

NIOSH Policy Statement

NIOSH Respirator Use Policy

Background. OSHA's new respiratory protection standard, 29 CFR 1910.134, became effective on April 8, 1998, with complete compliance required by October 5, 1998. The new regulation is an upgrade in many ways and is a significant advance for respirator wearers. The NIOSH Respirator Use Policy (RUP) Workgroup has carefully reviewed the new regulation and determined that it is generally consistent with previous NIOSH policy. The Workgroup identified only five differences between the previous NIOSH policy and the new 1910.134. The Workgroup reviewed these differences to determine if it would be appropriate for NIOSH to modify its policies to be in harmony with OSHA. The consistency between NIOSH and OSHA that would result from such harmonization was considered an advantage to respirator users in that it would tend to minimize confusion in the workplace. At the same time, the Workgroup recognized that the rulemaking process placed restrictions on OSHA that do not apply to NIOSH in making its public health recommendations.

NIOSH Respirator Policy Statement:

NIOSH endorses all provisions of OSHA's 29 CFR Part 1910.134, as published on January 8, 1998, except that NIOSH does not recommend (a) the use of irritant smoke for qualitative respirator fit testing, or (b) unsupervised medical evaluations conducted by health care professionals who are not licensed for independent practice to perform or supervise medical evaluations.

Discussion. Both NIOSH policy and the new OSHA regulation are in fundamental agreement that the primary means to prevent occupational diseases caused by breathing contaminated air is through the use of feasible engineering controls such as enclosures, confinement of operations, ventilation, or substitution with less toxic materials. Only when effective engineering controls are not feasible, or while they are being installed or maintained, should respirators be utilized as the primary means of worker protection.

The differences between the previous NIOSH respirator use recommendations and OSHA's 1910.134 are discussed below along with the basis of the new NIOSH recommendations.

- 1. Change Schedules.** Chemical-cartridge respirators typically use activated charcoal as a sorbent to filter toxic gases and vapors. They are essentially 100% efficient filters until the gas or vapor "breaks through." To use these respirators safely, the user must have some way of knowing when "breakthrough" has occurred and the chemical cartridge has to be replaced. This breakthrough can be identified in three ways. First, if the substance has good warning properties (smell, taste, irritation), the wearer detects breakthrough and knows to replace the cartridge (or canister). Second, an end-of-service-life-indicator (ESLI) for the specific gas or vapor of concern signals the wearer to replace the cartridge. Third, a cartridge "change schedule" is established to assure the cartridge is replaced well before breakthrough occurs. These change schedules must be specific for each workplace situation because the service life of a cartridge depends on many variables including: the contaminant concentration, humidity, temperature, interference from other gases and vapors, patterns of use (continuous or intermittent), and characteristics of each respirator model. Previously, OSHA and NIOSH recognized only the first two methods. The new 1910.134 now recognizes only the second and third (ESLIs and change schedules) and no longer recognizes the first (warning properties). Based on

the recommendations of the RUP Workgroup, NIOSH has updated its policy to be consistent with OSHA by recognizing the use of change schedules and by recommending against reliance on warning properties.

Developing cartridge change schedules is a new exercise for most respirator users; because standard approaches to setting change schedule have not been developed and validated, there is uncertainty about their efficacy. Endorsing the use of cartridge change schedules is done with the full knowledge of the uncertainty and problems associated with this approach. It is believed, however, that the uncertainties of change schedules present less of a public health problem than would the continued reliance on warning properties. Further, the new OSHA regulation will likely, over time, cause the development of improved methods of establishing cartridge change schedules. However, there is the possibility that some employers may develop and follow inadequate change schedules that can result in chronic overexposure. Research to develop and validate clear and practical methods for employers to establish change schedules is, therefore, critically needed.

Reliance on warning properties has long been recognized as problematic. The 1987 NIOSH Respirator Decision Logic described the typical wide variation of odor threshold in the general population (greater than two orders of magnitude). The recommendation made in that publication was for "screening tests for workers who wear air-purifying gas or vapor respirators to determine their ability to detect the odor below the exposure limit for that gas or vapor." However, NIOSH does not know of any employer who has tried to do this screening nor any established procedures for doing this screening. Even if screening were performed, other problems would remain: shift in odor threshold due to extended low exposures, shifts due to simple colds and other illnesses, failure to recognize odor because of distraction of the workplace competing for worker attention, and inaccuracies in the screening test itself.

Of the five differences between NIOSH and OSHA, this is the only one where following the previous NIOSH recommendation would preclude following the OSHA regulation and would therefore be in violation of OSHA's regulations.

- 2. Irritant Smoke Fit Testing.** This qualitative respirator fit test is conducted by directing the smoke stream from ventilation smoke tubes (intended to study building ventilation systems) at the respirator face seal. An inadequate face seal is indicated by an involuntary reaction (coughing or gagging) of the worker. The involuntary nature of the reaction is the reason many prefer this test over other qualitative fit tests.

NIOSH, in its formal comments to OSHA on the proposed revision of 29 CFR 1910, 1915, and 1926, strongly recommended against the use of this fit test method because of the health risk associated with exposure to the irritant smoke. That recommendation was primarily based on studies conducted as part of a NIOSH HHE (HETA 93-040-2315) and described in Appendix A of the NIOSH comments to OSHA dated May 15, 1995 (docket H-049). NIOSH continues to recommend against the use of irritant smoke fit testing for these same reasons.

A person's involuntary reaction after breathing irritant smoke is caused by a white hydrochloric acid fume produced by ventilation smoke tubes containing stannic chloride. Hydrogen chloride is immediately irritating at air concentrations of 5 parts per million (ppm) or more. Therefore, the NIOSH recommended exposure limit, the OSHA permissible exposure limit, and the ACGIH TLV® for hydrogen chloride are all ceiling limits of 5 ppm. (A ceiling limit is an air concentration that should not be

exceeded during any part of a workday.) Air sampling has shown that ventilation smoke tubes can produce highly variable and unpredictable hydrogen chloride concentrations far exceeding 5 ppm. The NIOSH HHE included measurements of the hydrogen chloride concentrations emitted from smoke tubes measured at a distance of 12 inches from the tube and generated from a single squeeze of an aspirator bulb. These concentrations ranged from near the ceiling limit (1 ppm, 4 ppm, and 9 ppm) in a room with low relative humidity to 100 times the ceiling limit (460 ppm, 520 ppm, and 1700 ppm) in a room with high relative humidity.

NIOSH reviewed the revised protocol for the irritant smoke test in OSHA's final respiratory protection standard and concluded that a risk still exists for overexposure to hydrogen chloride during a facepiece fit test. To check their sensitivity, test subjects are required to breathe irritant smoke both before and after a successful fit test. Generated concentrations to which test subjects are subjected are not measured in the test protocol. A concentration of 5 ppm is the accepted threshold level at which a response is evoked from most persons. A fit test is a failure when a test subject experiences an involuntary cough or irritation. Retesting requires repeating the sensitivity check. In each case, the responses of coughing and irritation are the adverse health effects for which hydrogen chloride's exposure limits are intended to protect against. Consequently, NIOSH maintains its recommendation against the use of irritant smoke as a fit testing agent.

- 3. Saccharin qualitative fit testing.** This test is conducted with an inexpensive, commercially available kit that challenges the respirator wearer with a sweet tasting saccharin aerosol. After previously having been screened to assure that he/she can taste saccharin at the required concentration, the respirator wearer is asked to report if saccharin is tasted during fit testing. If so, the respirator is considered to have an inadequate fit and fails the fit test.

NIOSH has previously recommended against the saccharin fit test because of its classification as a potential carcinogen [NTP 1981; IARC 1987; Niemeier 1991]. However, NIOSH recently re-examined the potential risk to workers that would be posed by saccharin used in fit testing [NIOSH 1999]. Finding that the risk to workers from use of saccharin in respirator fit testing is extremely small and may be zero, and in accordance with the new REL policy [NIOSH 1995], NIOSH recommends both saccharin or Bitrex® for use in qualitative respirator fit testing, consistent with OSHA's respiratory protection standard (29 CFR 1910.134).

NIOSH intends to include the saccharin fit test in its ongoing research program to assess the efficacy of fit test methods in general. That is, NIOSH plans to evaluate the ability of the saccharin fit test to identify those individuals who will achieve a fit sufficient to assure adequate protection when the respirator is worn in the workplace. NIOSH researchers have conducted, and are conducting, such studies of a variety of fit test methods.

- 4. Voluntary Respirator Use.** Previously, NIOSH recommended, and OSHA required, a full-blown respirator program whenever a respirator was used. Thus, for example, employees having a workplace exposure below the exposure limit but wanting to further reduce their exposure with voluntary respirator use could not do so unless the employer implemented a complete respirator program with all its elements (fit testing, written program, medical evaluation, record keeping, etc.). This tended to discourage the use of respirators to further reduce exposure to levels well below maximum exposure limits.

The new OSHA regulations require a complete respirator program whenever respirator use is required by the employer. However, when respirators are used voluntarily by employees, the employer needs only to establish those respirator program elements necessary to assure the respirator itself is not a hazard. The exception is that filtering facepiece respirators can be used without any respirator program when used voluntarily. Although there are no known studies of such voluntary respirator use, NIOSH supports OSHA's voluntary use provisions because they provide safe ways not previously available to use respirators to reduce exposure well below established exposure limits.

- 5. Medical Evaluation Responsible Person.** The previous OSHA 1910.134 stated: "Persons should not be assigned to tasks requiring use of respirators unless it has been determined that they are physically able to perform the work and use the equipment. The local physician shall determine what health and physical conditions are pertinent."

The new 1910.134 states: "The employer shall identify a physician or other licensed health care professional (PLHCP) to perform medial evaluations...." In the definitions section, OSHA states: Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by paragraph (e) of this section."

Thus the new OSHA regulation allows a non-physician, under certain conditions, to be the responsible person who determines medical fitness to wear a respirator. However, the definition in 1910.134(b) of a "physician or other licensed health care professional" does not limit the non-physician responsible person to those who are licensed for independent practice in all the health care services required by 1910.134(e). NIOSH recommends that the only non-physicians responsible for medical surveillance and medical clearance (either conducting the examinations or supervising them) should be nurse practitioners and physician assistants in those states where they are licensed for independent practice.

signed:\ Linda Rosenstock, M.D., M.P.H. August 4, 1999

Director, NIOSH Date

REFERENCES

IARC [1987]. IARC monographs on the evaluation of carcinogenic risks to humans; overall evaluations of carcinogenicity: an updating of IARC monographs, volumes 1-42, supplement 7. Lyon, France: World Health Organization, International Agency for Research on Cancer, pp. 334-339.

Niemeier RW [1991]. Letter of April 19, 1991, from R.W. Niemeier, Division of Standards Development and Technology Transfer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Public Health Service, U.S. Department of Health and Human Services to Donald Wilmes, 3M.

NIOSH [1995]. NIOSH Recommended Exposure Limit Policy, September 1995. In: NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

NIOSH [1999]. NIOSH Saccharin Use for Respirator Fit Testing Policy, July 1999. In: NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

NTP [1981]. Second annual report on carcinogens. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, NTP Publication No. 81-43.

Schulte PA [1999]. Memorandum of February 23, 1999, from P.A. Schulte, Education and Information Division, to Don Campbell, Chairperson, Respirator Use Policy Committee, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Public Health Service, U.S. Department of Health and Human Services.

Wilmes D [1994]. Letter of May 18, 1994, from Don Wilmes, 3M, to Richard W. Niemeier, Division of Standards Development and Technology Transfer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Public Health Service, U.S. Department of Health and Human Services.