



Developing a Performance Standard for Combination Unit Respirators: Workshop in Brief

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Developing a Performance Standard for Combination Unit Respirators—Workshop in Brief

On April 30, 2015, the Institute of Medicine (IOM) convened the public workshop Developing a Performance Standard for Combination Unit Respirators. This workshop resulted from discussions by the IOM's Standing Committee on Personal Protective Equipment for Workplace Safety and Health (COPPE). The workshop was sponsored by the National Personal Protective Technology Laboratory (NPPTL) at the National Institute for Occupational Safety and Health (NIOSH). An estimated 20 million workers use personal protective equipment on a regular basis to protect themselves from job hazards (Coffey and Palya, 2015). The mission of NPPTL is to prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technologies.

As part of the Consolidated and Further Continuing Appropriations Act of 2015 (Public Law 113-235), NIOSH was asked to provide an update on research and operational needs relevant to standards for combination unit respirators. The IOM workshop brought together user groups, manufacturer representatives, and government personnel to discuss the need and possible next steps for developing a performance standard for combination unit respirators (see Box 1).¹ As outlined by Maryann D'Alessandro, NPPTL, this workshop is part of a suite of activities (including prior public meetings, public docket requests for comments, stakeholder meetings, and a webinar [see, e.g., CDC, 2010, 2011, 2015]) that will inform the NIOSH update.

Background

A combination unit respirator is a multi-functional respirator that employs the technology of two or more types of respiratory protective devices that generally differ in assigned protection factors (APFs) (Coffey and Palya, 2015).² Maryann D'Alessandro, Chris Coffey, and Colleen Miller, NPPTL, provided the background and context for the study, including an overview of combination unit respirators. They noted that the types of respirators that can be part of a combination unit respirator include

- open circuit self-contained breathing apparatus (SCBA)
- closed circuit SCBA
- supplied air respirator (SAR)
- powered air purifying respirator (PAPR)
- air purifying respirator (APR)

The respirator user has the ability to switch between respirator modes without doffing the respirator. Mechanisms for switching between respirator modes vary. For example, some respirators have a physical toggle switch or valve that the user operates while others require the user to cover the filter with a hand and inhale sharply to activate a change in respirator mode.

¹ This summary represents the viewpoints of the speakers and does not necessarily represent the views of all workshop participants, the planning committee, or the National Academies.

² The assigned protection factor (APF) of a respirator denotes the level of protection that the respirator is expected to provide to users who are properly fitted and trained.

BOX 1 **Statement of Task**

An ad hoc Institute of Medicine committee will conduct a workshop to explore the following topics as they relate to the use of combination unit respirators and the development of a performance standard for this type of respirator. Questions to be addressed in the workshop include

- What combination unit respirator technology is currently available in the United States?
- What are the primary user groups interested in using National Institute for Occupational Safety and Health (NIOSH)-certified combination unit respirators? What are the anticipated hazardous atmospheres that each user group is expected to encounter or enter and how are they assessed?
- How do current regulations limit the use of combination unit respirators by the identified user groups?
- What regulatory options should NIOSH consider related to developing and adopting NIOSH certification performance standards for combination unit respirators?

Perspectives of Respirator Users

In the United States, combination unit respirators are used by some law enforcement and military units to respond to situations in which there are unknown and potentially dangerous respiratory hazards. These respirators also have some industrial uses and potential for use in emergency response, as noted by the user groups and manufacturers present at the workshop. Combination unit respirators offer unique capabilities that have tactical benefits in law enforcement and military operations, such as controlling the noise of the respirator and conserving available supplied air, noted Neil Coward, Los Angeles Police Department (LAPD). For example, combination unit respirators that include an APR, which has a low APF and is relatively quiet, can be used to quietly approach the operations site. The respirator can then be switched to an SAR with a higher APF to enter environments where hazards may be unknown. He described the combination unit respirator used by LAPD teams as a hybrid system that has APR, PAPR, and SCBA capabilities and stated that the LAPD special weapons and tactics team recently used its combination respirator units when it responded to a reported robbery in a fumigated structure. While using a quieter respirator to approach the structure, a hazmat technician monitored the environment for air contaminants and alerted the team when to switch its respirators to supplied air. When leaving the scene, the officers were able to switch back to the PAPR mode to conserve supplied air. Similarly, James Donnelly, Warminster Township Police Department in Pennsylvania, noted that having the ability to use combination unit respirators could change manpower needs and improve overall team responses to hazardous incidents.

Combination unit respirators could provide benefits to employers who manage respirator supply and training programs. Brian Clifford, Federal Bureau of Investigation, noted the advantage of a single mask and modular design. He explained that each of his team members has duplicate sets of deployment gear with five to seven respirator masks that require time- and resource-intensive fit testing each year. In addition to deploying respirators for CBRN (chemical, biological, radiological, nuclear) or hazmat situations, he noted that a combination unit respirator, which has a single mask, could also be useful for forensic evidence collections where the environmental conditions and hazards could change rapidly. Jon Szalajda, NPPTL, noted that fire fighters could use the flexibility in respiratory protection offered by combination unit respirators if they need to move between fire zones. However, Larry Petrick, International Association of Fire Fighters, stated that his agency did not currently endorse the use of these respirators in response to structural fires, citing concerns about misuse and the physiological aspects of additional weight from the unit.

Many users identified specific desired features of future products. Stephan Graham, U.S. Army Institute of Public Health, noted potential uses for combination unit respirators in chemical stockpile decontamination operations. He emphasized the following features that could be considered for these respirators: being lightweight, allowing for weapons sighting for military and law enforcement uses, ease of decontamination, and the potential

to incorporate global positioning systems and non-movement alarms. Szalajda also noted the need for a selection, care, and maintenance guidance document such as those compiled in conjunction with National Fire Protection Association standards.

Perspectives of Combination Unit Respirator Manufacturers

Manufacturers of combination unit respirators present at the workshop noted that their primary customers are military, law enforcement, and special forces operations teams. Lynn Feiner, Honeywell Safety Products, stated that Honeywell also sells combination unit respirators for industrial uses, including environmental remediation such as abrasive blasting and emergency escape. She emphasized the need for standards to be performance-based rather than design-based. Robert Sutton, Scott Safety, added other industrial uses, including entry and exit from high-risk work environments, such as spraying highly toxic paints on to fighter jets and asbestos stripping industries.

Regarding the standards and certification process, James Wilcox, Avon Protection Systems, stated that some international standards have been established for these respirators and explained that “within the European markets they do the testing between modes of operation and look for any decrease in protection factor [as the unit is switched from APR to PAPR to SCBA].” He suggested that testing by cycling through the respirator modes could be a simple validation method. Consideration is also needed regarding the ability to separately certify the various modules of combination unit respirators so that customers can have the flexibility to compile combination unit respirators to meet their specific operational requirements.

Human factors issues were raised by Emiel DenHartog, North Carolina State University, particularly regarding fatigue due to heat and to the weight of the equipment. Heather Dannhardt, MSA Safety, said that because the user might be wearing the mask for extended periods of time, options for combination unit respirators include a hydration tube and for a radio interface system to facilitate communications. Ken Lawson, Osen-Hunter Group Innovative Technologies, noted that current technologies do not include the wide range of sensors needed for a respirator system to automatically switch between modes.

Breakout Discussions

After the users and manufacturers presented, the workshop participants, speakers, and committee members met in breakout groups to brainstorm priorities in three areas: standards and regulations, training needs and hazard assessment, and research. When the groups came back together representatives from each breakout group: Howard Cohen (standards), David Prezant (training), and Barbara DeBaun and James Zeigler (research) presented the thoughts from individual participants. These comments should not be interpreted as consensus.

Benefits and Challenges of Combination Unit Respirators

In each breakout room the benefits and challenges of combination unit respirators were discussed, many of which relate to ensuring worker safety and health (see Box 2). As noted by Coward, the use of a combination unit respirator allows the worker to operate on the lower APF mode and delay the activation of supplied air until there is an immediate need. This can extend the duration of use for the limited amount of supplied air available in the canisters.

However, there can be significant challenges associated with the use of combination unit respirators. Having the ability to switch between respirator modes and have a backup of supplied air may give workers a false sense of security in terms of available air supply. In addition, providing users with the capability to switch between respirator modes and to make those decisions individually—and potentially without hazard assessment data—raises safety concerns, stated Zeigler. However, Clifford noted that a number of workers (particularly military personnel, police officers, and fire fighters) make numerous decisions about actions that could affect their safety during operations, and the safety decisions pertinent to combination unit respirators would not differ from those decisions.

BOX 2

Benefits and Challenges of Combination Unit Respirators

*Presented by Barbara DeBaun, Howard Cohen, David Prezant, and James Zeigler
as the Facilitators of the Individual Breakout Group Discussions*

Benefits to the User

- Convenience: less gear, less fit testing, flexibility, and versatility of the unit to perform in various situations; decreased size of the respirator
- Operational mode is changeable if the threat changes
- Familiarity and user confidence

Benefits to the Employer

- Reduced economic burden if modular units are available or fewer types of respirators are needed, reduced maintenance, less storage space required
- Reduced time and resources needed for fit testing

Benefits to the Situation

- Potential for greater worker protection due to adaptability to mission requirements
- Less risk in situations with the potential for unknown hazards
- Escape capability in confined spaces
- Potential to extend the use of the limited amount of supplied air as it may not be required at all times during the operation, such as during entry or exit

Challenges of Equipment

- Switchover mechanisms between modes: ensuring that respirators maintain the appropriate assigned protection factor (APF) during and after the switch between respirator modes
- Weight, ergonomics, hydration, heat stress
- Type and fit of the respiratory interface
- Technology for integrated sensors
- Decontamination
- Interchangeability and interoperability

Challenges of Use

- Ability of employers to provide accurate training and education
- Ability of users to make environmental hazard assessments
- Physiological factors: duration of use, heat stress, etc.
- Flexibility and complexity of use leading to potential risk of misuse or a false sense of security
- Communication while using the respirator
- Liability

Challenges Regarding Standards and Regulations

- Disconnect between Occupational Safety and Health Administration (OSHA) APF requirements and National Institute for Occupational Safety and Health (NIOSH) certification regulations
- Flexibility of regulations to allow for innovation and developing technologies
- Length of time required to establish new regulations and standards

^aBarbara DeBaun, Cynosure Health; Howard Cohen, Yale University; David Prezant, New York City Fire Department; and James Zeigler, J.P. Zeigler, LLC. These speakers are representatives from their respective breakout groups and the comments they presented should not be construed as group consensus.

Standards and Regulations

Currently there are disconnects in the federal regulations that apply to combination unit respirators, noted Cohen, who presented as a representative from the breakout group discussion. NIOSH, through the work of NPPTL, has the authority and responsibility to test and certify that respiratory protective devices meet the federal requirements outlined in Title 42 of the Code of Federal Regulations, Part 84. Each type of respirator has different performance requirements. Currently, NPPTL does not certify a single respirator for more than one APF setting. Specifically, NIOSH regulations stipulate that combination unit respirators be “classified by the type of respirator in the combination which provides the least protection to the user” (42CFR 84.63(b)). Occupational Safety and Health Administration (OSHA) regulations require that when using a combination respirator “employers must ensure that the assigned protection factor (APF) is appropriate to the mode of operation in which the respirator is being used” (29 CFR 1910.134(d)(3)(i)(A)) and also that respirator use follows the terms and conditions of NIOSH certification (29 CFR 1910.124(d)(1)(ii)). Graham pointed out that U.S. military equipment that meets military specifications for uses that are “unique to the national defense mission” may be exempt from OSHA standards, including the requirement to use NIOSH-certified respirators (29 CFR 1960.2(i)). He noted that NIOSH certification for combination unit respirators could improve regulatory decision making about these respirators. Cohen highlighted the need for the NIOSH and OSHA standards to be reconciled and urged that combination unit respirators be certified for use at all APF levels. He also noted the issues that were discussed during the workshop regarding the National Fire Protection Association (NFPA) 1986 respiratory protection standard. For example, variations exist among the operational needs of law enforcement, military, and fire service regarding supplied air canisters (particularly duration of the supplied air), and some of the alarms, such as the non-movement alarm, may emit noise or light in response to an emergency.

Regarding a regulatory and standards framework for combination unit respirators, Cohen outlined the discussion on several options and considerations deliberated during the breakout session. Standards for combination unit respirators have been developed in other countries and these standards (e.g., the European Union’s *Conformité Européene* [CE] standards) could be incorporated into NIOSH standards by reference. Sutton noted that the European CE standard specifies that the respirator system should not fall below the lower APF of the two modes being used. Another option, as described by Cohen, would be for NIOSH standards to outline the basic requirements and be used in combination with consensus standards that could specify the additional requirements for specific user groups. He highlighted the additional regulatory challenges that will be involved in developing the performance requirements for flow ratings, service life indicators, and the mechanisms for switching between respirator modes. Flexibility in the performance requirements will be important to allow for the incorporation of new technologies and innovation, including new designs to improve user awareness of the mode of operation. A conformity assessment plan will also need to be developed for combination unit respirators, and, as noted by Cohen, this could include third-party certification.

BOX 3

Standards and Regulatory Priorities

Presented by Howard Cohen as the Facilitator of the Breakout Group Discussion

- Require certification of combination unit respirators at assigned protection factor (APF) levels that reflect how the combination unit respirator is used in practice
- Examine the requirements for the supplied air canisters for entry into areas immediately dangerous to life or health
- Develop additional test requirements for combination unit respirators:
 - Verify the integrity of the interface and switching capabilities between respirator modes
 - Establish additional design or performance requirements to increase user awareness of the operating mode
 - Expand service life and flow rating specifications

Next steps identified and presented by Cohen were assessing the current standards and conducting a gap analysis, reconciling the disconnect in NIOSH and OSHA regulations, and examining conformity assessment options for combination unit respirators. These actions could be conducted in several phases. Box 3 describes the standards and regulatory priorities identified by individual workshop participants.

Training and Hazard Assessment

Because the occupational settings in which combination unit respirators could be used are varied, the training needs and hazard assessment processes are also diverse, noted Prezant on behalf of the breakout group discussion. In many tactical situations in which combination unit respirators would be used (e.g., military and law enforcement operations), the hazard assessment process, leading to decisions about respirator mode switching, will be more dynamic and will be ongoing as environmental conditions change. In other occupational environments, particularly in industries in which the supplied air would be used for escape situations, hazard assessments would be more standard and the decision to move to supplied air would be in response to an emergency, as noted by Cecile Rose, University of Colorado Denver. She also noted that hazmat work environments offer a somewhat different type of hazard assessment and training needs opportunity. Several types of training standards and guidance documents may be needed to outline the required level of proficiency and competency evaluation relevant to escape, general industry hazmat, and military and tactical operations with that of the tactical operations being a potential first step. These types of training standards could be done through consensus standards.

Program administrators, supervisors, and individuals caring for and maintaining the combination unit respirators need to be included in the training, noted Keri Rupe, University of Iowa College of Nursing, and Prezant. Supervisor training is particularly critical for this type of respirator in that supervisors will be involved in giving the commands to switch between different modes and need to be able to assess whether the team members have switched to the appropriate level of respiratory protection. The importance of hands-on training was emphasized by Graham, who stated that the need for realistic training units is particularly important for these respirators as they will require knowledge of how to quickly switch between modes in high stress and crisis conditions. Jeffrey Kravitz, Mine Safety and Health Administration, noted the need for requirements to be developed for training units to ensure quality training opportunities. Because the quality of the user instructions can vary, Prezant urged that minimum requirements in instruction be developed. Box 4 describes the training and hazard assessment priorities identified by individual workshop participants.

BOX 4

Training and Hazard Assessment Priorities

Presented by David Prezant as the Facilitator of the Breakout Group Discussion

- Recognize the differences in user needs and the diversity of training needs—different settings, occasional versus frequent use, etc.
- Hands-on training with real-life scenarios and realistic training units
- Training of supervisors and program administrators, as well as those who calibrate, maintain, and care for the equipment
- Detailed but easy to understand user instructions on the equipment that address multiple potential uses and user groups
- Training on care and maintenance
- Need for ongoing hazard evaluation
- Use of consensus standards to specify training information requirements

BOX 5 **Research Priorities**

*Presented by James Zeigler and Barbara DeBaun
as the Facilitators of the Breakout Group Discussion*

- Performance requirements for the switch mechanism
 - Ensuring the integrity of the switching mechanism
 - Verifying the levels of respiratory protection
- Switch control, display, and interaction
 - What control display is needed? For the user? For teammates/supervisors?
- Risk compensation: Will individuals accept more risk with combination unit respirators?
- Human factors and physiological factors: What are the specific needs regarding the weight of the unit and the ergonomics in considering gender, age, and duration of use?
- Training research: How can training be streamlined and standardized across product lines while ensuring individuals understand and remember how to safely operate the units in different environments?

Research

Because a combination unit respirator can be used to provide multiple levels of respiratory protection, the focus of research necessary for developing performance standards is on the switchover mechanism and the relevant human factors issues pertaining to switching between respirator modes. Discussion about the feasibility of automatic switchover focused on the limited capacity at the present time for sensors to detect a wide range of hazards. Sutton noted that while gas detection is a mature industry, the challenges are in the multiple types and combinations of hazards that could be present in the environment and the need for human decision making relevant to the tactical or occupational situation. The research needs for combination unit respirators as outlined by Zeigler, who presented on behalf of the group discussion, include research on manual switching, specifically identifying performance requirements to ensure the ability of the user to switch modes in high stress environments and while using and wearing other types of equipment and protective gear, understanding the performance requirements needed to validate the integrity of the switchover mechanism, and ensuring that the respirator operates in the desired mode. He also noted display and awareness issues, such as identifying mechanisms to ensure that the worker is aware of what respirator mode they are working in and the ability of teammates and supervisors to be cognizant of the operating mode of each respirator unit being deployed.

A number of ergonomic and physiologic factors were discussed, including the potential for heat stress, the weight of the unit, and the whole ensemble of protective clothing and equipment that the individual is wearing. DenHartog raised the issue of behavioral research on risk perception and risk compensation for combination unit respirators, specifically the challenges surrounding the risk of workers going further into a hazardous setting because they have increased capacity for respiratory protection and an escape option.

Further work is also needed to identify the specific performance requirements for the different user groups and respirator combinations, noted Zeigler. In addition, research into practical human performance evaluation requirements is needed, stated Miller. Box 5 describes the research priorities identified by individual workshop participants.

In concluding the workshop, DeBaun noted the range of occupational uses for combination unit respirators; the research, training, and standards-setting challenges; and the priority for ensuring the safety of the workers. 

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PLANNING COMMITTEE

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REVIEWERS: To ensure that it meets institutional standards for quality and objectivity, this workshop in brief was reviewed by **Brian Clifford**, Federal Bureau of Investigation, and **David Prezant**, New York City Fire Department. **Chelsea Frakes**, Institute of Medicine, served as review coordinator.

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For additional information regarding the workshop, visit www.iom.edu/Activities/PublicHealth/PPEinWorkplace/2015-APR-30.aspx.