

Usefulness of Respirator Manufacturer User's Instructions and NIOSH Approval Labels

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ABSTRACT

The National Institute for Occupational Safety and Health (NIOSH) conducted a nationwide respirator survey through the United States Department of Labor/Bureau of Labor Statistics (BLS). The purpose of the survey was to evaluate respirator use and practices to help guide NIOSH respirator certification and research. The survey was mailed in August 2001 to 40,002 establishments representing all of the private sector major industry divisions. Among other information collected on respirator use and practices, the survey included questions on respirator manufacturer user's instructions and NIOSH approval labels. The survey estimated that: 89% of all respirator-using establishments agree that manufacturer user's instructions are clear and easily understood; 90% agree that manufacturer user's instructions are beneficial in the use of respirators; nearly 85% agree that NIOSH approval labels are clear and easily understood; and 80% agree that NIOSH approval labels are beneficial in the use of respirators. These levels of agreement were generally uniform across all private industry. Although the respirator-using establishments generally agree that manufacturer user's instructions and NIOSH approval labels are clear, easily understood, and beneficial, the findings from other questions in the survey indicate apparent widespread inadequacies in the respiratory protection programs offered by establishments. For example, only 15% of establishments using airline respirators reported appropriate use of the air pressure range given on the NIOSH approval label or in the manufacturer user's instructions. Overall, approximately 91% of establishments requiring respirator use had at least one indicator of a potentially inadequate respiratory protection program, while nearly 54% had at least five indicators of a potentially inadequate respiratory protection program.

Keywords: respirator, survey, manufacturer user's instructions, NIOSH approval labels

INTRODUCTION

Respirators are a commonly-used method of protecting workers from health hazards. When respirators are used, the Occupational Safety and Health Administration (OSHA) requires the employer to select a NIOSH-approved respirator and the respirator must be used in compliance with the conditions of its approval (CFR, 2002a). The Mine Safety and Health Administration (MSHA) has a similar requirement for metal/nonmetal mining establishments (CFR, 2002b; CFR, 2002c). The MSHA respiratory protection regulations reference a 1969 consensus standard (ANSI, 1969). MSHA does not require respirator use in coal mining establishments; however, respiratory protection approved by NIOSH must be made available to all affected workers when an area in a coal mine establishment has been

determined to be in noncompliance with the applicable respirable dust standard (CFR, 2002d). For metal/nonmetal mining establishments, respiratory protection is required when:

- engineering controls are not feasible to reduce exposures below the threshold limit values (TLVs[®]) adopted by the American Conference of Governmental Industrial Hygienists (ACGIH[®], 1973),
- engineering controls are being established to reduce exposures below the TLV, and
- occasional entry into hazardous atmospheres is necessary to perform short-term maintenance or investigations (CFR, 2003e; CFR, 2003f).

When respirators are required, metal/nonmetal mine operators must establish a respiratory protection program consistent with the recommendations of ANSI (ANSI, 1969).

NIOSH has been approving respirators for over 30 years (CFR, 2002e). Respirator approval regulations were originally contained in 30 CFR 11 and were administered by the former U.S. Bureau of Mines. From 1972 through 1995, respirators were co-approved by NIOSH and MSHA (formerly MESA). Then, in 1995, NIOSH became the sole certifier with the move of the respirator approval regulations to 42 CFR 84. From 1995 to today, only respirators intended for emergency use in mining continue to have co-approval with MSHA. The NIOSH approval label (see Figure 1) includes the manufacturer's name and address, NIOSH approval number, NIOSH and Department of Health and Human Services logos, component part numbers, and associated cautions and limitations. This information appears on the NIOSH approval label in table form with a standardized format for consistency. NIOSH approval labels are packaged with each respirator, either on the container or on a piece of paper inside the container. Each respirator component must be marked with a part number, and some air-purifying respirator subassemblies (such as cartridges) also have abbreviated labels.

One element of NIOSH approval requires that the manufacturer provide detailed instructions for use with each respirator. These user's instructions are prepared by the manufacturers and reviewed and edited by NIOSH for content, clarity and accuracy.

Until recently, there was no nationwide information about the clarity and usefulness of manufacturer user's instructions and NIOSH approval respirator labels that are provided with each new respirator. Part of the purpose of the 2001 BLS/NIOSH national survey of respirator use (Bureau of Labor Statistics, 2003) was to fill this information gap.

METHODS

In August 2001, a questionnaire was mailed to 40,002 establishments randomly selected from a stratified sampling frame of 174,305 private sector establishments that were found to be usable for estimation in the 1999 BLS Survey of Occupational Injuries and Illnesses (Bureau of Labor Statistics, 1999). Establishments from all private industries were included, with the exception of agricultural establishments employing fewer than 11 employees. The response rate at the closing of the survey in February 2002 was 75.5%.

The results of the survey are national estimates based on the survey weighting and a selected probability sample, rather than a census of all establishments. The questions described in this paper asked the establishment's respirator program director/overseer about the types of respirators used and the manner in which they were required to be used (either by the employers or by federal regulation) in the 12 months prior to completion of the survey questionnaire. Results were reported by industry division, 2-digit Standard Industrial Classification (SIC) level within each industry division (Office of Management and Budget, 1987), and establishment employment size group.



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THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

| TC- | Protection ¹ | Face Piece | Alternate Filter | | | | | Alternate Cartridge | | | | | Alternate Retainer | | Filter | Cautions & Limitations ² |
|----------|-------------------------|------------|------------------|------------------|------------------|-----------------------|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--------------------|------------------|--------|-------------------------------------|
| | | | H A L O | A R C H | W I N G | C R O W N | | 1 0 0 0 1 | 1 0 0 0 2 | 1 0 0 0 3 | 1 0 0 0 4 | 1 0 0 0 5 | 9 4 3 5 | 9 4 3 5 | | |
| | | 1000 | | | | | | | | | | | | | | |
| 84A-AArA | N95/CL/MV | X | X | | | | | | | X | | X | X | | | ABCHJLMNOPS |
| 84A-AARb | R95/AM/MA | X | | X | | | | X | | | | X | X | | | ABCHJLMNOP |
| 84A-AARc | R95/OV | X | | X | | | X | | | | | X | X | | | ABCHJLMNOP |
| 84A-AARd | P99/OV | X | | | X | | X | | | | | | | X | | ABCHJLMNOP |
| 84A-AARe | R100/OV | X | | | | X | X | | | | | | | X | | ABCHJLMNOP |
| 23C-AARf | FM | X | | | | | | | | | X | | | | | ABCHJLMNO |
| 23C-AARg | CL/HC/SD/HS(esc) | X | | | | | | X | | | | | | | | ABCHJLMNO |

1. PROTECTION

| | | | |
|--|--|---|--|
| N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; Time use restrictions may apply | R100-Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply | P99-Particulate Filter (99% filter efficiency level) effective against all particulate aerosols | R95-Particulate Filter (95% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply |
|--|--|---|--|

AM – Ammonia MA – Methylamine FM – Formaldehyde CL – Chlorine OV - Organic Vapor
 MV – Mercury Vapor HC – Hydrogen Chloride SD – Sulfur Dioxide HS(esc) – Hydrogen Sulfide (escape only)

2. CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 percent oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
- J - Failure to properly use and maintain this product could result in injury or death.
- K - The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
- L - Follow the manufacturer User's Instructions for changing cartridges, canister and/or filters.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.
- S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

Figure 1. An example of approval label for half-mask respirator.

The BLS/NIOSH respirator survey included the following statements about the respirator manufacturer user's instructions and NIOSH approval labels:

- The respirator manufacturer's instructions and the NIOSH approval labels are received with all of our respirators.
- The NIOSH approval labels are clear and easily understood.
- The NIOSH approval labels are beneficial in our use of respirators.
- The respirator manufacturer's instructions are clear and easily understood.
- The respirator manufacturer's instructions are beneficial in our use of respirators.

For each of these statements, the respondents were asked to circle one of 5 choices: strongly agree, agree, uncertain, disagree, and strongly disagree.

The clarity and usefulness of manufacturer user's instructions and NIOSH approval labels are not intended to train users in respiratory protection or explain what is needed in a respirator program. Rather, they are only intended to explain the mechanics of the respirator and show that it has been approved by NIOSH. The reported clarity and usefulness of manufacturer user's instructions and NIOSH approval labels must be considered in the context of overall respirator program inadequacy. Therefore, the survey also asked several questions regarding characteristics of the establishments' respirator programs. The BLS/NIOSH respirator survey asked the following questions of establishments with airline respirator use:

- Which method BEST describes how employees adjust the airflow to these respirators? (The best response was "Airflow is only controlled where the air hose connects with compressed air source and is set according to pressures given on certification label or in user's instructions"; the other responses were "Employees adjust airflow to the maximum comfortable level", "Airflow is set at 4 or 6 cubic feet per minute", "Airflow rate is set according to the flow rate recommendations of the respirator manufacturer", and "Don't know.")
- Are the hose couplings compatible with couplings for other air or gas supply lines in your workplace? (The "No" response would best meet the OSHA and MSHA regulations; the other responses were "Yes" and "Don't know.")

The survey collected other data that led to 15 indicators of a potentially inadequate respiratory protection program. Examples of the questions are shown in the results.

RESULTS AND DISCUSSION

Perceptions of Manufacturer User's Instructions and NIOSH Approval Labels

The questions described above in the "Methods" section produced the following results:

- Nearly 90% of establishments find that the manufacturer user's instructions and NIOSH approval labels are received with each respirator (Figure 2);
- 90% of establishments find the manufacturer user's instructions clear and easily understood and nearly 85% find the NIOSH approval labels clear and easily understood (Figure 3);
- 90% of establishments find the manufacturer user's instructions beneficial and 80% find the NIOSH approval labels beneficial (Figure 4); and
- In establishments with less than 1,000 employees, approximately 90% find the manufacturer user's instructions beneficial and nearly 80% find the NIOSH approval labels beneficial. However, in establishments with 1000 or more employees, approximately 74% find the manufacturer user's instructions beneficial and 70% find the NIOSH approval labels beneficial (Figure 5).

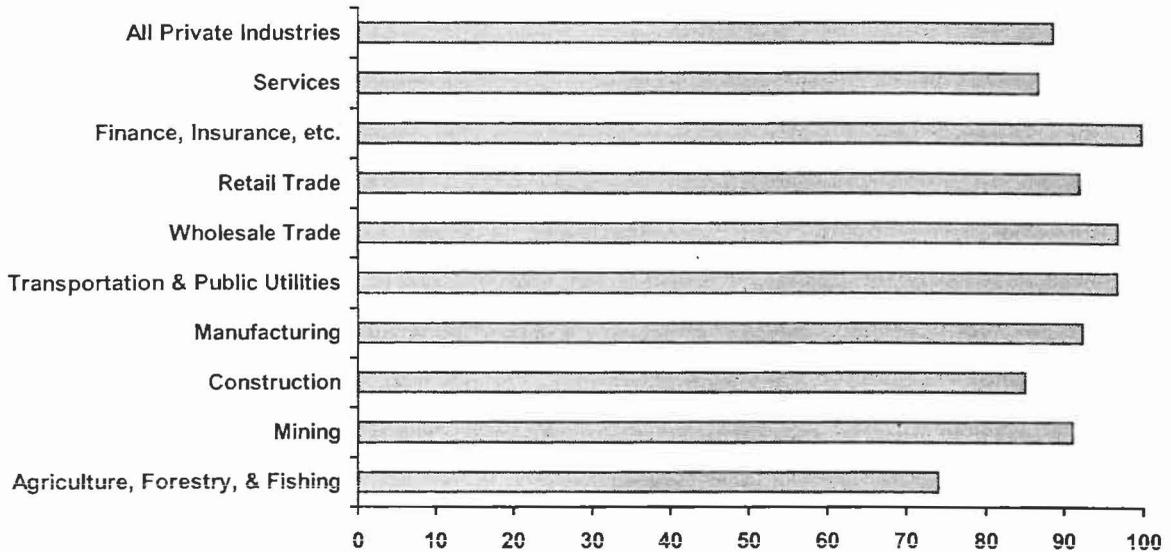


Figure 2. Percentage of establishments with required respirator use that 'strongly agree' or 'agree' that the manufacturer user's instructions and NIOSH approval labels are *received* with all respirators, by industry division.

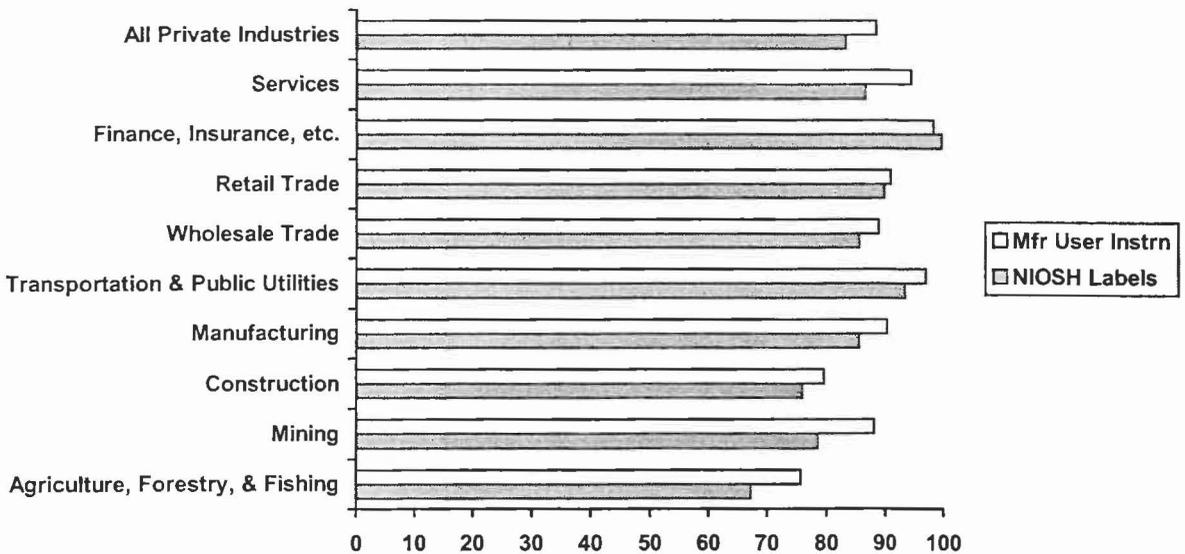


Figure 3. Percentage of establishments with required respirator use that 'strongly agree' or 'agree' that the manufacturer user's instructions and NIOSH approval labels are *clear and easily understood*, by industry division.

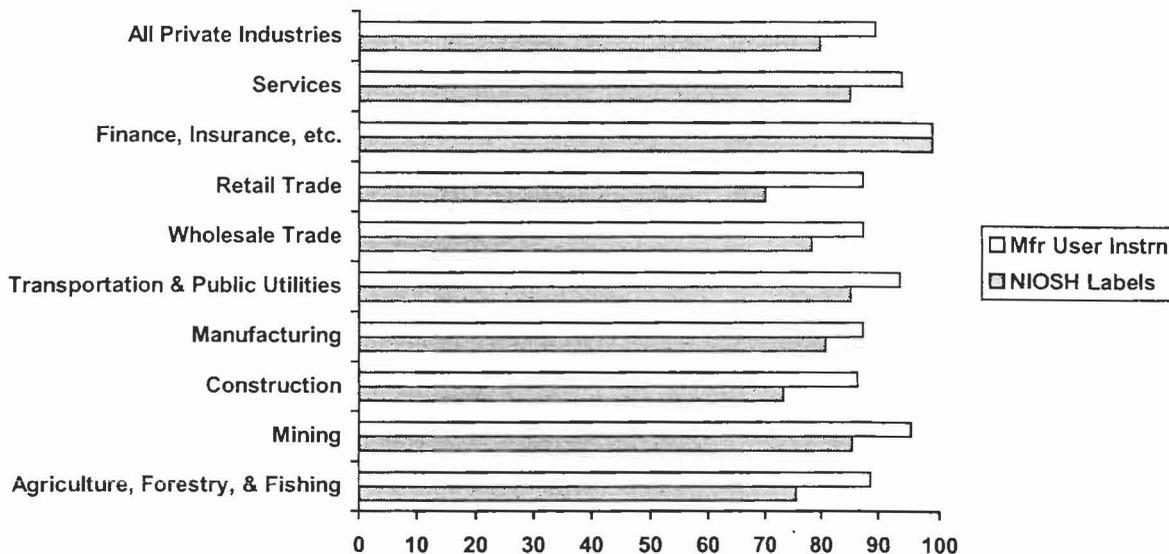


Figure 4. Percentage of establishments with required respirator use that 'strongly agree' or 'agree' that the manufacturer user's instructions and NIOSH approval labels are *beneficial in the use of respirators*, by industry division.

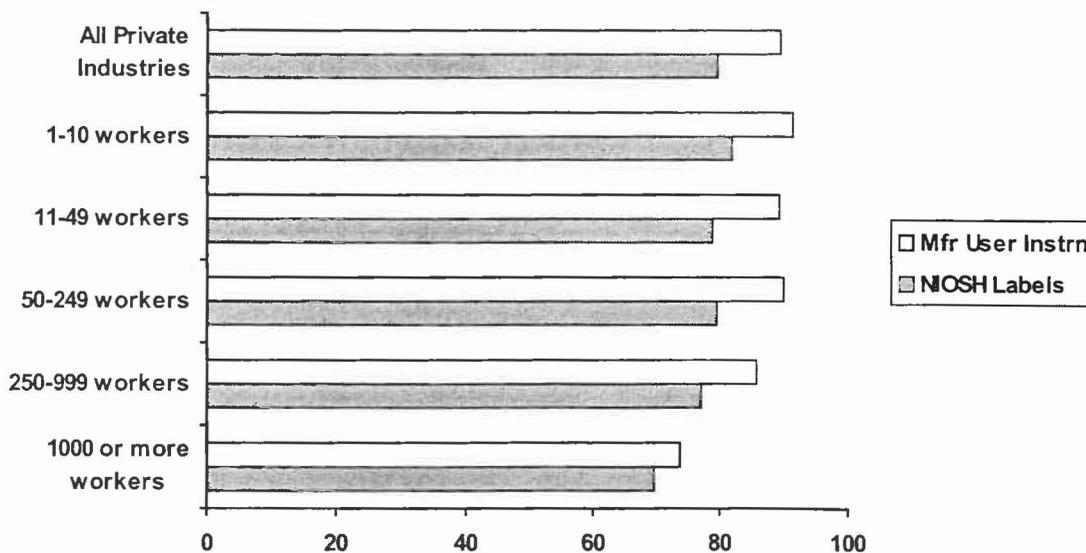


Figure 5. Percentage of establishments with required respirator use that 'strongly agree' or 'agree' that the manufacturer user's instructions and NIOSH approval labels are *beneficial in the use of respirators*, by employment size group.

Examples of Potentially Inadequate Respirator Usage

As noted in the "Methods" section, above, in addition to determining the perceptions towards the clarity and benefits of the respirator manufacturer user's instructions and NIOSH approval labels, the survey asked questions regarding characteristics of respirator programs which provided indicators of potentially inadequate respirator usage. Although the manufacturer user's instructions and NIOSH approval labels were perceived to be clear and useful, the findings from those questions regarding characteristics of respirator programs indicate apparent widespread inadequacies in the respiratory protection programs offered by establishments, as detailed below.

Use of Manufacturer User's Instructions and NIOSH Approval Labels for Airflow Control for Airline Respirators

For airline respirators to meet NIOSH approval, the airflow must be controlled where the air hose connects with the compressed breathing air source, and must be set according to the pressure given on the NIOSH approval label or in the manufacturer user's instructions (CFR, 2002a). Using the correct breathing air source pressure setting is necessary to achieve the correct airflow rate which is essential if a wearer is to be provided adequate protection.

Only 15% of establishments using airline respirators reported appropriate use of the air pressure range given on the NIOSH approval label or in the manufacturer user's instructions to achieve the airflow.

Airline Respirator Hose Coupling Compatibility

The wearers of airline respirators would be in imminent danger if an airline were inadvertently connected to a line that carried a substance other than breathing air, such as nitrogen or argon. From 1984 through 1995, 15 deaths related to coupling compatibility between airline respirators and non-respirable air supplies were reported (Suruda et al, 2003). The fatalities could have been prevented with proper training and compliance with existing coupling incompatibility regulations for airline respirators. To protect against this vulnerability, the respiratory protection regulations require the employer to ensure that hose couplings of airline respirators are incompatible with outlets for non-respirable worksite air or other gas systems (ANSI, 1969; CFR, 2002a). Subsequent to the BLS/NIOSH survey, OSHA issued a "Safety and Health Information Bulletin" describing the dangers involved with the inadvertent connection of air-line respirators to inert gas supplies and the recommendations to help prevent fatalities associated with this hazard (OSHA, 2004).

- 23% of all establishments requiring the use of airline respirators may have respirator hose couplings that are compatible with couplings for other air or gas supply lines. This includes 6% of establishments that do not know if airline hose couplings are compatible with couplings for other air or gas supply lines.
- 40% of the mining establishments that use airline respirators use respirator hose couplings that are compatible with couplings for other air or gas supply lines.

Indicators of Potentially Inadequate Respiratory Protection Programs

There were 15 indicators of potentially inadequate respiratory protection programs (two involving airline respirator usage were described above). Some other examples include:

- no written change-out schedule with the use of air-purifying gas/vapor cartridges/canisters;
- no written program to decide how respirators are used;

- no written procedure to periodically evaluate the effectiveness of respirator use;
- no assessment of the medical fitness of respirator-wearing employees;
- no written procedures and no schedule for maintaining respirators; and
- no fit testing for each tight-fitting respirator wearer.

Table 1 shows that 91% of establishments using respirators reported to have at least one indicator of a potentially inadequate respiratory protection program and 54% reported at least five. (This is not inconsistent with OSHA fiscal year 2003 compliance surveys in which greater than 4,100 citations were issued for respiratory protection (OSHA, 2003). This represents the fifth highest number of violations of a list of 460 different types of citations.)

Table I. Percent of Respirator-Using Establishments with Selected Numbers of Indicators of Potentially Inadequate Respirator Programs

| Number of Indicators | Percent of Respirator-using Establishments | Cumulative Percent of Respirator-using Establishments |
|----------------------|--|---|
| 9-15 | 5.2 | 5.2 (9 or more indicators) |
| 7-8 | 25.6 | 30.8 (7 or more indicators) |
| 5-6 | 23.0 | 53.8 (5 or more indicators) |
| 3-4 | 17.3 | 71.1 (3 or more indicators) |
| 1-2 | 19.5 | 90.6 (1 or more indicators) |
| 0 | 9.4 | |

CONCLUSIONS AND RECOMMENDATIONS

Most respirator-using establishments report receiving the manufacturer user's instructions and NIOSH approval labels, and find them clear, easily understood, and beneficial. However, manufacturer user's instructions and NIOSH approval labels alone (even if understood and beneficial) are not sufficient to assure adequacy of respirator protection programs and safe respirator usage.

Based on the survey responses, inadequacies exist in the practical application of respirators in the workplace. Some inadequacies are potentially extremely dangerous. For example, failure to provide appropriate airflow controls and hose couplings for airline respirators could be life-threatening. The survey identified numerous other inadequacies that could have health and safety consequences, as indicated by the frequency of OSHA citations of respiratory protection programs.

Therefore, we recommend that: (a) the content of manufacturer user's instructions and NIOSH approval labels should be reviewed to target important messages directly to those who need critical respiratory protection information, and (b) significant additional information and better training should be provided to establishments and users. Information provided to respirator-using establishments should include the health and safety significance of each feature of respiratory protection programs as required by OSHA. Training of respiratory protection managers and users should address the significance of: a written program to decide how respirators are used, fit testing for each tight-fitting respirator wearer, evaluating the effectiveness of respirator use, and a written procedure and schedule for respirator maintenance.

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