

A Case for Revising OSHA's  
Respiratory Protection Standard

by

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Management of occupational respiratory hazards is integral to workplace health and safety. At workplaces where airborne particulates and toxic vapors are present, a key part of the overall plan to protect the workers is the use of respirators. Over 5 million workers at 1.3 million workplaces in the United States use respirators (Occupational Safety and Health Administration [OSHA], n.d.).

While respirators are effective in preventing inhalation of particulates and dangerous vapors, the devices place a physiological and psychological burden on users ("Respiratory protection," 1998, pp. 1159-1160). Because of the stresses respirators create, the Occupational Health and Safety Administration (OSHA) has published detailed regulations governing the medical clearance of workers for respirator use. The regulations, however, are unwieldy, and they do not set objective medical standards for respirator clearance. Specifically, the regulations, last revised in 1998, do not differentiate between workers who are at high risk and those at low risk for respirator use. Nor do the regulations delineate the risk levels of the different conditions under which workers use respirators.

The failure of the federal regulations to address risk levels has led to confusion among employees, employers, and health professionals as to the requirements workers must meet to be approved for respirator use. The lack of objective standards is a serious deficiency of the regulations in light of the importance of accurately assessing workers for respirator use. Workers who are denied respirator clearance can lose their jobs, and employers can incur unnecessary costs when workers undergo needless testing.

Additionally, because health professionals have no objective standards for determining respirator clearance, they are placed in legal jeopardy when making decisions.

Despite the physiological and psychological burdens that respirators place on users, recent research has shown that wearing a respirator is remarkably benign. In view of this finding, and because of the importance of assessing workers against objective standards, the OSHA regulations governing medical clearance for respirator use need to be revised.

### Occupational Lung Diseases

Occupational lung diseases as a group are the most common work-related illnesses in the United States (Epler, 2004). They include asbestosis, lung cancer, mesothelioma, asthma, byssinosis, coal workers' pneumoconiosis, silicosis, and hypersensitivity pneumonitis (American Lung Association, n.d.). In 2002, approximately 22,000 cases of occupational lung diseases were reported, affecting 2.5 of every 10,000 workers (Bureau of Labor Statistics [BLS], 2003). Most occupational lung diseases result from multiple exposures over time to toxic gases or particulate matter, such as carbon monoxide, carbon dioxide, wood dust, metal fumes, silica, trichloroethylene, and chromic acid ("Respiratory protection," 1998, p. 1159).

The high human and economic costs associated with occupational lung diseases have resulted in steps to reduce the overall scope of the problem by minimizing risk to workers. Much of the effort has focused on removing respiratory hazards from the workplace through engineering, administration, and design solutions. Advances in environmental management and the use of alternative materials with low toxicity have helped to decrease morbidity and mortality. Reducing the presence of airborne hazards in

the workplace is the preferred way to control respiratory risk, but completely eliminating risk through engineering, administrative, and manufacturing advances is in many instances not possible. Other ways to prevent exposure to dangerous levels of airborne hazards include the use of personal protective equipment such as respirators. A respirator is a personal protective device that prevents the inhalation of harmful airborne substances or oxygen-deficient air (“Respiratory protection,” 1998, p. 1158).

### History of Respirators

The use of respirators dates back to Roman times when miners used a primitive air-filtering device. By the 1700s, respirators that supplied their own breathing atmosphere began to resemble modern-day respirators (OSHA, n.d.). The 1800s saw the development of encased filtering media and the use of activated charcoal as a filtering medium. In the 1900s, chemical weapons during World War I spurred a rapid acceleration in respirator technology, leading to the development of inexpensive, disposable filtering respirators with low breathing resistance (OSHA). Today’s respirators are highly efficient, relatively comfortable to wear and produce little breathing resistance.

### Respirator Types

Respirators fall into two basic categories: air purifying and atmosphere supplying. Air-purifying respirators are the more commonly used (Szeinuk, Beckett, Clark, & Hailoo, 2000). They are further divided into three subcategories based on whether they filter particulates or vapors, or both particulates and vapors.

Atmosphere-supplying respirators provide clean air from either a self-contained or external source. These respirators are used in firefighting, cleaning up hazardous spills, and other situations that pose an immediate danger to life or health.

A half-face respirator covers the nose and mouth, while a full-face respirator also covers the eyes. A respirator can also consist of only a mouthpiece, or it can be a hood or helmet covering the entire head.

The National Institute for Occupational Safety and Health rates respirators using assigned protection factors (National Institute for Occupational Safety and Health [NIOSH], 1998). Additionally, OSHA publishes detailed algorithms and e-tools to help employers choose the correct respirator for their workers.

#### Respirator Use

OSHA requires workers to wear respirators in environments contaminated with asbestos, lead, vinyl chloride, benzene, cotton dust, formaldehyde, hazardous waste, inorganic arsenic, coke oven emissions, 1,2-dibromo-3-chloropropane, acrylonitrile, ethylene oxide, and bis-chloromethyl ether (American Thoracic Society [ATS], 1996).

The number of respirator users, estimated at more than 5 million in the U.S., is growing (Harber, Merz, & Chi, 1999). One occupational field where respirator use is rapidly increasing is health care (Harber et al.). Respirator use is also now included in the training of law-enforcement and emergency-response personnel as a result of the possible use of airborne toxins by terrorists (Harber et al.). Generally, respirators are used in any environment where harmful particulates or gases are present, or where oxygen is insufficient.

### Physiological and Psychological Burdens of Respirator Use

A large amount of research has been undertaken regarding the physiological and psychological effects of respirator use. Nonpowered air-purifying respirators have dead space between the filtering medium and the lungs, adding to respiratory effort (Szeinuk et al., 2000). Because of the dead space, there is re-breathing of some exhaled carbon dioxide which decreases respiratory efficiency (OSHA, n.d.). Atmosphere-supplying respirators also create physical demands on users. Users of these respirators normally carry a self-contained breathing apparatus, commonly referred to as an SCBA. The added weight, as much as 40 pounds, causes fatigue in the skeletal muscles and a 3 to 6% increase in respiratory effort (Szeinuk et al., 2000).

Thermal stress and the amount of physical exertion required for a job are other factors that should be considered in clearing a worker for respirator use. Additionally, dermatological problems, such as skin conditions and rubber allergies, may make respirator use difficult. Depending on the respirator type, vision may also be impaired during use. The psychological effects of respirator use may include anxiety and claustrophobia. In addition communication is impaired by respirator use.

The physiological and psychological effects associated with respirator use have raised a concern that some chronic medical conditions could be exacerbated by respirator use, conditions such as asthma, chronic obstructive pulmonary disease, interstitial lung disease, and coronary atherosclerotic disease. OSHA has tried to address this concern in the medical clearance requirements of the 1998 respiratory protection standard, as detailed in CFR 29-1910.134(e).

## History of Respiratory Protection Standards

Four governmental bodies are primarily responsible for formulating respiratory protection standards and regulating respirator use: the National Institute for Occupational Safety and Health, the Mine Safety and Health Administration, OSHA, and the Nuclear Regulatory Commission. Additionally, four private-sector organizations propose standards: the American Conference of Governmental Industrial Hygienists, the American National Standards Institute, the American Thoracic Society, and the National Fire Protection Association (ATIS, 1996). The standard that currently applies to the vast majority of respirator users in the U.S. is the OSHA respiratory protection standard found in CFR 29 § 910.134.

OSHA adopted the first regulatory standard in 1971. It was based on a consensus view by the private-sector organizations of the procedures and practices in place at that time, borrowing heavily from the published standards of the American National Standards Institute (OSHA, n.d.). With its codification in 1971, the OSHA standard was made mandatory, whereas previous OSHA guidelines on respirator use were advisory (OSHA). Beginning in 1985, a revision of the 1971 standard was undertaken with the support of industry, respirator manufacturing, and research interests (“Respiratory protection,” 1994). The new standard was adopted 13 years later, in 1998, and remains the current standard. In adopting the standard, OSHA stated the new regulation would “avert hundreds of deaths and thousands of illnesses annually” (“Respiratory protection,” 1998, p. 1152). The annual cost of the new standard was estimated at \$111 million, or \$22 per employee per year in 1998 dollars (“Respiratory protection,” 1998, p. 1152). The standard details eight elements of a compliant respiratory protection program: (1)

respirator selection, (2) medical evaluation, (3) fit testing, (4) proper use, (5) respirator maintenance, (6) the quality of the breathing air, (7) training and (8) program evaluation.

This paper will focus on the standard's requirements for medical evaluation.

### Medical Evaluation Criteria Under The 1998 Respiratory Protection Standard

The purpose of the medical certification process is to ensure that individuals are able to wear a respirator without harm to themselves and to perform their work safely (Szeinuk et al., 2000). Medical assessment and approval for respirator use must take place before a worker is fitted for a respirator and allowed to wear it (Muhm, 1999). A worker may undergo the medical clearance process only one time, but the clearance process must be repeated if a significant change occurs in the worker's ability to wear a respirator or if the worker's job responsibilities are substantially altered ("Respiratory protection," 1998, p. 1208).

The 1998 respiratory protection standard provides two avenues for evaluating workers for respirator clearance. The first avenue is a medical *evaluation*, and the second is a medical *examination* (Muhm, 1999). Under either avenue, all respirator users are assessed against the same criteria regardless of the type of respirator used or the level of physical intensity of the work performed.

The first avenue, the medical evaluation, entails a self-administered medical evaluation questionnaire codified in the standard. Studies have shown that the questionnaire, developed for the purpose of identifying workers who could be at risk in using a respirator, has high sensitivity but low specificity (Harber et al., 1999). The questionnaire, after the worker completes and submits it, must be reviewed by a licensed

health care professional. The following section of the questionnaire (see Table 1), taken from the *Federal Register*, includes nine mandatory questions to be answered by every employee who will wear any type of respirator.

Table One

Part A. Section 2. (Mandatory) Questions 1 through 9 below must be answered by every employee who has been selected to use any type of respirator (please circle "yes" or "no").

1. Do you **currently** smoke tobacco, or have you smoked tobacco in the last month: Yes/No
2. Have you **ever had** any of the following conditions?
  - a. Seizures (fits): Yes/No
  - b. Diabetes (sugar disease): Yes/No
  - c. Allergic reactions that interfere with your breathing: Yes/No
  - d. Claustrophobia (fear of closed-in places): Yes/No
  - e. Trouble smelling odors: Yes/No
3. Have you **ever had** any of the following pulmonary or lung problems?
  - a. Asbestosis: Yes/No
  - b. Asthma: Yes/No
  - c. Chronic bronchitis: Yes/No
  - d. Emphysema: Yes/No
  - e. Pneumonia: Yes/No
  - f. Tuberculosis: Yes/No
  - g. Silicosis: Yes/No
  - h. Pneumothorax (collapsed lung): Yes/No
  - i. Lung cancer: Yes/No
  - j. Broken ribs: Yes/No
  - k. Any chest injuries or surgeries: Yes/No
  - l. Any other lung problem that you've been told about: Yes/No
4. Do you **currently** have any of the following symptoms of pulmonary or lung illness?
  - a. Shortness of breath: Yes/No
  - b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Yes/No
  - c. Shortness of breath when walking with other people at an ordinary pace on level ground: Yes/No
  - d. Have to stop for breath when walking at your own pace on level ground: Yes/No
  - e. Shortness of breath when washing or dressing yourself: Yes/No
  - f. Shortness of breath that interferes with your job: Yes/No
  - g. Coughing that produces phlegm (thick sputum): Yes/No
  - h. Coughing that wakes you early in the morning: Yes/No
  - i. Coughing that occurs mostly when you are lying down: Yes/No
  - j. Coughing up blood in the last month: Yes/No
  - k. Wheezing: Yes/No
  - l. Wheezing that interferes with your job: Yes/No
  - m. Chest pain when you breathe deeply: Yes/No
  - n. Any other symptoms that you think may be related to lung problems: Yes/No
5. Have you **ever had** any of the following cardiovascular or heart problems?
  - a. Heart attack: Yes/No
  - b. Stroke: Yes/No
  - c. Angina: Yes/No
  - d. Heart failure: Yes/No
  - e. Swelling in your legs or feet (not caused by walking): Yes/No
  - f. Heart arrhythmia (heart beating irregularly): Yes/No

- g. High blood pressure: Yes/No
  - h. Any other heart problem that you've been told about: Yes/No
6. Have you **ever had** any of the following cardiovascular or heart symptoms?
    - a. Frequent pain or tightness in your chest: Yes/No
    - b. Pain or tightness in your chest during physical activity: Yes/No
    - c. Pain or tightness in your chest that interferes with your job: Yes/No
    - d. In the past two years, have you noticed your heart skipping or missing a beat: Yes/No
    - e. Heartburn or indigestion that is not related to eating: Yes/ No
    - f. Any other symptoms that you think may be related to heart or circulation problems: Yes/No
  7. Do you **currently** take medication for any of the following problems?
    - a. Breathing or lung problems: Yes/No
    - b. Heart trouble: Yes/No
    - c. Blood pressure: Yes/No
    - d. Seizures (fits): Yes/No
  8. If you've used a respirator, have you **ever had** any of the following problems? (If you've never used a respirator, check the following space and go to question 9 \_\_: )
    - a. Eye irritation: Yes/No
    - b. Skin allergies or rashes: Yes/No
    - c. Anxiety: Yes/No
    - d. General weakness or fatigue: Yes/No
    - e. Any other problem that interferes with your use of a respirator: Yes/No
  9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire: Yes/No
- 

A “yes” answer to one or more of the above questions automatically triggers further medical evaluation or an examination by a health care professional. The follow-up evaluation can be as simple as a phone conversation between the health care professional and worker to clarify the worker’s “yes” responses, or it can entail an in-office medical examination which may include testing such as spirometry, electrocardiogram, or exercise testing. The final decision on respirator clearance is left to the discretion of the health care professional.

“No” answers to all of the questions usually results in clearance for respirator use without further medical evaluation. The questionnaire may be completed at the worksite and then reviewed later by a health care professional. As another option, a respirator manufacturer offers the questionnaire online and has a physician review the completed

questionnaires remotely. The physician issues letters of clearance for a fee of \$25 each (3M United States, n.d.).

In evaluating workers for respirator clearance, the questionnaire may be substituted for a medical examination that gathers the same information (Muhm, 1999). Studies have been conducted for the purpose of comparing the two pathways to clearance—the medical evaluation and the medical examination—with regard to approval rates. One notable study by Pappas et al. (1999) found that of 413 workers completing questionnaires at a U.S. Department of Energy site in Washington State, 19% were cleared initially and all others were cleared by the subsequent medical examinations. The workers among the 81% not cleared by the questionnaire had either at least one “yes” answer or had checked the space that indicated they had not ever used a respirator. Restrictions were imposed on only 3% (n=10) of the workers, with most of these few restrictions precluding SCBA use due to workers’ musculoskeletal pain. One worker was restricted to a powered air-purifying respirator secondary to asthma, and one individual was restricted from wearing an air-purifying respirator secondary to claustrophobia (Pappas et al.).

The most striking finding of the study, however, was not with regard to the sensitivity or specificity of the questionnaire versus the medical exam. More remarkable was the finding that, out of 413 workers screened under the standard, 413 were cleared for respirator use. Although a few restrictions were imposed due to workers’ musculoskeletal pain, making it difficult for them to carry the heavy SCBA, and two workers were issued restrictions based on medical conditions, all workers were cleared to wear some type of respirator, with 97% cleared for any type of respirator. This finding

suggests that if workers are fit to do their jobs without a respirator, they are likely fit to do their jobs with a respirator.

### Problems with the Current Standard for Medical Clearance

#### *Presumption of Harm*

The current process for determining respirator clearance is based on the presumption of harm to a worker resulting from respirator use if the worker has an underlying medical condition. Studies in laboratory settings have clearly shown that wearing a respirator creates physiological and psychological burdens. A question remains, however, whether these burdens, as demonstrated in physiology laboratories, are replicated to the same extent under actual workplace conditions. It is known that the demands respirators place on individuals with normal and impaired lung function appear to be well tolerated (ATS, 1996). Is respirator use, then, really that dangerous?

Studies have shown that respirator users with lung disease experience only a minor physiological burden during sub-maximal exercise (Pappas et al., 1999). Workplace data seem to confirm the benign nature of respirator use. During the 12 years from 1984 through 1995, OSHA received reports on 45 workplace fatalities associated with respirator use (Suruda, Milliken, Stephenson, & Seseck, 2003). Most of the fatalities were related to improper equipment or improper use of equipment in environments immediately dangerous to life or health (Suruda et al.). None of the fatalities were associated with an underlying medical condition. Inadequate medical screening, then, was not responsible for any of the 45 fatalities (Suruda et al.). With over 5 million respirator users in the United States, either the system works remarkably well in identifying those who should not wear respirators, even though one study found not one

worker among 413 was so identified, or respirator use despite some physiological demands is generally benign.

### *Subjectivity*

Objectivity in evaluating a worker for respirator clearance ends as soon as the worker considers a response to the first of the nine mandatory questions in the questionnaire. Assuming that workers will answer the questions truthfully despite the knowledge that a “yes” answer to any of the nine mandatory questions will hurt their chances of being approved, how a worker interprets each question still remains entirely subjective. Objectivity is likewise absent in evaluating a completed questionnaire. A completed questionnaire on which one health care professional would base an approval could be the basis for a disqualification by another professional.

Several different guidelines and algorithms have been published, but employers and health care professionals have no clear agreement on them, and no solid evidence demonstrates their protective benefit (OSHA, n.d.). Abnormalities in pulmonary function, for example, have not been shown to affect a worker’s ability to wear a respirator (Harber et al., 1999). The American Thoracic Society (1996) states there is “no medical test that can completely predict which user will encounter difficulty” (p. 1153). The only objective finding that appears related to a worker’s suitability for respirator use is the worker’s previous use of a respirator (ATS).

If no objective data exist for making clearance determinations, then determinations can be based only on clinical judgments. Whether clinical judgments are reliable in deciding who should and should not wear a respirator remains unproven (Harber et al., 1999). No scientific basis exists for the present fail criteria (Szeinuk et al.,

2000). The fallibility of the process due to the unsubstantiated fail criteria is exacerbated by a lack of requirements for appropriate training among the health care professionals who evaluate workers for respirator clearance. Many of the professionals who certify workers are not trained in occupational medicine and do not otherwise have the background necessary for making nuanced judgments regarding respirator use. The deficient qualifications of these professionals render their decisions questionable.

#### *One Size Fits All*

The physical demand of carrying 40 pounds of self-contained breathing gear is clearly much greater than the burden created by wearing a simple half-face air-purifying respirator. Similarly, it has been shown that respirator use at sub-maximal exercise levels has minimal physiological effects, whereas respirator use at maximal exercise levels can be demanding. Further, a worker who uses a respirator for protection from welding fumes does not need the same type of respirator and does not face the same physical demands as a firefighter who enters a burning building for a rescue attempt. Yet, in spite of these vast differences, the current OSHA respiratory protection standard treats all users alike.

#### *Time Consuming and Expensive*

The current system is expensive. Certification through the use of an online questionnaire and evaluation service costs at least \$25 per worker (3M United States, n.d.). Review of an employee's questionnaire by a local physician or other licensed health care professional, based on the author's experience, can cost up to \$60. But if the worker has answered "yes" to any of the nine mandatory questions, then a visit to the office of the health care professional may be necessary. The American Iron and Steel Institute has

estimated that the cost of a medical opinion and examination could be as high as \$150, plus \$45 in lost work time (NIOSH, n.d.).

#### *Lack of Portability*

Frequent job changes are common for workers who use respirators. During a single year, skilled welders and millwrights often work for several different companies. Because respirator clearance certification does not transfer with the worker from a present or former employer to a new one, workers must undergo medical screening whenever a new employer hires them. The same health care professional might certify the same worker several times within the same year, as the author of this paper has done.

#### *Employee Considerations*

A few “yes” answers on the questionnaire could easily lead a professional to make a completely subjective opinion that would keep a worker from being hired or cause a worker already on the job to be discharged. Not qualifying for respirator use can be devastating to workers whose livelihoods depend on being certified for using respirators. For workers, an objective standard for clearance is certainly no less important than it is for employers and medical professionals.

#### *Unwise Use of Resources*

The majority of workers approved for respirators are workers whose use is low risk. If the medical evaluation of workers focused on high-risk uses, the overall cost of the clearance process would decrease significantly. Medical personnel and financial resources would be freed for addressing other issues in occupational health and safety.

A Proposed Revision for  
OSHA's Respiratory Protection Standard

The current process for clearing workers for respirator use needs to be changed. The "one-size-fits-all" medical evaluation standard is inappropriate because of the differences in respirator types and uses.

A respirator clearance process that considers risks to workers would be more practical given that most workers today use low-risk negative-pressure air-purifying respirators. Additionally, most workers who use air-purifying respirators perform job activities that are sub-maximal in physical intensity. Rarely are these respirators used in situations immediately dangerous to life or health (IDLH). Even for individuals with impaired lung function, respirator use at sub-maximal exercise levels has been shown to be well tolerated (Pappas et al., 1999). The majority of workers being screened for respirator clearance under the current standard are unlikely, then, to have any problem with respirator use.

A new clearance process for respirator use could have two tiers— one tier where the risk to workers is low and one where the risk is high. The two-tiered process would consider *respirator type* and *respirator use*. Respirator type is important because studies have demonstrated a difference in the level of physiological burden among various types of respirators, notably the much higher level of burden on workers who carry a heavy SCBA used with an atmosphere-supplying respirator.

The situation in which a respirator is used is important because of the significant difference in the level of physiological burden between job activities that involve low- and high-intensity work. Three uses should be given careful consideration. The first is the

use of respirators in IDLH environments, where safety is clearly enhanced when the excellent physiological condition of workers is assured before placing them in dangerous settings. The second use of respirators that deserves careful consideration is in rescue and hazardous materials (HAZMAT) operations. These operations are often conducted in IDLH environments, can require high-intensity work, and often involve carrying a SCBA. The third use to be considered regards any other high-intensity work. In these three cases, medical clearance through the use of a questionnaire and likely a medical examination with testing is indicated.

The first tier of the clearance process, then, would consider high-risk respirators—those with a self-contained breathing apparatus—and high-risk uses. The medical examination would remain a part of the clearance process, to be used when indicated by “yes” answers in the questionnaire.

The second tier of the questionnaire would consider low-risk respirators and low-risk uses. In these cases, a worker’s trial use of a respirator at the worksite would pose no safety concern because a worker who can perform a job’s activities without a respirator can likely perform the activities with a respirator (BLS, 2003). Workers who may encounter difficulties during the worksite trial could in most cases remove their respirators with negligible risk.

The worksite trial for low-risk respirators used in low-risk situations would be conducted according to procedures similar to those for fit testing, as found in the current regulation. No questionnaire would be used. Before the trial, however, the employee would be asked to report any prior problems with respirator use. A prior problem would

trigger a referral to the first tier, where the employee would complete the questionnaire and undergo a medical examination if called for by “yes” answers.

The worksite trial would be conducted under the supervision of worksite safety personnel. While wearing the respirator, the employee would perform simulated tasks or mild exercise, such as climbing stairs for five minutes. The safety personnel would then ask the worker about any difficulties experienced while using the respirator. An employee who reports a problem is then referred to the first tier for the questionnaire and a medical examination if indicated by “yes” answers. An employee cleared for respirator use by the worksite trial but who reports difficulty in wearing the respirator after starting work could also be referred to the first tier for completing the questionnaire.

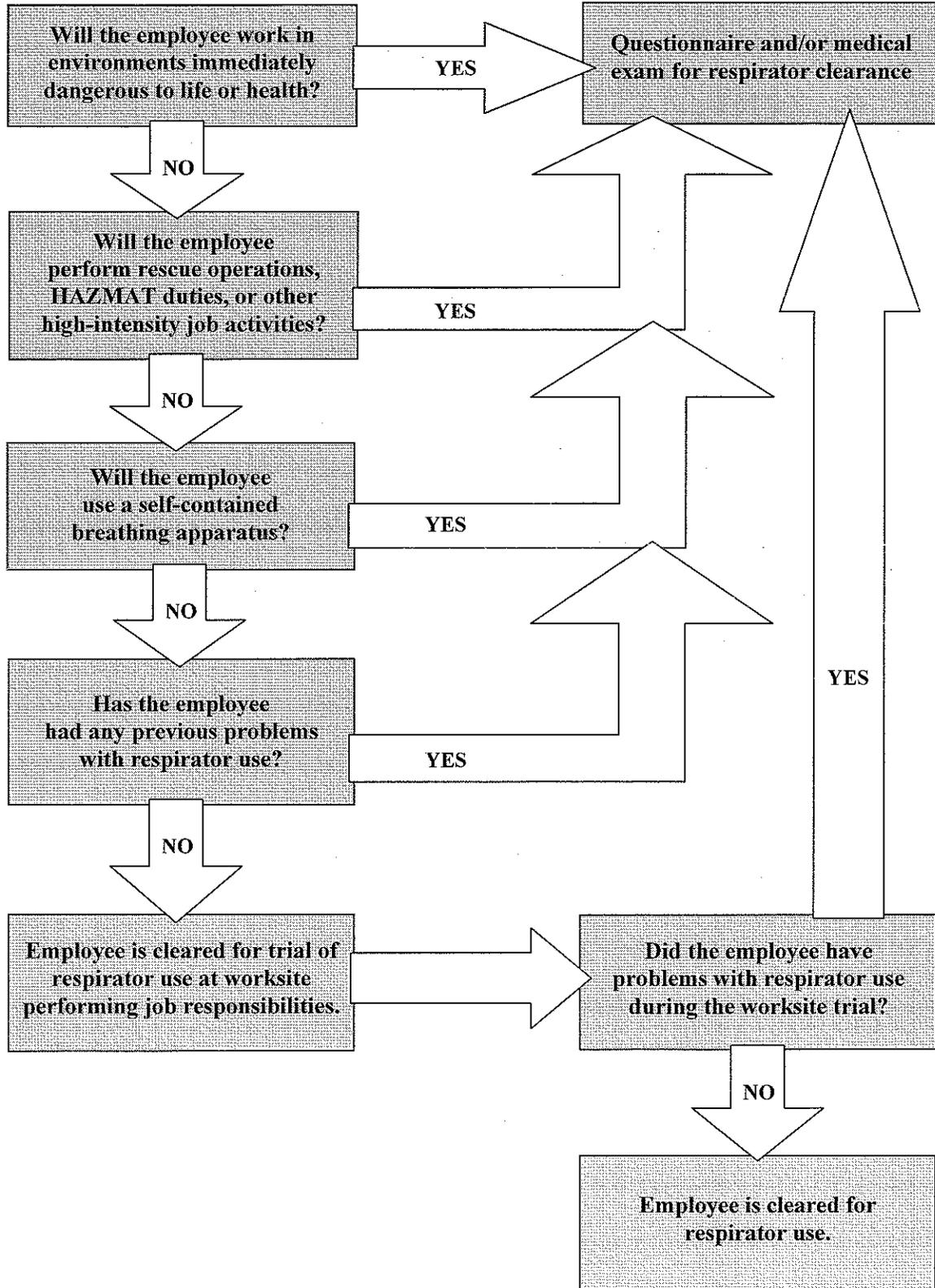
The proposed two-tiered system for respirator clearance provides a “real-world” trial with a failsafe should the worker has difficulties. At the same time, the process recognizes the low- and high-risk levels of respirator use, as determined by work conditions, the kind of respirator, and a worker’s previous experience. Users in high-risk work situations, users who carry SCBAs, users who have had previous problems with respirator use, and users who have problems during the worksite trial are processed for clearance under the current procedures—the questionnaire followed by a medical examination if necessary.

Once workers are cleared for respirator use—whether by the worksite trial, the questionnaire, or a medical examination—they could be issued a card that states they are certified for a specified class of respirators for a specified class of jobs. A certification card, which could be effective for as long as five years, would make a worker’s respirator clearance transferable from one employer to another. The transferability of clearance

would eliminate the need for workers to undergo repeated evaluations whenever they hire on with new employers.

For workers, the proposed process would save time and inconvenience. For employers, it would save the expense of unnecessary medical evaluations and medical examinations. (See figure one for graphic representation of process)

Figure 1: Flowchart for Respirator Clearance by Worksite Trial



## Barriers to Change

Several barriers would hinder the adoption of any proposed changes to OSHA's respiratory protection standard. The first and likely the most significant would be the rule-making process itself. The complexity of the process is evident in the 13 years it took to revise the original 1971 standard, an effort undertaken in 1985 and not completed until 1998. The revised OSHA standard is derivative of standards recommended by the private-sector standard-setting organizations. Their own current standards as a result do not contain notable deviations from the OSHA standard. The private-sector organizations would likely not propose regulatory changes unless they desired to amend their own standards in the same way.

Other barriers to change could include the active opposition of labor unions and governmental officials who may view the proposed changes as a way for management to cut costs at the expense of workers' health. The occupational health industry itself might oppose the changes. With over 5 million respirator users in the United States, medical clearance for respirator use has become a significant commercial activity, and many observers have noted that money does often influence the regulatory process. A Web site such as the 3M site for clearance could raise hundreds of thousands of dollars with minimal effort from health care professionals who realize substantial income from clearance evaluations. Even a small medical practice can generate significant income through the evaluation of workers for respirator use, nearly all of the workers low risk. Respirator clearance made up over 10% of the total receipts of the author's practice. It is occupational health professionals who mainly drive occupational health research, notwithstanding the potential for conflicts of interest.

Another barrier would be the lack of adequate surveillance in the worksite for adverse events associated with respirator use. The evidence to date seems to support the argument that most respirator use is benign, but no on-site data have been collected to prove or disprove this view. This lack of surveillance would make adverse events associated with implementation of the policy change difficult if not impossible to detect.

#### Plans to Advance Agenda

Several steps could be taken to advance a change in OSHA's medical evaluation process for respirator use. The first step would be to identify the groups that would have a stake in the policy change, with the intention of enlisting their support. These groups would include respirator users, employers of respirator users, respirator manufacturers, occupational health professions, industrial safety personnel, the private-sector standard-setting organizations, and representatives of OSHA and the National Institute for Occupational Safety and Health.

The second step would be to collect more data. Few workplace studies have been conducted regarding the safety of respirator use, and any solid data showing the benign nature of respirator use in actual work settings would serve to encourage support for the policy change. The American Thoracic Society has advocated for such research in the past (ATS, 1996).

A third step would be to mobilize the support to encourage and fund additional research. The industrial sector would seem a natural partner in the effort to secure research funding in view of the cost savings it could realize through a policy revision. Companies would, however, be vulnerable to conflict-of-interest charges. Another approach, one that would likely be more widely accepted, would be for an organization

such as NIOSH to obtain a research grant from a government agency. Several of the private-sector standard-setting organizations might partner in the research, given that their recommendations generally form the basis for OSHA's standard.

A fourth step would be to institute a surveillance program for respirator use. Monitoring the current respiratory protection program and tracking any adverse events could provide data supportive of a change in the standard. OSHA would be the appropriate agency to administer the surveillance program.

If further research were to support previous findings of the benign nature of most respirator use, then the next step would be to place the proposed changes to the respiratory protection standard on OSHA's agenda. A variety of approaches could be employed in encouraging OSHA to consider the proposed revision.

One approach would involve first convincing the private-sector standard-setting organizations to revise their respiratory protection standards to conform to the proposed two-tiered system for respirator clearance. The standards of these organizations have been in the past the precursors for OSHA's standard.

A second approach would be to petition OSHA directly for a revision of its current standard. Because OSHA has a record of heeding the advice of those whom the agency serves, letters of support for the proposed revision from safety and health personnel could lead to a rules-making process that incorporates the proposed revision.

A third option, which would be much more expensive than either of the other two, would be to hire lobbyists to advance the proposed changes. The necessary funds would likely need to come from industrial interests.

## Conclusions

The current OSHA respiratory protection standard as written and applied does not represent an efficient use of money and human resources. Clearing workers for whom respirator use poses a low risk presently consumes large sums of money and considerable time. The data suggest that wearing the more commonly used respirators in situations that do not demand intense physical exertion is a benign activity. The present medical clearance procedure, however, is entirely subjective, with no established pass-fail criteria and no consideration of risk levels for various types and uses of respirators.

A two-tiered system of medical clearance based on respirator type and use would be more efficient and consistent. Such a system would differentiate between high- and low-risk users. High-risk users would continue to be screened under the current guidelines, while low-risk users would participate in a worksite trial, using their respirators in a simulated performance of their job activities. The proposed change to the current procedure represents a common-sense approach to the medical clearance of workers for respirator use.

Two other issues that stakeholders in respiratory protection programs need to address are field-based research and the establishment of a surveillance program. Because research on respirator use has been limited mostly to laboratory studies of the physiologic effects of respirator use, field-based studies must be undertaken. Finally, a surveillance program would be useful in monitoring the effectiveness of the current respiratory protection standard and evaluating in the future any revisions that may be adopted.

## References

- 3M United States, Inc. (n.d.). Frequently asked questions: How much does it cost?. [Web site posting.] Retrieved October 23, 2005, from <http://www.respexam.com/faq.asp#cost>
- American Lung Association. (n.d.). Lung disease data at a glance: Occupational lung disease. [Web site posting.] Retrieved October 23, 2005, from <http://www.lungusa.org/site/pp.asp?c=dvLUK900Eb=326735>
- American Thoracic Society. (1996). Respiratory protection guidelines. *American Journal of Respiratory Critical Care Medicine*, 154, 1153-1165.
- Bureau of Labor Statistics. (2003, December 18). Workplace injuries and illnesses in 2002. [News release.] Washington, DC: U.S. Department of Labor. Retrieved October 23, 2005, from <http://permanent.access.gpo.gov/website/www.bls.gov/news.release/pdf/osh.pdf>
- Epler, G. R. (2004). Environmental and occupational lung diseases. Dynamics in healthcare [Web site]. Retrieved October 23, 2005, from <http://www.epler.com/occul.html>
- Harber, P., Merz, B., & Chi, K. (1999). Decision model for optimizing respirator protection. *Journal of Occupational and Environmental Medicine*, 41, 356-365.
- Muhm, J. (1999). Medical surveillance for respirator users. *Journal of Occupational and Environmental Medicine*, 41, 989-984.
- National Institute for Occupational Safety and Health. (n.d.). NIOSH safety and health topic: Respirators. [Web site posting.] Retrieved October 23, 2005, from <http://www.cdc.gov/niosh/npptl/topics/respirators/>
- Occupational Safety and Health Administration. (n.d.). [Web site posting.] Washington, DC: U.S. Department of Labor. Retrieved October 23, 2005, from <http://www.osha.gov/SLTC/respiratoryprotection/index.html>
- Pappas, G., Takaro, T., Stover, B., Beaudet, N., Salazar, M., Calcagni, J., Shoop, D., & Barnhard, S. (1999). Medical clearance for respirator use: Sensitivity and specificity of a questionnaire. *American Journal of Industrial Medicine*, 35, 395-400.
- Respiratory protection; final rule. 63 Fed. Reg. 1151-1300 (1998) (29 CFR § 1910 and 1926). Retrieved from [http://www.frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1998\\_register&docid](http://www.frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1998_register&docid)
- Respiratory protection; proposed rule. 59 Fed. Reg. 58884-58956 (1994) (to be codified at 29 CFR § 1910, 1915, and 1926). Retrieved from <http://frwebgate4.access.gpo.gov/cgi?WAISdocID=82552715228+0+0+0&WAISaction=retrieve>

Suruda A., Milliken W., Stephenson D., & Sesek R. (2003). Fatal injuries in the United States involving respirators, 1984-1995. *Applied Occupational and Environmental Hygiene, 18*, 289-292.

Szeinuk, J., Beckett, W., Clark, N., & Hailoo, W. (2000). Medical evaluation for respirator use. *American Journal of Industrial Medicine, 37*, 142-157.

## Appendix

## The OSHA Respirator Medical Evaluation Questionnaire

**Appendix C to § 1910.134: OSHA Respirator Medical Evaluation Questionnaire (Mandatory)**

**To the employer:** Answers to questions in Section 1, and to question 9 in Section 2 of Part A, do not require a medical examination.

**To the employee:**

Can you read (circle one): Yes/No

Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.

**Part A. Section 1.** (Mandatory) The following information must be provided by every employee who has been selected to use any type of respirator (please print).

1. Today's date: \_\_\_\_\_
2. Your name: \_\_\_\_\_
3. Your age (to nearest year): \_\_\_\_\_
4. Sex (circle one): Male/Female
5. Your height: \_\_\_\_\_ ft. \_\_\_\_\_ in.
6. Your weight: \_\_\_\_\_ lbs.
7. Your job title: \_\_\_\_\_
8. A phone number where you can be reached by the health care professional who reviews this questionnaire (include the Area Code): \_\_\_\_\_
9. The best time to phone you at this number: \_\_\_\_\_
10. Has your employer told you how to contact the health care professional who will review this questionnaire (circle one): Yes/No
11. Check the type of respirator you will use (you can check more than one category):
  - a. \_\_\_\_\_ N, R, or P disposable respirator (filter-mask, non-cartridge type only).
  - b. \_\_\_\_\_ Other type (for example, half- or full-facepiece type, powered-air purifying, supplied-air, self-contained breathing apparatus).
12. Have you worn a respirator (circle one): Yes/No  
If "yes," what type(s): \_\_\_\_\_

**Part A. Section 2.** (Mandatory) Questions 1 through 9 below must be answered by every employee who has been selected to use any type of respirator (please circle "yes" or "no").

1. Do you **currently** smoke tobacco, or have you smoked tobacco in the last month: Yes/No
2. Have you **ever had** any of the following conditions?
  - a. Seizures (fits): Yes/No
  - b. Diabetes (sugar disease): Yes/No
  - c. Allergic reactions that interfere with your breathing: Yes/No
  - d. Claustrophobia (fear of closed-in places): Yes/No
  - e. Trouble smelling odors: Yes/No
3. Have you **ever had** any of the following pulmonary or lung problems?
  - a. Asbestosis: Yes/No
  - b. Asthma: Yes/No
  - c. Chronic bronchitis: Yes/No

- d. Emphysema: Yes/No
  - e. Pneumonia: Yes/No
  - f. Tuberculosis: Yes/No
  - g. Silicosis: Yes/No
  - h. Pneumothorax (collapsed lung): Yes/No
  - i. Lung cancer: Yes/No
  - j. Broken ribs: Yes/No
  - k. Any chest injuries or surgeries: Yes/No
  - l. Any other lung problem that you've been told about: Yes/No
4. Do you **currently** have any of the following symptoms of pulmonary or lung illness?
- a. Shortness of breath: Yes/No
  - b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Yes/No
  - c. Shortness of breath when walking with other people at an ordinary pace on level ground: Yes/No
  - d. Have to stop for breath when walking at your own pace on level ground: Yes/No
  - e. Shortness of breath when washing or dressing yourself: Yes/No
  - f. Shortness of breath that interferes with your job: Yes/No
  - g. Coughing that produces phlegm (thick sputum): Yes/No
  - h. Coughing that wakes you early in the morning: Yes/No
  - i. Coughing that occurs mostly when you are lying down: Yes/No
  - j. Coughing up blood in the last month: Yes/No
  - k. Wheezing: Yes/No
  - l. Wheezing that interferes with your job: Yes/No
  - m. Chest pain when you breathe deeply: Yes/No
  - n. Any other symptoms that you think may be related to lung problems: Yes/No
5. Have you **ever had** any of the following cardiovascular or heart problems?
- a. Heart attack: Yes/No
  - b. Stroke: Yes/No
  - c. Angina: Yes/No
  - d. Heart failure: Yes/No
  - e. Swelling in your legs or feet (not caused by walking): Yes/No
  - f. Heart arrhythmia (heart beating irregularly): Yes/No
  - g. High blood pressure: Yes/No
  - h. Any other heart problem that you've been told about: Yes/No
6. Have you **ever had** any of the following cardiovascular or heart symptoms?
- a. Frequent pain or tightness in your chest: Yes/No
  - b. Pain or tightness in your chest during physical activity: Yes/No
  - c. Pain or tightness in your chest that interferes with your job: Yes/No
  - d. In the past two years, have you noticed your heart skipping or missing a beat: Yes/No
  - e. Heartburn or indigestion that is not related to eating: Yes/ No
  - f. Any other symptoms that you think may be related to heart or circulation problems: Yes/No
7. Do you **currently** take medication for any of the following problems?
- a. Breathing or lung problems: Yes/No
  - b. Heart trouble: Yes/No
  - c. Blood pressure: Yes/No
  - d. Seizures (fits): Yes/No
8. If you've used a respirator, have you **ever had** any of the following problems? (If you've never used a respirator, check the following space and go to question 9:)
- a. Eye irritation: Yes/No
  - b. Skin allergies or rashes: Yes/No
  - c. Anxiety: Yes/No
  - d. General weakness or fatigue: Yes/No
  - e. Any other problem that interferes with your use of a respirator: Yes/No
9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire: Yes/No

Questions 10 to 15 below must be answered by every employee who has been selected to use either a full-facepiece respirator or a self-contained breathing apparatus (SCBA). For employees who have been selected to use other types of respirators, answering these questions is voluntary.

- 10. Have you **ever lost** vision in either eye (temporarily or permanently): Yes/No
- 11. Do you **currently** have any of the following vision problems?
  - a. Wear contact lenses: Yes/No
  - b. Wear glasses: Yes/No
  - c. Color blind: Yes/No
  - e. Any other eye or vision problem: Yes/No
- 12. Have you **ever had** an injury to your ears, including a broken ear drum: Yes/No
- 13. Do you **currently** have any of the following hearing problems?
  - a. Difficulty hearing: Yes/No
  - b. Wear a hearing aid: Yes/No
  - c. Any other hearing or ear problem: Yes/No
- 14. Have you **ever had** a back injury: Yes/No
- 15. Do you **currently** have any of the following musculoskeletal problems?
  - a. Weakness in any of your arms, hands, legs, or feet: Yes/No
  - b. Back pain: Yes/No
  - c. Difficulty fully moving your arms and legs: Yes/No
  - d. Pain or stiffness when you lean forward or backward at the waist: Yes/No
  - e. Difficulty fully moving your head up or down: Yes/No
  - f. Difficulty fully moving your head side to side: Yes/No
  - g. Difficulty bending at your knees: Yes/No
  - h. Difficulty squatting to the ground: Yes/No
  - i. Climbing a flight of stairs or a ladder carrying more than 25 lbs: Yes/No
  - j. Any other muscle or skeletal problem that interferes with using a respirator: Yes/No

**Part B** Any of the following questions, and other questions not listed, may be added to the questionnaire at the discretion of the health care professional who will review the questionnaire.

- 1. In your present job, are you working at high altitudes (over 5,000 feet) or in a place that has lower than normal amounts of oxygen: Yes/No  
 If "yes," do you have feelings of dizziness, shortness of breath, pounding in your chest, or other symptoms when you're working under these conditions: Yes/No
- 2. At work or at home, have you ever been exposed to hazardous solvents, hazardous airborne chemicals (e.g., gases, fumes, or dust), or have you come into skin contact with hazardous chemicals: Yes/No  
 If "yes," name the chemicals if you know them: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
- 3. Have you ever worked with any of the materials, or under any of the conditions, listed below:
  - a. Asbestos: Yes/No
  - b. Silica (e.g., in sandblasting): Yes/No
  - c. Tungsten/cobalt (e.g., grinding or welding this material): Yes/No
  - d. Beryllium: Yes/No
  - e. Aluminum: Yes/No
  - f. Coal (for example, mining): Yes/No
  - g. Iron: Yes/No
  - h. Tin: Yes/No
  - i. Dusty environments: Yes/No
  - j. Any other hazardous exposures: Yes/No
 If "yes," describe these exposures: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

4. List any second jobs or side businesses you have: \_\_\_\_\_  
\_\_\_\_\_
5. List your previous occupations: \_\_\_\_\_  
\_\_\_\_\_
6. List your current and previous hobbies: \_\_\_\_\_  
\_\_\_\_\_
7. Have you been in the military services? Yes/No  
If "yes," were you exposed to biological or chemical agents (either in training or combat): Yes/No
8. Have you ever worked on a HAZMAT team? Yes/No
9. Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter medications): Yes/No  
If "yes," name the medications if you know them: \_\_\_\_\_
10. Will you be using any of the following items with your respirator(s)?
  - a. HEPA Filters: Yes/No
  - b. Canisters (for example, gas masks): Yes/No
  - c. Cartridges: Yes/No
11. How often are you expected to use the respirator(s) (circle "yes" or "no" for all answers that apply to you)?:
  - a. Escape only (no rescue): Yes/No
  - b. Emergency rescue only: Yes/No
  - c. Less than 5 hours **per week**: Yes/No
  - d. Less than 2 hours **per day**: Yes/No
  - e. 2 to 4 hours per day: Yes/No
  - f. Over 4 hours per day: Yes/No
12. During the period you are using the respirator(s), is your work effort:
  - a. **Light** (less than 200 kcal per hour): Yes/No  
If "yes," how long does this period last during the average shift: \_\_\_ hrs. \_\_\_ mins  
Examples of a light work effort are **sitting** while writing, typing, drafting, or performing light assembly work; or **standing** while operating a drill press (1-3 lbs.) or controlling machines.
  - b. **Moderate** (200 to 350 kcal per hour): Yes/No  
If "yes," how long does this period last during the average shift: \_\_\_ hrs \_\_\_ mins.  
Examples of moderate work effort are **sitting** while nailing or filing; **driving** a truck or bus in urban traffic; **standing** while drilling, nailing, performing assembly work, or transferring a moderate load (about 35 lbs.) at trunk level; **walking** on a level surface about 2 mph or down a 5 degree grade about 3 mph; or **pushing** a wheelbarrow with a heavy load (about 100 lbs.) on a level surface.
  - c. **Heavy** (above 350 kcal per hour): Yes/No  
If "yes," how long does this period last during the average shift: \_\_\_ hrs \_\_\_ mins.  
Examples of heavy work are **lifting** a heavy load (about 50 lbs.) from the floor to your waist or shoulder; working on a loading dock; **shoveling**; **standing** while bricklaying or chipping castings; **walking** up an 8-degree grade about 2 mph; climbing stairs with a heavy load (about 50 lbs.).
13. Will you be wearing protective clothing and/or equipment (other than the respirator) when you're using your respirator: Yes/No  
If "yes," describe this protective clothing and/or equipment: \_\_\_\_\_  
\_\_\_\_\_
14. Will you be working under hot conditions (temperature exceeding 77 deg. F): Yes/No
15. Will you be working under humid conditions: Yes/No
16. Describe the work you'll be doing while you're using your respirator(s):  
\_\_\_\_\_  
\_\_\_\_\_

17. Describe any special or hazardous conditions you might encounter when you're using your respirator(s) (for example, confined spaces, life-threatening gases):

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18. Provide the following information, if you know it, for each toxic substance that you'll be exposed to when you're using your respirator(s):

Name of the first toxic substance: \_\_\_\_\_

Estimated maximum exposure level per shift: \_\_\_\_\_

Duration of exposure per shift: \_\_\_\_\_

Name of the second toxic substance: \_\_\_\_\_

Estimated maximum exposure level per shift: \_\_\_\_\_

Duration of exposure per shift: \_\_\_\_\_

Name of the third toxic substance: \_\_\_\_\_

Estimated maximum exposure level per shift: \_\_\_\_\_

Duration of exposure per shift: \_\_\_\_\_

The name of any other toxic substances that you'll be exposed to while using your respirator:

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19. Describe any special responsibilities you'll have while using your respirator(s) that may affect the safety and well-being of others (for example, rescue, security): \_\_\_\_\_

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