA MOU for the evaluation of the effectiveness and health effects of the biocide/antimicrobial treatments.

In 2006, the PPT Program research activity prepared two additional research proposals as a result of the IOM report to assess reusability of disposable filtering facepiece respirators used for protection against infectious aerosols. One initiative focuses on the committee's recommendation of wearing a surgical mask loosely over an N95 FFR to extend the usable time of the disposable NIOSH-certified FFRs used for respiratory protection against influenza and other infectious aerosols. Laboratory studies are being conducted using a metabolic breathing simulator (1) to evaluate the additional physiological burden due to the increased breathing resistance from the addition of the surgical mask and (2) to understand the risks of potential breathing air quality problems that may be caused due to carbon dioxide buildup in the breathing zone due to the increased breathing resistance.

In 2007, another research project was initiated to extend the laboratory based simulator experiments to human test subjects using the PPT Program's exercise physiology laboratory. Furthermore, a collaboration has been established with the Department of Veterans Affair's North Florida/South Georgia Veterans Health System related to an on-going study it is conducting on the tolerability of respirators in hospital settings. The three projects have agreed to use the same respirators for testing in the three different environments (simulator, human subjects exercising in a laboratory, and health care workers) and to exchange data.

The second PPT Program initiative focuses on the issues of changes in a half-facepiece respirator fit to a user's face over time for specified time periods (e.g., 6, 12, 18, 24 months). Laboratory studies will be conducted to (1) determine the rate of change of critical facial dimensions affecting fit for 200 human subjects at 6-month increments for a 3-year study period and (2) the effects of the changes over time in facial dimensions on the quantification of the level of protection attained with fitted half facepiece respirators. Work is beginning on the research proposals in 2007.

PPT Program research is in progress to better understand the production of aerosols by coughing. The results of this research will give scientists and health professionals' greater insight into the

airborne transmission of disease and allow them to better assess the potential effectiveness of preventive measures. The specific objectives of the project are:
1) Measure the quantity and size distribution of aerosol produced during normal human coughs. Human subjects will exhale or cough into a spirometer, and the aerosol produced by each subject will be characterized to determine the quantity and size distribution of the aerosol produced by human coughs.
2) Determine the effectiveness of surgical masks and N95 respirators at filtering cough-generated aerosols. Human subjects will cough into a spirometer, and the aerosol produced by each subject will flow through a mask or respirator and then be analyzed. These experiments will determine how effective each mask or respirator is at preventing the release of cough-generated aerosols.
3) Study the dissemination of virus-laden aerosols produced by coughing. This work will use laboratory and field studies to gain a better understanding of the dissemination of viral aerosols, and to develop and refine detection methods for airborne influenza virus.

The PPT program is sensitive to the effect activities in its respirator certification program can have on the national inventory of respirators. Consequently, PPT Program scientists in the respirator certification program have been aligned to allow expeditious processing of applications for new N95 FFR designs, including those using innovative or novel technologies. The aforementioned collaboration with the FDA CDRH is an example where these efforts are already underway.

The implementation of the new TIL requirements to assess a respirator’s ability to fit a range of facial dimensions will need to be sensitive to the continued availability of existing inventories of half-facepiece respirators. Hundreds of millions of N95 half-facepiece respirators are being stockpiled in preparation for a pandemic outbreak. These are in addition to those used daily by workers who use them as a regular part of performing their jobs.

Outputs of the PPT Program research activity could provide technologies that enable respirators with novel fit designs that provide, for example, continuous indication of fit. The reliability of PPT protection from inhalation hazards could be improved significantly from such advances in respirator design.

List of Outputs

Peer Reviewed Publications

Viscusi, D., King, W., Shaffer, RE [2007], Effect of Decontamination on the Filtration Efficiency of Filtering Facepiece Respirators, manuscript currently in internal peer-review. [158]

Roberge R. [2007] "Evaluation of the Rationale for the Concurrent Use of N95 Filtering Facepiece Respirators with Loose-fitting Powered Air-purifying Respirators During Aerosol-generating Medical Procedures" Accepted for publication in American Journal of Infection Control. [159]

Roberge R. [2007] Effect of surgical masks worn concurrently over N95 filtering facepiece respirators: extended service life vs. increased user burden. Accepted for publication in the Journal of Public Health Management [160]

Rengasamy A, Zhuang Z, BerryAnn R [2004]. Respiratory protection against bioaerosols: literature review and research needs. Am J Infect Control. 32(6):345-54. [161]

Conferences and Presentations

Roberge R, [2006] Powered air-purifying respirator use by first receivers: personal performance issues. 13th Conference of the International Society for Respiratory Protection, Toronto, Canada, August 28 – 31, 2006. [162]

Gardner P, Richardson A, Hofacre K, Rengasamy A, [2006] Efficiency of respirator filters against a viral aerosol. 13th Conference of the International Society for Respiratory Protection, Toronto, Canada, August 28 – 31, 2006. [163]

Roberge, R [2005], Powered Air Purifying Respirator Use Among First Receivers: Personal Performance Issues, presented at the First Responder Conference at Virginia Tech in Blacksburg, VA. October 2005. [164]

Other Media

A PPT Program scientist was interviewed by the editor of Advance for Nurses about the reusability of NIOSH certified N95 filtering facepiece respirators. She was provided background information about the project and the methods that will be used to transition this research to practice. The importance of fit testing was also discussed. The editor requested information about PPT Program outreach to the healthcare worker and nursing communities. In April 2007, the article appeared in the trade magazine Advance for Nurses titled "Certain facemasks are appropriate PPE in the event of a pandemic: reusability, fit and type are important". [165]

3.6 Evaluate the Nanofiber-Based Fabrics and NIOSH-Certified Respirators for Respiratory Protection Against Nanoparticles

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Issue

Increasing numbers of workers are potentially exposed to nanomaterials in research laboratories, startup companies, production facilities, and in operations where nanomaterials are processed, used, disposed, or recycled. Nanoparticles present a very large surface area to mass ratio and their toxic effects appear to be increased accordingly. Early evidence from mammalian toxicity studies indicates that nanoparticles exhibit increased reactivity and toxic effects following inhalation exposure.[166] The need for high levels of respiratory protection is growing to ensure the safety of workers in healthcare and other industrial workplace settings. PPT Program research activities investigating nanoparticles as dermal hazards are discussed in Chapter 4.1.

Background

Nanotechnology is the term used to describe new methods that have been developed to manipulate and build materials at the molecular level and engineer materials at a scale of less than 100 nm (one billionth of a meter).[167] New materials, structures, and devices are being developed and produced that exhibit unique physical, chemical, and biological properties. Although the risks of exposure are still unknown, an increasing number of nanoscale products and materials are becoming commercially available. These include powders, solutions and suspensions, as well as composite materials and devices having a nanostructure.

The Federal government is currently investing approximately $1 billion per year in nanotechnology research and development, under the coordination of the National Nanotechnology Initiative (NNI). The global nanotechnology market will be worth more than an estimated $2.6 trillion by 2014, and will involve approximately two million new workers worldwide and employ one million workers in the U. S. alone.

Since February 2004, NIOSH has developed a strategic research plan that contains 10 critical topic areas of activity—including PPT research—specific to understanding the health and safety implications of developing, producing, or using engineered nanoparticles, and the potential applications of nanotechnology in the prevention of occupational disease and injury.
In response to the concerns that have been raised regarding the possible hazards and risks associated with producing or using engineered nanoparticles, NIOSH has created its Nanotechnology Research Center (NTRC) in 2005. To guide the activities of the NTRC, NIOSH scientists developed several documents as shown below.

In 2005, the PPT Program also became a member of the Center for Filtration Research (CFR), established by the University of Minnesota, Minneapolis. Members include manufacturers of filter media, aerosol equipment, electronic equipment and computers, and academic and government agencies. CFR is focused on research activities including filtration mechanisms, filter testing methods, filter pleating design, electret filtration, bioaerosol filtration, ultrafine aerosol filtration, and nanoaerosol filtration. CFR conducts review meetings two times a year. Members can propose research projects that may be investigated by the University of Minnesota.

Approach

As noted in the 2007 NIOSH nanotechnology progress report [168] the majority of the PPT research was focused on activities that will lead to guidance for the safe handling of nanomaterials in the workplace. Shortly after the formation of the NIOSH NTRC, the PPT Program developed a research strategy to address the key information gaps related to the performance of respiratory protection devices against nano-sized aerosol inhalation hazards. All of the work completed to date has focused on the filtration of nanoparticles using filter media and NIOSH approved FFRs.

The first research study funded by the PPT Program investigated the respirator filter efficiency against nano-aerosols (20 to100 nm), which are potential particulate exposure hazards associated with nanotechnology, and larger size aerosol particles (>100 nm) produced in traditional industrial workplace settings. The filtration efficiencies of NIOSH-approved P100 and N95 particulate respirator FFRs and cartridge filters were measured at high volumetric and peak flow rates. Four cyclic flow conditions (40, 85, 115, and 135 L/min minute volume) with peak flows up to 430 L/min and three constant flow rates (85, 270, and 360 L/min) were evaluated. As expected, aerosol penetration was found to increase with increased cyclic and constant flow rate. The magnitude and significance of this increase was dependent on the specific filter type and design. The most penetrating particle size was generally between 100 and 200 nm for the P100 cartridge filters and 50 and 100 nm for the N95 cartridge filters and all FFRs. In general, the filters met the penetration requirements for N95 and P100 filters for all particle sizes tested at a constant flow of 85 L/min. However, nano-aerosol penetrations in excess of 0.03 % and 5.0 % for the P100 and N95 filters, respectively, were observed at constant and cyclic flow conditions above 85 L/min. Comparison of the penetrations measured under cyclic and constant flow indicates that the mean and peak inhalation flow rates are important parameters to consider when evaluating filtration performance. For the P100 and N95 cartridge filters, similar penetrations were measured under constant and cyclic flow if the constant flow was equivalent to the mean inhalation flow rate. The penetrations measured at constant flow rates equivalent to the peak inhalation flow under cyclic flow conditions tended to provide a more conservative estimate of filter performance. [169-171]

The first research study provided information on the laboratory performance of NIOSH approved respirators against aerosols larger than 20 nm in diameter. However, less is known about particles smaller than 20 nm size in size. It has been speculated that particles in this size range or smaller may simply pass through filter media due to thermal rebound effects. To increase knowledge and understanding of these smaller particles, the PPT Program and the NTRC funded another study in 2005 at the University of Minnesota's CFR. The purpose of this study was to measure the penetration of nanoparticles between 3nm and 20nm in size through various filter media, including glass fiber, electret, and nanofiber. Particle penetration decreased with decreasing particle diameter. [172] The respirator filter media tested in this study effectively collected nanoparticles down to 3 nm size. Particle penetration results also showed no deviation from the classical single-fiber theory for particles as small as 3 nm in diameter. No evidence for thermal rebound was found in the particle size ranges tested. These findings allowed the PPT Program to provide preliminary recommendations to the NTRC related to the performance of respirators currently certified for respiratory protection against nanoparticles. [170]

In 2006, the PPT Program initiated an in-house research program to conduct a laboratory study to determine whether nanoparticle face seal leakage is consistent with the leakage seen by larger particles and gases/vapors and to validate the filter efficiencies levels seen by the University of Minnesota team using NIOSH approved respirators, rather than flat sheet filter media. The first phase of this project focused on a comparison of monodisperse and polydisperse NaCl particle penetration through N95 filtering facepiece respirators. Important findings from this study include that polydisperse aerosol penetration levels were less than 1.24% by the NIOSH certification test method. Penetration levels of 40 nm monodisperse aerosol (the most penetrating particle size range) was slightly higher than 5% for two of the five models tested, but the average penetration levels were not statistically larger than 5%. The polydisperse aerosol test provided a consistent rank-ordering of the filtration performance seen with the 40-300 nm monodisperse particles. These data support the previous findings that NIOSH certified air purifying respirators will provide protection consistent with their assigned protection factor when used in a complete respirator program even in the nanoparticle range.

Consistent with the NIOSH/NTRC strategic plan, the PPT Program also conducts research on the applications of nanotechnology to occupational safety and health. In 2005, the program initiated research to evaluate nanofiber-based fabrics for respiratory protection against airborne particulate aerosols. Filter media that incorporate nanofiber materials have the potential to significantly increase the capture efficiency of particles in the 50 to 300 nm range, without increasing the pressure drop across the filter media. Nanofiber based filter media were produced by an electrospinning process. Different diameter size media were generated and their physical properties characterized. The media were tested for filtration efficiency and pressure drop. No significant increase in filtration efficiency or decrease in pressure drop were observed. The research partners were not experienced in producing nanofibers and were unable to produce consistent, quality nanofiber filter media. Therefore, the research project was terminated in 2006 without being able to have adequate samples to be analyzed for filtration efficiency and pressure drop under different humidity conditions and face velocities, as proposed.

Output and Transfer Highlights

PPT Program researchers contributed to development of four NIOSH Scientific Information Products and five sponsored conferences.

PPT Program researchers contributed to two peer-reviewed journal articles/manuscripts.

PPT Program researchers were active in planning and implementing a number of forums to interact with researchers and entrepreneurs engaged in nanotechnology development, all of which involved the consideration of PPE precautions.

PPT Program researchers presented research or guidance at more than 15 conferences.

The NTRC Applications research program is in its early development stages. Research is primarily focused on improving worker health and safety by applying emerging nanotechnologies in the workplace. Sensors can warn workers of a hazardous exposure or develop better materials that can be used in making protective equipment and clothing. Within

the NTRC, as well as through partnerships and collaborations, the PPT Program scientists with other NIOSH experts accomplished the following according to the recent progress report: [168]

- Developed a methodology to identify emerging nanotechnologies that may pose a safety and health risk to workers.
- Developed a prototype sensor that can detect organic vapors and be embedded into respirator cartridges.
- Developed a non-invasive bio-monitoring capability to evaluate exposure to organophosphorus insecticides.
- Developed an extremely sensitive, low temperature, low cost, and miniaturized sensor that can be mounted inside a respirator to warn users when toxic organic vapors are inside the respirator.
- Designed, developed, and demonstrated improved sensor technology for detecting hydrogen sulfide.

The PPT Program certification part alerts general public on respirator products in the market with misrepresentation of NIOSH approval. The certification part of the PPT Program is also active in monitoring the misrepresentation of the respirator approval status. In 2006, the PPT Program issued a notice that the Nano Guard Particulate Respirator was not NIOSH-approved as advertised.[173]

The PPT Program researchers were part of the NIOSH initiative to develop several web-based documents: *Nanoparticle Information Library,* and *Nanotechnology Frequently Asked Questions*. *Approaches to Safe Nanotechnology* (October 2005, updated August, 2006) [174-176] is available on the NIOSH website and provides interim risk management recommendations, with a focus on eliminating the primary route of exposure, namely, inhalation. The Web-based *Nanoparticle Information Library* (2005) collects and disseminates information on the morphology, chemical, and physical characteristics of nanoparticles and is intended to be a resource to toxicologists and occupational health practitioners in predicting the activity of nanoparticles. The Web-based document *Frequently Asked Questions* (2005) was produced to provide answers to questions regarding health concerns associated with nanotechnology. In addition, the NIOSH staff has published more than 70 articles in peer-reviewed scientific journals and published symposia proceedings, and made more than 170 invited and contributed presentations at technical meetings, conferences or special symposia—some directly PPE-related—on occupational health aspects of nanotechnology.

Intermediate Outcomes

Appendix R provides more than 100 examples of demonstrations of use of PPT Program outputs for workplace safety and health. Several examples applicable to respiratory protection against nanoparticles include:

NIOSH partnered with other government agencies primarily through participation in the NNI, a federal R&D program established to coordinate the multiagency efforts in nanoscale science, engineering, and technology. The NNI is managed within the framework of the National Science and Technology Council. NIOSH is a member of the NTSC's Nanoscale Science, Engineering, and Technology Subcommittee. Within that subcommittee, it co-chairs, with the U.S. Food and

Drug Administration, the interagency Nanotechnology, Environmental and Health Implications Working Group. NIOSH's collaboration with other agencies includes a joint grant solicitation with the Environmental Protection Agency and the National Science Foundation to fund new research on questions of environmental and human health effects of manufactured nanomaterials.

Two of six grants awarded under this solicitation related to PPE research. One grant for research between NanoScale and Gentex Corp. entitled, F*rom Nanoparticles to Novel Protective Garments*, [177] aims to investigate the use of highly adsorbent and reactive nanoparticles in protective garments and create and test new materials for use in the production of protective clothing. The other grant to the University of Iowa entitled, *Assessment Methods for Nanoparticles in the Workplace*, [178] aims to provide the scientific community and practicing industrial hygienists with verified instruments and methods for accurately accessing airborne levels of nanoparticles and assess the efficacy of respirator use for controlling nanoparticle exposures.

The Synergist reported in 2006 on NIOSH taking action at the forefront of solving problems before they arise regarding nanotechnology. With businesses involved in nanotechnology research and applications ranging from small lab groups, to startup companies, to multinational companies, there is probably a large discrepancy in the PPE and controls used to protect workers. There is also a large discrepancy in the amount of fugitive emissions of nanoparticles. The magazine reported that a study of various respirator filtration media was underway at the PPT Program with initial results that showed that the capture efficiency for particles in the three to 30 nanometer range was very good. Many other issues required examination including particle size leakage related to a mask's fit. In addition, safe handling practices for nanoparticles need to be developed based upon the investigation of various fabrics used in gloves and protective clothing.[179]

Business & Legal Reports commented on the NIOSH report, *Progress toward Safe Nanotechnology in the Workplace*, in March 2007.[168] It reported that preliminary evidence showed that respirators can be effective in protecting workers from particulates as small as 2.5 nanometers in diameter. While this evidence needs confirmation, it suggests that it is likely that NIOSH-certified respirators will be useful for protecting workers from nanoparticle inhalation when properly selected and fit tested as part of a complete respiratory protection program.[180]

The University of Dayton posted a policy based upon NIOSH's lead in conducting research and partnering with other organizations involved in nanoparticle health and safety research, which referred to an in-depth review of the current information regarding nanoparticle toxicity and control at http://campus.udayton.edu/~UDCampusPlanning/EnvironmentalHealth/Heath-Safety/Nanosafety.html [181] The policy included requirements regarding PPE:

- Ensure respirators are correctly specified and fitted.
- Use P-100 filter media.
- Ensure proper installation of HEPA filters and secure sealing of housing to prevent nanoparticles from escaping around housing.
- Wear Tyvek coveralls, latex or nitrile gloves, and eyeglass protection and gloves should adequately cover full hand and wrist area.

In draft guidelines for safe nanotechnology research, dated May 15, 2007, the University of California at Berkeley recommended a requirement that when work occurred outside of a ventilated area with nanomaterials that could become airborne, that a respirator be worn with NIOSH-approved cartridges that filter particles (N100 filters approved by NIOSH are more than 99.97% efficient for particles).[182]

As a result of the production of *Approaches to Safe Nanotechnology* [175] and other NIOSH activities such as sponsoring the first international conferences on nanotechnology and its occupational safety and health implications, the United States has provided strong international leadership and vision during formation of the new ISO Technical Committee on Nanotechnologies; this resulted in the United States being granted the chairmanship of the Working Group on Safety and Health Standards.

The digital magazine, ChemicalProcessing.com, reported on the utility of the 2006 document, *Approvals to Safe Nanotechnology: An Information Exchange with NIOSH*. While cautioning that there is limited information about the health risks associated with occupational exposures to nanoscale materials, the document urged stakeholders to embrace precautionary work protections including personal protective clothing and respiratory protection.[183]

CNA Commercial Insurance reported on the NIOSH document posted for public comment and entitled, *Approaches to Safe Nanotechnology*.[184] The organization reported that personal protective equipment should be used when exposures cannot be eliminated by engineering controls. Regarding airborne exposures, properly selected and fit tested NIOSH-certified respirators are expected to be the most effective protection for particulates as small as 2.5 nm in diameter. Gloves should always be worn when handling nanomaterials. Disposable nitrile gloves are expected to provide protection in most situations.[185]

The PPT Program is working with the DuPont Occupational Safety & Health consortium on the identification of test methods for protective clothing and respirators. The PPT Program is collaborating with the International Safety Equipment Association on respirator filter media work being conducted at the University of Minnesota to assess the filtration efficiency against nanoparticles.

External Factors

Despite the widespread use of this technology, there are still unanswered questions for risk assessment. More than $30 billion in products incorporating nanotechnology were sold globally in 2005. By 2014, Lux Research estimates this figure will grow to $2.6 trillion. Scientists have hailed nanotechnology as the next great scientific revolution, poised to create revolutionary changes in the daily lives of people worldwide, but the unpredictable properties materials exhibit at the nanoscale may have as much potential to harm as to help. To date only a few safety risk assessments have been conducted, despite more than 500 consumer products labeled as containing nanotechnology.

Two examples show the spreading interest of nanotechnology applications in PPE development. To protect against the avian influenza virus, a “Nano Zen Mask” is being developed using silver

nanotechnology to meet the requirements of the N95 grade filter material.[186] The NanoMask, with claims of 27 nanometers filtration capability, claims to use a patented nanotechnology to enhance the capture-and-isolation characteristics of the filter media.[187]

Nanotechnology is yielding innovative commercial products, yet it still needs to mature into a full industry. Nanotechnology arrived in consumer products, even without labeling as such, decades ago in varnishes and medicinal products. Nanoparticles from titanium dioxide or zinc oxide have also been used in cosmetics for some time as UV filters. Materials scientists and engineers have improved methods of synthesis of nanomaterial solids leading to the rise of re-engineering existing products.

Nanotechnology offers a myriad of applications for producing new gas sensors, optical sensors, chemical sensors, and other energy conversion devices to bio implants, and it opens the opportunity to produce cheaper and friendlier solar cells. The future soldiers' uniform could incorporate soft woven ultra-strong fabric with capabilities to become rigid when, for example, a soldier breaks his leg. It could also protect the soldier against poisoning and other hazards.

Nanotechnology offers unlimited opportunities to produce new generation pressure, chemical, magneto-resistive and anti-collision automobile sensors. Nanotechnology is viewed as a key technology for the development of ultra-light materials which would result in energy, fuel and materials savings and development of specialized materials with complete control over structure and properties at a subatomic level.[188]

An important external factor regarding the safety and health implications of nanotechnology is the NNI by the Federal government. The NNI is a federal R&D program. The NNI was established to coordinate the multiagency efforts in nanoscale science, engineering, and technology and is managed within the framework of the National Science and Technology Council, the Cabinet-level council by which the President coordinates science, space, and technology policies across the Federal government. The goals of the NNI are to:

- Maintain a world-class research and development program aimed at realizing the full potential of nanotechnology;
- Facilitate transfer of new technologies into products for economic growth, jobs, and other public benefit;
- Develop educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology; and,
- Support responsible development of nanotechnology.

What's Next?

Nanotechnology holds great promise and challenge for occupational safety and health. Already, respiratory protection products are being marketed with nanoparticle-related performance claims. One set of performance claims assert that particulate respirators certified to the PPT Program respirator standards do not filter nanoparticles. The second set presents claims that particulate filters exhibit significant performance benefits when constructed of engineered nanoparticles. Performance benefits are claimed to include the unique ability to capture and filter hazardous

nanoparticles from the ambient air. The PPT Program recognizes the need to continue to monitor claims regarding NIOSH respirator certification and performance capabilities.

Consistent with the strategic plan of the NIOSH NTRC, the PPT Program will continue to seek opportunities for research that utilize nanomaterials to improve occupational safety and health. Nanotechnology based sensors and communication devices may help in handling emergencies and in empowering workers to take preventive steps to reduce their exposure to risk of injury. Their small size coupled with wireless technology may facilitate development of wearable sensors and systems for real-time occupational safety and health management. For example, the research discussed in Section 3.7 utilizes nanomaterials as a chemically sensitive layer to detect respirator cartridge breakthrough.

The majority of the planned future research will continue to focus on laboratory-based studies to address the remaining key information gaps needed to produce guidance for workers handling nanomaterials. Research described earlier in this section will expand beyond N95 FFRs to include P100 FFRs as well as other commercially available respirators that are not NIOSH approved. Other research will seek to address nanoparticle leakage around the face/mask interface using nanoparticles in the range of 4 to 400 nm. These studies will use a manikin and controlled leak sites to determine if the leakage behavior of nanoparticles in this size range is different from those of larger particles.

List of Outputs

PPT Program researchers contributed to development of four NIOSH Scientific Information Products and five sponsored conferences.

NIOSH Publications

NIOSH [2007] Progress toward Safe Nanotechnology in the Workplace. A Report from the NIOSH Nanotechnology Research Center. DHHS (NIOSH) Publication No. 2007-123. [168]

NIOSH [2006] Approaches to Safe Nanotechnology: An Information Exchange with NIOSH. July 2006. [184]
http://www.cdc.gov/niosh/topics/nanotech/safenano/pdfs/approaches_to_safe_nanotechnology_28november2006_updated.pdf

NIOSH [2005]. Draft Document for Public Review and Comment: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide, NIOSH Docket #100. November 22, 2005. [189]

NIOSH 2005. Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps, Draft. September 28, 2005. Nanotechnology Research Program. National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. [190]

Peer Reviewed Publications

Rengasamy S, Verbofsky R, King WP and Shaffer R [2007]. Nanoparticle penetration through NIOSH-approved N95 filtering facepiece respirators. Journal of International Society for Respiratory Protection, 24:49-59. [191]

Kim SC, Harrington MS, Pui DYH [2007]. Experimental study of nanoparticles penetration through commercial filter media. Journal of Nanoparticle Research 9:117-125. [172]

Forums

PPT program researchers were active in planning and implementing a number of forums to interact with researchers and entrepreneurs engaged in nanotechnology development, all of which involved the consideration of PPE precautions. The forums included:

Third International Symposium to be held in Taiwan in 2007. [192]

First International Meeting on Nanotoxicology: Biomedical Aspect in 2006. [193]

A half-day professional development training course that focuses on the inhalation toxicology of engineered nanoparticles and recommendations on risk management practices intended to eliminate inhalation exposure.

A roundtable discussion on nanotechnology and personal protective equipment issues at the American Industrial Hygiene Conference and Exposition— 2006, Chicago, IL, May 2006. [194]

International Conference on Nanotechnology, Occupational and Environmental Health and Safety: Research to Practice. December 4-7, 2006, Cincinnati, Ohio. [195]

Frontiers in Aerosol Dosimetry Research, October 24–25, 2005, Irvine, CA. [196]
Mechanisms of Action of Inhaled Fibers, Particles, and Nanoparticles in Lung and

Cardiovascular Disease, October 25–28, 2005, Research Triangle Park, NC. [197]
Second International Symposium of Nanotechnology and Occupational Health, October 3–6, 2005, Minneapolis, MN. [198]

First International Symposium on Occupational Health Implications of Nanomaterials, October 12–14, 2004, Buxton, UK. The conference is co-sponsored by the U.K. Health and Safety Executive and NIOSH. [199]

Conferences and Presentations

Research or guidance presented at over 10 conferences

Shaffer R and Rengasamy A [2007]. Air purifying respirators for the nanotechnology industry. Presented at the NRT Worker Safety and Health Conference August 2-3. [200]

Shaffer, R. [2007] Overview of NIOSH Nanotechnology Research. Presentation at the Air & Waste Management Association, Pittsburgh, PA, June 29. [201]

Rengasamy A., Shaffer, R. [2007] Respiratory protection against nanoparticles. Presentation at the Chesapeake Area Biological Safety Association Meeting, Columbia, MD, June 14. [202]

Shaffer R. [2007] Update on Nanoparticle Filtration, Respirator, and PPE Research at NIOSH. Ask the Experts: An Update on NIOSH Research in Nanotechnology. Round table discussion at the American Industrial Hygiene Conference and Exposition, Philadelphia, PA June 2-7. [203]

Rengasamy A, Verbofsky R, King WP and Shaffer R [2007]. Filtration efficiency of CDC/NIOSH-approved N95 filtering facepiece respirators against nanoparticles. Presented at the American Industrial Hygiene Conference and Expo meeting. Philadelphia, June 3-7. [204]

Shaffer R [2006]. Controls/PPE. Talk given at the Tech Talks session at the International Conference on Nanotechnology Occupational & Environmental Health and Safety, Cincinnati, OH 4-6 Dec, 2006. [205]

Shaffer R, Rengasamy A, Gao P [2006]. Penetration of nanoparticles through respirators and protective clothing. Poster Presentation, presented at the International Conference on Nanotechnology Occupational & Environmental Health and Safety, Cincinnati, OH 4-6 Dec, 2006. [206]

Shaffer R, Gao P, Rengasamy A [2006]. Penetration of nanoparticles through protective clothing and respirator filters. Presented at the Elevated Wind Studies International Conference. Arlington, VA, September 25–26. [207]

Richardson A, Hofacre K, Gardner P, Rengasamy A, [2006] Efficiency of particulate respirator filters under high flow conditions. 13th Conference of the International Society for Respiratory Protection, Toronto, Canada, August 28 – 31, 2006. [171]

Geraci C, Castranova V, Hoover M, Dunn K, Gao P [2006]. Ask the Expert—An update on NIOSH research in nanotechnology. Presented at a roundtable section at the American Industrial Hygiene Conference and Exposition, Chicago, IL, May 16. [208]

Seong Chan Kim, Matt Harrington, Samy Rengasamy, and David Pui (2006): "Collection efficiency of filter media for nanoscale particles". Presented at the American Industrial Hygiene Conference & Exposition, Chicago, IL, May 14-18, 2006. [209]

Seong Chan Kim, Matt Harrington, Samy Rengasamy, and David Pui (2005): "Collection efficiency of filter media for nanoscale particles". Presented at the 2nd International Symposium on Nanotechnology and Occupational Health in Minneapolis, Minnesota. [210]

Paul Gardner, Samy Rengasamy and Aaron Richardson (2005): "Efficiency of respirator filters against nano-aerosols under high flow rate conditions". Presented at the 2nd International Symposium on Nanotechnology and Occupational Health in Minneapolis, Minnesota. [211]

Media Inquiries

PPT Program researchers were interviewed by a reporter from Chemical & Engineering News in April 2006. The aim of the interview was to better understand the current developments on respiratory protection against nanoparticles. An article entitled "How well do gloves and respirators block nanoparticles?" was published in the May 1, 2006 issue of Chemical and Engineering News pp.14-15.

PPT Program researchers were interviewed by a reporter for "Occupational Hazards" magazine and discussed nanoparticle filtration. An article entitled "NIOSH-funded study looks at filter efficiency for nanoparticles" was published in September, 2005 (volume 67, pp. 42). [212]

PPT Program researchers were interviewed by a reporter from BNA in October 2005, and highlighted the current developments on respiratory protection against nanoparticles. An article entitled "NIOSH planning more respirator studies after nanoparticle tests find penetration" in BNA publication, October 19, 2005, pp. 8-22.

PPT Program researchers were interviewed by a reporter with the AIHA publication "The Synergist" in October, 2005 and discussed current nanotechnology research activities in NPPTL that address workers health and safety issues. An article entitled "Accelerating research sizes up the implications of nanotechnology in the workplace" was published in "The Synergist" (2005): Volume17 (1), pp. 37-39.

PPT Program researchers were interviewed by a reporter from the AIHA publication "Synergist". An article entitled “Small wonders, big questions” was published in Synergist, October 2004, pp.7-12.

Contract Reports

Richardson AW, Eshbaugh, JP, Hofacre KC and Gardner PD. [2006]. Respirator filter efficiency against particulate and biological aerosols under moderate to high flow rates. U.S. Army Edgewood Chemical Biological Center Report for Contract # SP0700-00D-3180, Task No. 335, ECBC-CR-085. [170]

3.7 Sensor Technology Development for End of Service Life Indicators

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Issue

A report by the NIOSH/BLS [3] indicated that approximately 250,000 work establishments used respirators. The report also noted that 20% of them left respirator cartridge change-out up to the discretion of their employees. Under OSHA guidelines, this is unacceptable. OSHA requires that the use of an end-of-service life indicator or a formal plan (such as the use of a service life calculator) must be in place. Service life calculators require sophistication on the part of the user, which may not be practical in any number of workplace settings.

Prior to this OSHA requirement, odor detection was permitted and it was frequently used as the determination method for changing cartridges. Obviously, due to variations in the ability of people to detect odors, gases and/or vapors, this method was unreliable. In general, the availability of ESLI is very limited and there are no ESLI indicators for organic vapors.

Approach

To address the OSHA requirement for ESLI, PPT Program researchers developed software models to provide users a method for predicting the cartridge service life. The software enables administrators of workplace respiratory protection programs to consider the effects of relative humidity on the service life of NIOSH approved organic vapor chemical cartridges. This software thus assists program administrators in workplaces where APRs are used to reduce on-the-job respiratory exposures to potentially harmful organic vapors from a single volatile source, such as an individual paint, thinner, or solvent.

The software was developed as a result from research conducted by Los Alamos National Laboratory (LANL), in conjunction with a partnership with the PPT Program, OSHA, ISEA, the American Chemistry Council, the Synthetic Organic Chemical Manufacturers Association, the National Paint Coatings Association, and the American Petroleum Institute, organized and led by ORC Worldwide.[213]

The PPT Program is collaborating with Carnegie Mellon University to develop sensor systems that can detect multiple gases and vapors. The objective is to embed the sensors in the respirator cartridges. Embedded sensors will help users of APRs by enabling manufacturers to incorporate the technology in their cartridges to measure cartridge breakthrough. The research will facilitate producing low power, small and low-cost sensors that can be integrated into APR cartridges to provide end-of-service life information as well as that for residual service life. The sensors system is being developed to have sufficient flexibility so that it can be incorporated into other personal protective devices.

A formal peer review was conducted on the PPT Program’s sensors effort in the spring of 2005 with a panel of scientific experts and stakeholders. The peer review resulted in the recommendation to continue the research effort, but suggested the effort be refined to focus on a specific end product: an embedded sensor in a respirator cartridge. Over the next several years,

the research effort has continued and the PPT Program researchers have aggressively pursued the recommendations suggested by the peer review panel.

Researchers working on this project successfully designed a sensor package. Based on problems identified during the evaluation phase, the device was redesigned to allow independent sensing of target organic vapors with up to three independent signals. In addition, changes were made in the electronic circuitry to reduce thermal and electrical drift and interferences in the sensor signals. This should provide more stable operation and more accurate sensor signaling of the target organic vapors.

Output and Transfer Highlights

The computer software programs, Breakthrough and Multivapor have been made available as CD-ROMs that can be ordered from NIOSH. [214, 215]

Multivapor and Gas Remove models were made available to the public and have been downloaded more than 4,500 times since posted on OSHA website in December 2003.

More than 1,000 CD ROMs of the Multivapor and Gas Remove models have been requested since 2003.

In May 2007 the Multivapor software [215] was released to the public as a downloadable program. It permits the user to calculate the service time for air purifying respirator cartridges for up to five organic chemicals; the calculations allow for the effects of relative humidity. For the first 2 months of availability, the program was accessed 688 times on the PPT Program website.

An article entitled "Optical fiber-mounted porous silicon photonic crystals for sensing organic vapor breakthrough in activated carbon" [216] was submitted to the Journal of Advanced Materials. The paper was authored by PPT Program participants at NPPTL Brian H. King, Anne M. Ruminski, Jay L. Snyder, and Michael J. Sailor. It details the application of photonic crystals to determining end-of-service life for organic vapor cartridges. The work is being done in conjunction with the chemistry department at the University of California at San Diego.

Intermediate Outcomes

Downloadable copies of the Breakthrough and Multivapor software are currently available from the OSHA website http://www.osha.gov/SLTC/etools/respiratory/

What’s Next?

A respirator cartridge simulator designed to accommodate the products of this research project (low-power, low-cost sensors) has been constructed and successfully evaluated against the PPT Program certification criteria. Testing was conducted to put the sensors in the cartridge simulator and evaluate them to determine if they function as designed to operate in a carbon bed. The PPT Program intends to distribute 80 sensors to the manufacturers who volunteered through the Federal Register Notice published in August 2004 for participation in this study. This notice

resulted in eight prominent manufacturers volunteering to collaborate with the PPT Program to integrate sensor systems into respirators.

In July 2007, chemical sensors were tested in a cartridge that had gone through the manufacturing process. A breakthrough measurement of the carbon bed in a cartridge was made. The issue of survivability came up repeatedly in conversations following the April manufacturers meeting. An empty cartridge was fitted with a sensor and run through the manufacturing process and functioned as expected.

There have been several new developments in the field of sensors. The response of sensors has been increased significantly (50%) with changes in jetting. Three barrier or diaphragm materials were investigated and one was found to be superior in protecting the sensors from carbon dust. A generation V chip has been completed and will be available to use in the integration study. This chip has the feature of being able to monitor temperature at the chip level. It is expected that this will provide significant information regarding sensor response. The effort to embed the sensors in manufacturer cartridges and conduct testing is projected to continue in FY08.

List of Outputs

NIOSH Scientific Information Products

The computer software programs, Breakthrough and Multivapor have been made available as CD-ROMs that can be ordered from NIOSH. [214, 215]

Multivapor and Gas Remove models were made available to the public and have been downloaded more than 4,500 times since posted on OSHA website in December 2003.

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In May 2007 the Multivapor software [215] was released to the public as a downloadable program. It permits the user to calculate the service time for air purifying respirator cartridges for up to five organic chemicals; the calculations allow for the effects of relative humidity. For the first 2 months of availability, the program was accessed 688 times on the PPT Program website.

Peer Reviewed Publications

Wood GO [2005] "Estimating Service Lives of Air-Purifying Respirator Cartridges for Reactive Gas Removal", Journal of Occupational and Environmental Hygiene Volume 2, Number 8, August pp 414-423 A mathematical model was developed to calculate the service time for an acid-base cartridge used on an air purifying respirator. A training video tutors users on proper use of the software. Cartridge performance from cartridge manufacturers before it can be released for public use. [217]

"Integration of Sensor Technologies into Respirator Vapor Cartridges as End of Service Life Indicators: Literature and Manufacturer's Review and Research Roadmap, NRL/MR/6112-05-8875, May 6, 2005. IAA 04-26 This report provides a state-of-the-art review of sensor integration into respirator vapor cartridges for ESLI. This report provides a review of the literature, the results of discussions conducted with commercial manufacturers, user-group representatives, and key research groups, a description of the state of the art sensor technology, and concludes with recommendations for future research and development. The key finding from the study was that an active research program is necessary to move the field forward and make ESLI devices commercially available and cost-effective. The information was used to establish goals and craft future work for the ESLI sensor program. [218]

Wood, GO [2004] "Estimating Service Lives of Organic Vapor Respirator Cartridges at All Relative Humidities," Journal of Occupational and Environmental Hygiene Volume 1, Number 7, July pp 472-492 A mathematical model developed to predict the service life of air purifying respirator cartridges at various levels of relative humidity. A training video tutors users on proper use of the software. Over 4500 software downloads from the OSHA website and 1000 requested CDs mailed out by NIOSH during the initial two years. [219]

An article entitled "Optical fiber-mounted porous silicon photonic crystals for sensing organic vapor breakthrough in activated carbon" [216] was submitted to the Journal of Advanced Materials. The paper was authored by PPT Program participants at NPPTL Brian H. King, Anne M. Ruminski, Jay L. Snyder, and Michael J. Sailor. It details the application of photonic crystals to determining end-of-service life for organic vapor cartridges. The work is being done in conjunction with the chemistry department at the University of California at San Diego.

Conferences and Presentations

Untitled presentation on the new Multivapor Model end-of-service-life indicator for chemical cartridges, ISEA respiratory protection group in Washington, DC., November 15, 2005, Presenter: Jay Snyder. [220]

Nov 1-3, 2005: Jay Snyder attended the IEEE Sensors 2005 conference in Irvine, California. Jay was co-author of the paper Volatile Organic Compound Discrimination using Nanostructured Polythiophene Sensors. This paper came about as a result of research currently being done by Carnegie Mellon University through a contract with NPPTL to develop sensors for end-of-service life applications. [221]

Presentation to Others

Untitled presentation on the new Multivapor Model end-of-service-life indicator for chemical cartridges, ISEA respiratory protection group in Washington, DC., November 15, 2005, Presenter: Jay Snyder.

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3.8 Respirator Use Surveillance and Dissemination Back to the Table of Contents

Issue

Insufficient information exists on the use of respirators in the workplace and their corresponding employer programs, creating the need for surveillance, educational efforts, and further employer program development.

Approach

The PPT Program and the BLS conducted a voluntary survey of U.S. employers regarding the use of respiratory protective devices in 2001. The objectives were to gather information to develop educational interventions for specific user populations and to understand the frequency and effectiveness of respirator use in the workplace.[3]

The PPT Program personnel worked with BLS on the survey design and methodology. PPT Program researchers participated in the development of the survey questionnaire by providing BLS employees with direction and training on respirator use. They also provided information on technical subjects such as respirator standards and regulations, respirator types and uses, and specific substances that require respirator use. BLS subjected the survey to cognitive evaluation and field testing resulting in more focused questions. The overall field tests provided valuable insights and enhanced the administration of the survey. The overall field test response rate was 80% while the survey response rate was 75.5%. PPT Program researchers have analyzed the survey results and prepared more than 12 manuscripts to disseminate the information.

The survey found that an estimated 619,400 workplaces used respirators. In nearly half of these, the respirators were used by employees on a voluntary basis only; in about 12% of the total, they were used when required because of emergencies. Approximately 281,800 of the total reported use only for required purposes in the 12 months prior to the survey. Respirators had been used by employees in about 10% of private industry workplaces.

Fifty-three percent of the establishments in which respirators had been used had 10 or fewer employees. Fifty-eight percent of these small establishments had only voluntary use of respirators, although 8.5% of the small establishments using respirators had at least some required emergency use. By comparison, 42% of the largest establishments (with 1,000 or more employees) using respirators had at least some required emergency use. In general, smaller establishments reported more voluntary respirator use than did larger establishments. Conversely, larger employers reported more required use. [3]

In 2004, PPT Program researchers developed a research protocol and follow-on research study as a next step toward gathering additional PPE surveillance data. Follow-on activities involved work with the construction industry to conduct intervention strategies. Per the request of American Road and Transportation Builders Association (ARTBA), Society for Protective Coatings (SSPC), and the National Demolition Association (NDA), findings were presented at national conferences and published in appropriate trade journals. These findings educated the partners' members to reduce workers' exposures and minimize hazards associated with improper

respirator usage to prevent future fatalities and respiratory diseases of U.S. workers. The PPT Program collaborated with the NDA to develop successful respirator program concepts that will be considered for application in other construction sectors. Ideas were obtained by conducting respiratory protection program observations and interviews at several NDA sites and through a meeting at the Association's headquarters in 2006.

The PPT Program solicited input from OSHA, MSHA, and the ISRP for the development of the publications to disseminate information regarding this work.

To improve the quality, relevance and impact of the PPT Program future surveillance activities and to maximize the use of the Survey of Respirator Use and Practices (SRUP), the PPT Program asked the National Academies to examine the informational foundations of the PPT Program to promote the effective use of respirator equipment in the workplace. A National Academies Committee was formed, whose primary focus was to review the SRUP, conducted by BLS under the sponsorship of PPT Program in 2001. This review was to critique the survey and render judgment on the fitness and relevance of the survey methodology to provide valid information to impact future respiratory protection policy development.

Output and Transfer Highlights

PPT Program researchers have analyzed the survey results and prepared more than 12 manuscripts to disseminate the information.

From the review of the NIOSH/BLS survey, the National Academies Committee pointed out that in the years since the objectives and methodology for the SRUP were developed and the results made available, NIOSH's approach to respiratory protection and personal protective equipment, in general, has changed dramatically. Since 2001, the PPT Program has forged new directions and adopted new statements of emphasis. In light of this new focus, the National Academies committee included in their report a number of recommendations on future data gathering activities for the PPT Program beyond the SRUP. These recommendations include recommended approaches for PPT Program surveillance efforts. The panel suggested that any future information gathering efforts should focus on the PPT Program's evolving mission statement categories of surveillance, certification, research, technology and standards. The committee formulated a table of mission-related data elements as well as proposed different information gathering approaches that could be used, and then made recommendations for a comprehensive survey program for the future.

A survey report entitled *Respirator Usage in Private Sector Firms* (2003) [3] was developed to describe findings of the NIOSH/BLS survey. This report led to a total of 14 presentations at conferences (several including employer organizations such as SSPC, ARTBA, NDA, etc), five trade journal publications (with 12 more in the approval process), and seven peer-reviewed publications. Findings were published to specifically disseminate results across a number of different industries, including agriculture, forestry and fishing, manufacturing, construction, transportation, demolition, and mining. Findings were also specifically described with respect to existing employer programs and other aspects of optimizing respirator fit among workers. Overall, the survey report and subsequent publications and presentations provide a

comprehensive description of the current state of respirator use and corresponding programs in the workplace, as well as recommendations for future improvement.

The NIOSH collaboration with the NDA, and subsequent work on developing successful respirator program concepts, is being considered for application in other construction sectors.

Intermediate Outcomes

The BLS/NIOSH Respirator Use in Private Sector Firms Report and subsequent presentations and publications have been, and are being used by various other government agencies to develop alerts, notices and regulatory updates and changes, including the following. [3]

MSHA Health Hazard Alert for Airline Respirators:
http://www.msha.gov/Alerts/airlinerespirator12142004.pdf posted in December 2004 [222]

OSHA Safety and Health Information Bulletin titled "Deaths Involving the Inadvertent Connection of Air-line Respirators to Inert Gas Supplies" at
http://www.osha.gov/dts/shib/shib042704.html (see above). [223]

OSHA used the data from the joint BLS/NIOSH publication to develop the Assigned Protection Factor (APF) portion of the 1910.134 respirator standard. [224]

According to John Steelnack of OSHA's Directorate of Standards and Guidance, findings from the BLS/NIOSH survey are being used extensively for regulatory reform for the proposed assigned protection factor of the OSHA 1910.134 Respiratory Protection standard.

What’s Next?

The PPT Program leadership is currently developing an action plan to address the recommendations in the report provided by the National Academies. The action plan will contain a framework for moving forward, including plans for future surveillance work. The PPT Program intends to develop a pilot project for a feasibility study using the proposed framework. The Healthcare and Social Assistance Sector has been proposed as the study sector. This industry sector has been chosen because of the nearly completed National Academies' evaluation and assessment of PPT needs and requirements relative to research, certification and evaluation, policy and standard development, and outreach regarding pandemic influenza preparedness in the health care sector. In addition, the Healthcare and Social Assistance sector, specifically hospitals, was chosen by the NIOSH National Exposures at Work Survey (NEWS) for a feasibility evaluation of tools and methods for surveillance of health and safety hazards. Information from this feasibility study may be useful in evaluating the best approach to surveying workers and workplaces within this sector.

The PPT Program data gathering activities will take place within a consistent framework aligned with the PPT Program mission and goals. The PPT Program intends to work with the NIOSH Sector leadership to ensure PPT components are incorporated in Sector surveillance activities to fulfill PPT Program surveillance objectives. The PPT Program leadership is aware that

information is lacking on the effectiveness and use of PPE and PPT. The PPT Program intends to focus future surveillance efforts on the culture of PPE and PPT use and non-use, as well as misuse and abuse, defects, recalls, claims, complaints, and incidences of and circumstance surrounding injuries, illnesses and deaths related to improper PPE and PPT design and use.

To further translate identified weaknesses (from survey results) into program changes, the PPT Program and ARTBA will collaborate on a project to conduct respirator program interventions at 24 road construction sites during 2007 through 2009. Air sampling will be conducted for respirable crystalline silica dust, lead fumes/particulates, asphalt fumes, and welding and painting fumes at seven sites. Where appropriate, findings from these collaborations will be translated into PPE recommendations.

List of Outputs

Peer Reviewed Publications

Doney B, Greskevitch M, Groce D, Syamlal G, Bang KM. Respirator Use and Practices in Auto Body Repair Shops: Results of a National Survey of Private Sector Employers. BodyShop Business. (In clearance). [225]

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Doney B, Greskevitch M, Groce D, Bang KM. Respirator Use Among ARTBA Member Companies. Transportation Builder (March/April 2007) (In press). [229]

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Greskevitch M, Doney B, Groce D. A Survey of Respirator Use in the Mining Industry. The Society of Mining, Metallurgy, and Exploration, Inc. (SME) 2006 Annual Transactions 320:1-5. [240]

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