Miller, Diane M. (CDC/NIOSH/EID)

From: Larry Green [lgreen@bio-md.com]
Sent: Monday, November 27, 2006 8:47 AM
To: NIOSH Docket Office (CDC)
Cc: Hoffman, William (CDC/NIOSH/NPPTL)
Subject: RE: Draft standards for PAPR efficiency testing

Attachments: 125943867-Proposed testing for N series PAPRs 11_06.doc

Proposed testing for N series ...

Please find my comments and proposals regarding the revision of the PAPR standards in the attached file.

If it is necessary to submit it in another format please advise me.

Larry Green
Syntech Intl.

NIOSH Docket #008
Particulate Testing for PAPRs Nov 27, 2006

I feel strongly that the draft testing standard for PAPR 95 is deficient. The major shortcoming is that it allows some types of filters into general use when they should be restricted.

As always I oppose any standard which does not include provisions for N type filters. The N type filters offer the best options for many applications. They are less expensive and highly adaptable to novel configurations to meet targeted markets. It is these factors which allow the success of N95 and N100 respirators.

I propose adding certification of ***both N95 and N100 type filters*** for PAPRs, additional requirements or ***labeling for loading and non loading type*** filters, and wording to allow NaCl testing of N95 and N100 type PAPRs when the equipment becomes available. OSHA has a similar specification for ESL indicators which allow economic justification for development of such.

Lack of Loading Requirement:

In hospital use, where there is almost no foreseeable loading, the low airflow resistance of some types of high efficiency media offers distinct advantages. For a PAPR, the power required to pull air through the filter means noise. Noise is unacceptable. Surgical systems operate around 60 dB or lower.

This media is also attractive for high flow PAPRs which would probably be targeted outside the healthcare market. In many markets where a 95% efficient product would be acceptable, there would be significant loading (construction, agriculture, disaster response and cleanup, etc.). Without a loading requirement, filters which degrade in efficiency quickly could be incorrectly marketed.

The accompanying spreadsheet (TSIdata-BioMed-HP300-10MB (Hollinee).xls) shows that it is very simple to make these media pass a loading test. This small change still increased the resistance almost 40% with negligible effect on the initial efficiency. As high flow PAPRs are developed, a 40% increase in resistance creates a significant burden.

*** As there are market specific advantages to both load resistant and not resistant types of filters, a labeling requirement is justified to prevent improper use.

Only 95% efficient rating for non-oily filters:

Information from current healthcare customers indicates that normal hazards are low and an N95 rating is desirable because the filters are ½ the cost of N100 filters. They also require less power (noise) to maintain airflow. A 95% efficiency is acceptable because most biohazards are not life threatening and do not result in permanent damage.

In unknown and against more toxic or debilitating hazards they want the high level of protection on an N100 filter. The ability to have a system capable of switching between the two types of filters allows the hardware to be used on a regular basis and in heightened hazard situations.

The addition of a N100 type filter to the standard is necessary. Both N95 and N100 filtering face pieces are very popular, therefore similar classifications for PAPRs makes sense. If it is necessary to have only one rating, an N100 type rating makes more sense for the additional cost of helmets, blowers and other hardware.

*** If NaCl testing is unavailable for N type filters, DOP testing can be used for both N95 type and N100 type filters in the same manor as now specified for the PAPR 95 concept.

Difficulties associated with NaCl testing:

NIOSH personnel have conveyed several problems associated with high flow NaCl testing. The TSI proposed testers are essentially the same as the current 8130 testers modified for higher flows therefore the maintenance issues should be similar. NIOSH personnel have indicated that past high-flow testers they have used have trouble maintaining particle consistency and that the concentrations generated are to low for reasonable test times for loading filters.

I spoke with an engineer at TSI and he felt increasing particle concentrations was simply a mater of ganging together multiple generator modules. This may not have been an option on equipment which NIOSH has but should be feasible on complete new models. The size of the equipment may be significantly larger. If there are technical difficulties these can be more expected to be overcome on a commercially viable product than a single sale custom designed unit unless all cost overruns are guaranteed. As these machines are not commercially viable unless required, justifying development costs to overcome technical difficulties will not be possible unless the applicable standards allow for the sale once viable.

These and similar limitations in 1994 were at least partially responsible for preventing the update of the PAPR standards in the 42 CFR part 84 final rule in 1995. Without a market, industry failed to develop appropriate testers and now more than 10 years later we are stuck with the same limitations.

Competitive media bias:

There are a number of electrostatic filter media manufacturers; most of the media manufactured by them tend to loose their electrostatic properties quickly when exposed to oily particulate. One corporation holds patents for a fiber treatment which allows these media to resist charge degradation. This has allowed them to dominate the production of oil resistant media to the point where production of competitive oil resistant media, which may or may not be inferior, becomes economically unjustifiable. As proposed, the PAPR classifications enforce this competitive advantage into the non-oily market for PAPRs where it would not exist but for the testing criteria dictated.

****

Proposed testing for N series PAPRs.

Excerpted from 84 CFR part 84 ***Proposed Rule***, May 24, 1994.

84.184.g.1 ... concentration not exceeding 200mg/m3. ... For powered air-purifying respirators, the penetration test shall continue until maximum penetration is achieved or until a mass of at least 2000+/-50 mg has contacted the filter unit.

Concepts for consideration. (N95 or N100).

1. For filters labeled "FOR CLEAN AREA USE ONLY" or "FOR NON-LOADING CONDITION USE ONLY" (or something similar) the initial penetration value is considered. The test would be shortened appropriately.

2. For general use filters, the ultimate penetration is considered .

3. If suitable test means is not available to test the full filter at actual flow rate with NaCl, the manufacturers quality control plan must demonstrate the ability maintain efficiency as the filter is loaded.

    a. Alternate test

        i. Instantaneous test of the entire filter using DOP (PAPR 95 concept)
        ii. Using TSI 8110 or 8130 filter testers, test the filter media at a flow rate of max flow / (effective filter area / test area)
            1. For clean area use test instantaneous penetration.

            2. For general use test according to 1994 proposed rule (full load would be divided in same manor as flow rate.)

Larry Green
Syntech, Intl.

Ph: 949-752-9642
Fax: 9-752-9658
Email: lgreen@bio-md.com