Reuss, Vicki A. (CDC/NIOSH/EID)

From: C.T. Bien [c.t.bien@usa.net]
Sent: Saturday, January 31, 2009 5:54 PM
To: NIOSH Docket Office (CDC); NIOSH Docket Office (CDC)
Subject: Comments on NIOSH PAPR standard -NIOSH Docket 008
Attachments: PAPR Comments-0109.pdf

Good evening,

I'm submitting my comments on the NIOSH PAPR standard, proposed Concept (NIOSH Docket 0008). Please contact me if you have any questions.

Thank you.

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January 31, 2009

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Dear Sir or Madam:

Subject: Comments on NIOSH Docket 008 - Powered Air-Purifying Respirators.

I am submitting my comments on the Proposed Concept, Powered Air-Purifying Respirator Standard, under Subpart P of 42 CFR 84.

I appreciate the opportunity to submit comments on this proposal. Please contact me if you have any questions regarding my comments.

Sincerely,

Ching-tsen Bien

Ching-tsen Bien, P.E., CIH

Comments on the Proposed Concept: Powered Air-Purifying Respirator Standard

General Comments

In the mid-1980s, the Occupational Safety and Health Administration (OSHA) sponsored two simulated workplace protection factor studies to evaluate the performance between the tight fitting PAPR and loose fitting facepiece PAPRs.

The Lawrence Livermore National laboratory (LLNL) (1) conducted one simulated workplace study; it was performed on three powered air-purifying respirators. The purpose of the study was to determine whether these **positive pressure** respirators would maintain positive pressure under a heavy workload and the effect of airflow on the performance of the PAPR.

One tight fitting half-mask PAPR and two loose fitting facepiece PAPRs were selected for testing. All PAPRs were equipped with high-efficiency particulate air (HEPA) filters. The approval airflow requirement is 115 liters/min (lpm or 4 cfm) for the tight fitting PAPR, and 170 liters/min (6 cfm) for other two PAPRs. To assess the effect of airflow, the flow to the PAPR was controlled by replacing the battery pack with a dc power supply. When the test subject's work rate reached 80% of the maximum, the airflow varied for each PAPR in the following sequence:

Tight fitting PAPR: 170, 198, 142, 114, 86, and 170 lpm.

Loose fitting facepiece PAPRs: A: 202, 226, 170, 142, 114, 202; B: 255, 283, 198, 170, 114, and 255 lpm.

Six test subjects participated in this study. The work rate was controlled by the treadmill grade. At first, the subject walked on the treadmill at 5.3 km/hr (3.3 mph) at a grade of 2.5%, the grade of the treadmill was increased until the subject reached 80% of his cardiac reserve, which usually took 10 minutes. Then the penetration of the inlet covering of each type of PAPR was measured at the airflow rate listed above. The flow rate changed at a two-minute interval.

The treadmill was placed in a large quantitative fit testing chamber. The challenge aerosol was polyethylene glycol 400 (PEG 400) with a MMAD of 0.78 µm and a concentration of approximately 20 mg/m^3. The pressure inside the inlet covering of each PAPR was measured to determine whether a positive pressure could be maintained at a heavy work rate.

The following conclusions can be drawn from the test results.

1. For the tight fitting PAPR, a positive pressure cannot be maintained inside the facepiece at the approved flow rate of 115 liters per minute at a high work rate. A minimum flow rate of 170 liters per minute (6 cfm) is required to maintain a positive pressure inside the facepiece.

2. The pressure inside the two loose fitting facepiece PAPRs does not change much with airflow.

3. The loose fitting helmet type PAPRs provided very low protection when the test subjects perform heavy work.

4. The loose fitting facepiece PAPRs could not consistently maintain a positive pressure inside the inlet covering, even at a flow rate as high as 280 liters per minute (10 cfm).

Another study was conducted by the Los Alamos National laboratory (LANL) (2). Seven respirators were selected for this study. The negative pressure respirators consisted of a half-mask and a full facepiece respirator. The positive pressure respirators included a half-mask PAPR, two loose fitting facepiece helmet type PAPR, an abrasive blasting supplied air hood, and a full facepiece pressure demand supplied air respirator (PDSAR). All air-purifying respirators were equipped with HEPA filters.

The study was performed in a controlled environmental chamber large enough to allow two test subjects to perform at the same time a variety of exercises that simulate actual work conditions. The test aerosol was di-2-ethyl-hexyl sebacate (DEHS), having an average concentration of 25 mg/m^3 and an average mass median aerodynamic diameter (MMAD) of 0.67 micrometer (μm). Three temperature and two humidity combinations were selected for investigation. They include: 0 °C, 21 °C, 32 °C; with 15% and 85% relative humidity. The exercise regimen consisted of five exercises: step up and back down a two-step platform (5 min.); move oiled gravel between two bins (10 min.); pound nails into an overhead board (10 min.); move and lay cinder blocks (10 min.); pound a board with a sledge hammer (5 min.). A five-minute rest period was added between exercises. Twenty-two male and female test subjects participated in this study, but only ten subjects tested each respirator. Test subjects wore hardhat, gloves, safety glasses, safety boots and coveralls during the test.

The test results were in good agreement with WPF studies and the Hyatt quantitative fit testing data (3), with the helmet type loose-fitting PAPRs showing low protection and the half-mask PAPR and the PDSAR providing the highest level of protection. The temperature and humidity had less effect on the PAPRs and SARs than the negative pressure respirators. Under high humidity and temperature, the sweat would cause the facepiece to slide down the nose, downgrading the protection.

Results of the Lawrence Livermore study indicated that airflow alone does not determine whether the device can maintain positive pressure under a heavy workload or extreme environmental conditions. NIOSH should consider adding the treadmill test to determine if the PAPR can maintain a positive pressure under a heavy workload. A few years ago, NIOSH proposed to use total inward leakage test as a requirement for respirator certification. Since PAPRs are use for protection against high concentrations of CBRN agents and highly toxic air contaminants such as asbestos, cadmium, or hexavalent chromium, the LANL tests protocol should be considered as the total inward leakage test for certifying all PAPRs.

To prolong the service life of sorbents and the battery, NIOSH should consider certifying pressure demand (PD) PAPRs. The PDPAPRs should be more useful for protecting against the CBRN agents since the first responders or health care workers need to stay in the contaminated area until the mission is completed. The PDPAPR is already available on the market.

To certify PAPR based on the work rate is not appropriate. Unless the employer has conducted a treadmill test to determine the work rate of each task, the average user cannot be determine which work rate PAPR to select. An incorrect selection would lead to the overexposure of the toxic air contaminant. NIOSH should consider certifying PAPR with only one work rate that covers all workplace situations.

Specific Comments

1. Definitions (2.4)

Does this term imply that only a PAPR equipped with a full facepiece is called a Gas Mask PAPR?

2. Power level (4.1.2.1)

A battery service life meter should be required. The battery meter is commonly appeared on cell phones and digital cameras. It should not a cost issue. Based on the battery level, the wearer should have an idea how long the device could last.

3. Respirator inlet coverings (4.1.6.1.2)

This paragraph should be deleted since it is unlikely one size facepiece would fit all users. Almost all elastomeric half-mask air-purifying respirators have three sizes and many manufactures provide full facepiece in three sizes.

4. Low pressure indicator (4.1.9.1)

The activation time of 12 breaths may be too long. The low-pressure indicator should be based on the state-of -the-art response time of the pressure transducers.

5. Low pressure indicator (4.1.9.2)

The performance requirement for low-pressure indicators should be defined, such as the color and intensity of the light; dB A level and frequency of the sound; and the intensity of vibration. These parameters should be specified to avoid confusion.

6. Power (4.1.10)

The major advantage of the PAPR is its mobility. It does not require external source of air supply. The external power can become a tripping or electrical hazard that may cause injury. If the power cord is cut or immersed in water, then it becomes an electric hazard. NIOSH should not test or certify PAPRs with an external power. If NIOSH would like to certify PAPRs with an external power, the length of electric cord should be limited to a short length and limited for bench use. The power cord should be subject to mechanical strength or other tests to ensure its integrity during use.

7. Power indicator (4.1.10.4)

The performance requirement for power indicators should be defined, such as the color and intensity of the light; dB A level and frequency of the sound; and the intensity of vibration should be specified to avoid confusion.

8. Battery life (4.1.11.2)

Since the PAPR can be used under extreme environmental conditions, such as low temperature, high temperature and humidity, the battery life test should cover these use conditions, e.g. 0°C or 40°C and 85% RH. NIOSH, but not the manufacturer, should set the test requirements.

9. ESLI criteria (4.1.12)

The development of ESLI involves considerable time and resources. In the meantime, NIOSH should ask the applicant to supply cartridge or canister service life data during use as required in the OSHA respiratory protection standard (29 CFR 1910.134).

10. ESLI criteria (4.1.12.1.6)

It is quite common that the relative humidity (RH) in most locations of the nation is higher than 85% in the summer. The test RH level should be set at 85% as a minimum.

11. FMEA (4.1.14)

What is FMEA? The acronym should be spelled out when it is firs appeared in a document.

12. Test humidity (4.2.7.2)

The test relative humidity should be raised to 85%. It reflects the summer humidity in most parts of the country.

13. P95 filter efficiency level determination (4.2.8)

The PAPRs are often used at high dust concentrations. If the user is exposed to submicrometer particles such as the welding fume, or nano particles, the P95 filter may allow significant filter leakage. NIOSH has applied the worse case scenario for filter testing under 42 CFR 84. NIOSH should consider allowing P100 filters as the only filter for the PAPRs.

14. Enhanced CBRN requirements (5.1.2)

This section requires several tests for CBRN PAPRs, such as rough handling, transportation vibration, and drop tests. The OSHA permits the use of PAPRs for protection against highly toxic substances that are no less hazardous than the CBRN agents. These tests are required in the European Union CEN standards on respiratory protection. NIOSH should require these tests specified in 5.1.2 for other PAPRs since they may be used for protection against highly toxic air contaminants such as, asbestos, arsenic, hexavalent chromium, benzene, or acrylonitrile.

References

1. da Roza, RA; Cadena-Fix, CA; Kramer, JE: Powered Air-Purifying Respirator Study final Report. Lawrence Livermore National Laboratory, UCRL-53757 (1986).

2. Skaggs, BJ; Loibl, JM; Carter, KD; Hyatt, EC: Effect of Temperature and Humidity on Respirator Fit Under Simulated Work Conditions. Los National Laboratory, NUREG/CR-5090, LA-11236 (1988).

3. Hyatt EC: Respirator Protection Factors. Los Alamos Scientific Laboratory, UC-41, Los Alamos, New Mexico (1976).

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