

April 13, 2004

NIOSH Docket Office
Robert A. Taft Laboratories
M/S C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

RE: Docket number, NIOSH-001, Quality Assurance Module Concept.

Dear Sir/Madam:

The International Safety Equipment Association (ISEA) is the leading organization representing manufacturers and suppliers of personal protective equipment and apparel. We offer the following comments that address administrative issues and fees as indicated in the July 5, 2000 *Federal Register* notice. Our comments are specific to the revision of the Quality Assurance and Administrative modules for respirator certification and as outlined in NIOSH's QA Module Concept paper, dated July 21, 2003. ISEA members believe that the important issue of respirator labeling has been omitted in NIOSH's concepts thus far and urge NIOSH to consider the following recommendations.

ISEA members have noted that in many cases, approval labels have grown in size and complexity to the point that they no longer are a functional or useful means of conveying information. ISEA members receive numerous inquiries from respirator users with the NIOSH label in hand, asking for assistance in determining what the approval number of their respirator is or what constitutes an approved configuration. The label including the matrix does not appear to provide the information in a format that is usable for many respirator users. In an effort to simplify the label information and provide the most vital user information in a helpful format, ISEA proposes that manufacturers be given the option of retaining the current system or using an alternative labeling option.

Specifically, ISEA is proposing a change in the approval label that accompanies the facepiece, filter, cartridge, or other major component of a respirator. ISEA has carefully reviewed section 42 CFR 84.33 of the regulation and, based on previous changes made to the approval label, believe that this proposal is consistent with the intent of that section.

42 CFR 84.33 (b) states, "Approval labels shall bear the emblem of the National Institute for Occupational Safety and Health and the seal of the Department of Health and Human Services, the applicant's name and address, an approval number assigned by the Institute and, where appropriate, restrictions or limitations placed upon the use of the respirator by the Institute." Our proposal includes all of these requirements, with the exception of the approval number assigned by the Institute. However, with the use of the matrix placed on the label, this requirement was administratively changed as it went from "an approval number" to "approval numbers".

Rec'd
4/16/04

The proposed option would allow the respirator manufacturer to replace the approved respirator matrix with the statement:

“Respirators (cartridges) (filters) (etc.) must only be used in approved configurations. For approved respirator configurations call 1-800-xxx-xxxx or check online at www.xxxxx.xxx.” The phone number and web address indicate the means to contact the manufacturer.

The respirator manufacturer, upon determining the configurations the person was interested in, would fax, e-mail, or mail that portion of the label identifying the approved configuration in its current form to the user.

The alternative label that would accompany the facepiece, cartridge, filter or other component would contain the NIOSH and HHS logos, the manufacturer’s name, address and phone number or web address, the commercial designation of the component, the above approved configuration statement and the applicable cautions and limitations. Examples of approval labels following this format are included at the end of these comments.

Because most users are only interested in some of the information on the label, ISEA believes that this option would provide the user with information in a much more useful format. For less complex systems the manufacturer may elect to continue to use the current form of the label.

If a change to the regulations is necessary to implement this option we propose that section 84.33 (b) of 42 CFR 84 be changed to:

“Approval labels shall bear the emblem of the National Institute for Occupational Safety and Health and the seal of the Department of Health and Human Services, the applicant’s name and address, an approval number assigned by the Institute or instructions from the applicant on how to obtain the approval number and assembly information and, where appropriate, restrictions or limitations placed upon the use of the respirator by the Institute.”

ISEA feels this change would allow the above proposal to meet the labeling requirements.

Another option exists if NIOSH feels a TC number needs to be included on the approval label. This option, which may require more development, could include a new approval number since the exact format of the approval number is not specified in 42 CFR 84. An example for this new number may be a number such as “TC- [mfr. 3 letter identifier] –[respirator code]” that could help direct the user to the number either on a website or via a representative on the telephone. For example: “TC- MMM –7800” may be the number for the first approval label example included in the proposal.

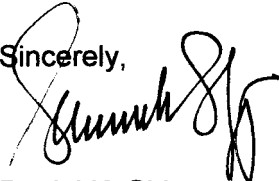
The user could contact the manufacturer for the information or the user could answer some simple questions on the website to obtain the specific approval. Other means may also be available depending on the type of software the manufacturer employs.

Summary

In summary we propose an alternative labeling method to the current use of the matrix that is typically used for more complex respirator systems. For less complex systems, the manufacturer may reserve the right to continue to use the current form of the label. But ISEA believes this

ISEA Comments to Docket No. NIOSH- 001
April 13, 2004

optional proposal would provide the user with information in a much more useful form ensuring they are using the most appropriate respirator configuration for their application.

Sincerely,


Daniel K. Shipp
President

Enclosures

A facepiece label would look like this.

HHS Logo

NIOSH Logo

XYZ Company
Any city, Any state, Any country
1-800-xxx-xxxx

7800 Fullface Respirators

Respirators must only be used in approved configurations. For approved configurations call 1-800-xxx-xxxx. Additionally, respirators must be used as a part of a complete program such as defined by OSHA's 29 CFR 1910.134.

Cautions and Limitations

For all respirators;

B-Not for use in atmospheres immediately dangerous to life or health.

C-Do not exceed maximum use concentrations established by regulatory standards.

I-Contains electrical parts which have not been evaluated as an ignition source in flammable or explosive atmospheres by NIOSH.

J-Failure to properly use and maintain this product could result in injury or death.

M-All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, or 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 users instructions, and/or maintenance manuals for information on the use and maintenance of these respirators.

For air purifying respirators;

A-Not for use in atmospheres containing less than 19.5 percent oxygen.

L-Follow the manufacturer's instructions for changing cartridges and/or filters.

For Chemical cartridge respirators;

H-Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.

For particulate removing respirators;

P-NIOSH does not evaluate respirators for use as surgical masks.

For Mercury vapor respirators;

S-special or critical users instructions and/or specific use limitations apply. Refer to instruction manual before donning.

For supplied air respirators;

D-Air line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of GCA G-7.1 grade D or higher quality.

E-Use only the pressure ranges and hose lengths specified in the user instruction.

For combination air line and air purifying respirators;

G-If airflow is cut off, switch to filter and/or cartridge and immediately exit to clean air.

A chemical cartridge label would look like this.

HHS Logo

NIOSH Logo

XYZ Company
Any city, Any state, Any country
1-800-xxx-xxxx

6001 Organic vapor cartridge

Cartridges must only be used in approved respirator configurations. For approved configurations call 1-800-xxx-xxxx. Additionally, respirators must be used as a part of a complete program such as defined by OSHA's 29 CFR 1910.134.

Cautions and Limitations

For all respirators;

B-Not for use in atmospheres immediately dangerous to life or health.

C-Do not exceed maximum use concentrations established by regulatory standards.

I-Contains electrical parts which have not been evaluated as an ignition source in flammable or explosive atmospheres by NIOSH.

J-Failure to properly use and maintain this product could result in injury or death.

M-All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, or 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 users instructions, and/or maintenance manuals for information on the use and maintenance of these respirators.

For air purifying respirators;

A-Not for use in atmospheres containing less than 19.5 percent oxygen.

L-Follow the manufacturer's instructions for changing cartridges and/or filters.

For Chemical cartridge respirators;

H- Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs

For particulate removing respirators;

P-NIOSH does not evaluate respirators for use as surgical masks.

For combination air line and air purifying respirators;

D-Air line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of GCA G-7.1 grade D or higher quality.

E-Use only the pressure ranges and hose lengths specified in the user instruction.

G-If airflow is cut off, switch to filter and/or cartridge and immediately exit to clean air.

A particulate filter label would look like this.

HHS Logo

NIOSH Logo

XYZ Company
Any city, Any state, Any country
1-800-xxx-xxxx

2071 P95 particulate filter

Filters must only be used in approved respirator configurations. For approved configurations call 1-800-xxx-xxxx. Additionally, respirators must be used as a part of a complete program such as defined by OSHA's 29 CFR 1910.134.

Cautions and Limitations

For all respirators;

B-Not for use in atmospheres immediately dangerous to life or health.

C-Do not exceed maximum use concentrations established by regulatory standards.

I-Contains electrical parts which have not been evaluated as an ignition source in flammable or explosive atmospheres by NIOSH.

J-Failure to properly use and maintain this product could result in injury or death.

M-All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, or 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 users instructions, and/or maintenance manuals for information on the use and maintenance of these respirators.

For air purifying respirators;

A-Not for use in atmospheres containing less than 19.5 percent oxygen.

L-Follow the manufacturer's instructions for changing cartridges and/or filters.

For Chemical cartridge respirators;

H- Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs

For particulate removing respirators;

P-NIOSH does not evaluate respirators for use as surgical masks.

For Mercury vapor respirators;

S-special or critical users instructions and/or specific use limitations apply. Refer to instruction manual before donning.

For combination air line and air purifying respirators;

D-Air line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of GCA G-7.1 grade D or higher quality.

E-Use only the pressure ranges and hose lengths specified in the user instruction.

G-If airflow is cut off, switch to filter and/or cartridge and immediately exit to clean air.