LABELS MEETING NOTES

Hyatt Regency Hotel, Pittsburgh International Airport December 8, 2010

Introduction

NIOSH labels were in paragraph form prior to 1995.

 NIOSH labels were changed to matrix format in 1995 which, initially, greatly simplified labeling requirements. As respirator component interchangeability increased, labels grew as well.

 In 1996 some companies wanted internet based labels (no paper). However, in 1996 it was believed that too few users had web access, so the paper format was maintained. Today, internet access is virtually everywhere and everyone has access.

Matrix labels continue to grow larger.

Topics for discussion: NIOSH presented a series of topics for discussion. The replies to the topics did not strictly pertain to each topic and may be more relevant to other topics. However, they are presented under the topic in which they were stated. When the same comment was repeated by several parties, it is only listed once.

Topic #1: What are the current problems or issues with respirator labeling requirements?

I. General meeting comments for Topic #1 from attendees

- Manufacturers are simply running out of "real estate" (space) on respirators for labels.
- b. Labels are making Users Manuals excessively long.
- c. Could move to just saying "NIOSH" on the label if Internet access was permitted
- d. [This comment pertains to approval numbers] Workers are often not fit tested with the versions they are using, so the approval number does not assure that the respirator is good for a particular user.
- e. Some of the full respirator labels are the size of wallpaper.
- f. Paper Labels are not "green" (environmentally friendly).
- g. Even abbreviated labels are a challenge they need further abbreviation.

II. Problems for multiple-authority approval labels

- a. When dual labels or multiple labels (approval labels for more than one country) are required, the size problem is much worse.
- b. Color coding requirements present further problems for consistency and space on the product.
- c. Color coding is difficult with multiple gas combinations and multiple country approvals.

III. Purpose of labels

- a. Approval labels are not intended to show how to assemble a respirator.
- b. Approval labels are intended to show approved configurations and protections.
- c. Labels and assembly matrixes can be a useful tool for general identification of approved configurations.
- d. Assembly matrixes are useful but it isn't a good idea to try to turn them into an approval labels.
- e. Most users view the approval label as only a NIOSH "stamp of approval".

IV. Approval verification

- a. Some customers want to see a certificate of approval or at least a letter with a signature.
- b. There really is no "NIOSH certificate" and the approval label and even a NIOSH letter is sometimes not enough. Customer wants further proof that a respirator is approved by NIOSH.
- c. Other countries have 3rd party certification which is why some users expect a certificate. They may not be familiar with the NIOSH process.

Topic #2: 42CFR84 requires a number of different labels. Which label is the most useful/relevant for each respirator type?

I. Label specific comments

- a. Label usefulness depends on the label.
- b. Labels can be and are often lost.
- c. The abbreviated label is useful but it needs further abbreviation.
- d. Color coding can be a problem: shading and combinations.
- e. Many users do not understand the 2 letter codes and would not understand the chemical symbols either.

Topic #3: Should purchases of respirators from individuals or companies through standard commercial channels be based on approval numbers (or required to reference approval numbers)?

I. Restated question: Do customers purchase respirators based on approval numbers?

- a. No, they purchase based on use and simply want to know that its approved.
- b. At one time one approval number went with one unique configuration.
- c. No one cares what the number is.
- d. Often using the TC number is just a point of confusion.
- e. It would be more useful if the approval number indicated or was linked to the protection factor.

Meeting date: 12/08/2010

f. Customers are more concerned with cost and just knowing its approved.

II. New approval concept: If it fits together, its been tested and approved. If it won't go together- it's not approved.

a. This concept was presented in 1996 when the matrix labels were beginning to grow large.

- b. Similar concept to auto parts (EPA), electrical (NEC) or plumbing
- c. Not intended to apply between manufacturers, but only with each manufacturer (OEM only).
- d. This approach creates many design issues for manufacturers.
- e. This concept is not true for CBRN. Canisters of different manufacturers <u>can</u> be used together.
- f. Manufacturers, generally, remain opposed to this concept.
- g. A fully electronic Mobile Application system with integrated system was discussed. Due to the length and detail, this is presented at the end of this document

Topic 4: How do approval holders notify users of current multiple component respirators that there has been an update to the approved configuration?

I. It depends on the change.

- a. Small changes do not dictate or warrant notification of customers.
- b. Often customers are not notified until repair or replacement parts are requested.
- c. If a new part replaces an old part, notification is given when the new part is ordered.
- d. The manufacturer's reorder system redirects sales/customers to the correct replacement part.

Topic 5: Can approval holders provide a supplemental (in addition to required labels) electronic look-up to verify Approval Number and component parts for approved configurations? What are the advantages/disadvantages to this?

Yes- there are several ways [to provide electronic look-up].

- a. Manufacturers have configuration manager software.
- b. The CEL could be used and linked to the assembly matrix.
- c. Customers often contact the manufacturer for additional information.

II. What about listing old respirators as obsolete?

- a. Manufacturers generally don't do this.
- b. Not a good method, as very old respirators may still be in good repair and useable by customers.
- c. Many manufacturers don't obsolete products. They have 3 states: *Active:* presently being manufactured.

Supported: No longer manufactured, but parts are still available.

Inactive: Parts are no longer available, but those in field can still be used.

- d. While discussing this topic, it was suggested that printed instructions are also obsolete. It was suggested that rather than printed user instructions, offering a DVD or CD was a better alternative.
- e. DVDs and CDs still must be packaged, inventoried, updated, and sent. Interactive web-based approvals and user information is the best way to go. (This comment was further supported by several manufacturers.)

Mobile Application Concept Discussion and Highlights:

From Topic 3, Comment IIg.

Note: This is was an extended technical comment from an individual. It is not a reflection of NPPTL policy or intentions.

Mobile Application (Mobile Apps) was described as a process of transforming existing software used by computers into software which can be used in any mobile device. Software Development Tools that software developers would use to create Mobile Apps that can be created once and run on all major mobile platforms such as iPhones, Droids, etc. The phone, for example, is the only hardware that would be required for the Mobile App. By integrating Symbian's web application creation tools and Nitobi's PhoneGap 'write once, run anywhere' platform, mobile developers can now easily make app store ready applications for all major mobile platforms. There may be other development tools that may provide developers with the same functionality so that Mobile Apps can be created once and run on all major platforms of mobile phones.

The NIOSH Certified Equipment List (CEL) was discussed as being the central component for a mobile application, providing all the information listed below. Two key benefits are that 1) the CEL part of the Mobile Apps would be open to allow customers access to information on NIOSH Approvals for verification and authentication prior to purchasing a respirator and 2) real time up to date information would be available on new approvals, existing approvals, approved configurations, verification for enforcement personnel, determining if the assembly is in an approved configuration, and many other uses/needs. Use of a Mobile Application would likely increase customer confidence in a NIOSH Approval, potentially reducing at least some of the counterfeiting. It could save manufacturers money in printing and packaging costs. It is a much more environmentally responsible mode of information presentation. Some specific benefits are below:

- a) <u>Assembly Matrix</u> Manufacturers feel there is a better way to submit, locate, and review information. Since the Assembly Matrix is used to create a respirator configuration, NIOSH based Mobile Apps could easily be searched by Task Number or NIOSH Approval, which would make it easier for manufacturers to view or add parts to the parts database for NIOSH Approval.
- b) Approval Label Manufacturers indicated that there is a large cost associated with printing NIOSH Approval Labels. With NIOSH based Mobile Apps, this can be accomplished such that the NIOSH Approval number is used and would be associated with a NIOSH Approval Label to view. The Approval Label would be viewed and read similar to a Kindle that is used these days to read books from online sources. NIOSH Mobile Apps could also include the electronic signature of the NIOSH Branch Chief for verification.
- c) <u>User's Instructions</u> User's instructions could be accessible and useable based on the Approval Number associated with the NIOSH Configuration, part number,

- model number, or other searchable criteria. The User Instructions (UI) contain detailed information for use, maintenance, donning and respirator approval. The UI could be viewed and read similar to a Kindle that is used these days to read books from online sources.
- d) <u>User Notices</u> Respirator users could have instant access to NIOSH-issued User Notices informing them of problems, issues, recalls, rescinding of approvals, etc. related to respirators. The cost, amount of paper, and time to deliver associated with mailing would be virtually eliminated.
- e) <u>Dual Labels</u> Manufacturers expressed concern and difficulty processing Dual Labels (i.e. labels showing approvals for different countries) and physically fitting this information on respirator components. By have a component label simplified and referencing the Mobile App, the NIOSH label (or approval information) could easily be verified.
- f) Interactivity Manufacturers are looking for interactivity with NIOSH since NIOSH currently maintains a parts database of approved parts used in respirator configurations that are submitted for NIOSH Approval. Some benefits of this interactivity are listed below.
 - 1. <u>Common Database</u> NIOSH and Manufacturers could use a common database to process information that could include status reporting (Certification times, processing queue, percent complete, estimated completion dates, etc.) on all projects submitted to NIOSH.
 - Submitting New NIOSH Configurations Searching a common database by part number and/or configuration would allow manufacturers the ability to duplicate information to create additional configurations easily and reduce errors on the part of manufacturers and review times for NIOSH.
 - 3. NIOSH Configuration Views Configuration views could be created that identify and allow manufacturers to view mandatory parts for NIOSH Approval and Accessory Parts (Optional Parts) to aid in submitting new or modified respirators for approval. Another aspect of this could be configuration views that allow users, enforcement, and others to view configurations based on a NIOSH Approval, Part Numbers, model numbers, etc. to determine approved configurations.
 - 4. Revoking and Rescinding NIOSH Approvals and Parts NIOSH and/or the Manufacturer would be able to revoke and/or rescind NIOSH Approvals and/or Parts that are found defective via a CPIP Investigation or by the Manufacturer. NIOSH could maintain the authority over the entire process and would be able to have the NIOSH Approval removed from the CEL. The other benefit is that once a NIOSH Approval has been revoked or rescinded then customers could be easily notified via the NIOSH Mobile App. So this would provide real-time

- information to the user and is especially useful if they are using, or plan to use, the product,
- 5. One more far-reaching item may include the ability to identify counterfeit respirators. This could possibly be accomplished with New Technology that incorporates Radio Frequency ID (RFID) Bar-coding and/or Smart Card Technology.