ISO Respiratory Protective Device Standards

Emphasis on “Assisted” Respirators

Craig E. Colton, CIH
3M Company
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Outline

• Overview of ISO/TC94/SC15
• Powered Air-Purifying Respirator Terminology
• ISO/CD 17420-2.2
  – RPD Performance Requirements – Filtering Devices
• Summary of what ISO could mean
ISO Background

- ISO, the International Organization for Standardization as we know it today, began operations in 1947
- In 2001 the Technical Committee on Personal safety – Protective clothing and equipment (TC94) voted to form a sub-committee (SC15) to write standards for “Respiratory protective devices”
  - Initiated through the EN Technical Committee 79 in response to ISO TC94 SC14 beginning to draft standards for Respiratory Protection for Fire Fighting
- First meeting was March 2002 – have met every year since
TC94 / SC15 Background

- In ISO TC94/SC15 the United States is represented by ANSI via an accredited Technical Advisory Group (USTAG)
  - NIOSH is the administrator for the SC15 USTAG
    - Bill Newcomb, NIOSH/NPPTL - Administrator
    - Geoff Betsinger, 3M - Technical chair
    - Dan Shipp, ISEA - Secretary/Treasurer
Powered Air-Purifying Respirators (PAPRs)

From 29 CFR 1910.134

- **Powered air-purifying respirator (PAPR) means an air-purifying respirator** that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

- **Types of (Respiratory) Inlet Coverings**
  - Half facepiece (mask)  APF of 50
  - Full facepiece  APF of 1000
  - Hood or Helmet  APF of 25/1000**
  - Loose-fitting facepiece  APF of 25

- **The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/ hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.**
PAPRs – Tight-fitting

Tight-Fitting Full Facepiece
Powered Air-Purifying Respirator (PAPR)
APF=1,000
*Needs to be fit tested*

Tight-Fitting Half Facepiece
Powered Air-Purifying Respirator (PAPR)
APF=50
*Needs to be fit tested*
PAPRs – Loose-fitting

Loose-Fitting Powered Air-Purifying Respirator (PAPR)
APF=25

Hooded Powered Air-Purifying Respirator (PAPR)
APF=25 (1,000)*
## Comparison of Key Classification Differences

<table>
<thead>
<tr>
<th></th>
<th>Today</th>
<th>ISO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Basic Classification</strong></td>
<td>Type</td>
<td>TIL Lab Test</td>
</tr>
<tr>
<td><strong>Work Rates</strong></td>
<td>Not classified – some validation e.g. fire fighting SCBA</td>
<td>4 Work Rate Classes</td>
</tr>
<tr>
<td><strong>Particle Filters</strong></td>
<td>NIOSH – 9 particle filters EU ~ 6 particle filters</td>
<td>Potential for 20 particle filters (4 Work rates and 5 Efficiencies)</td>
</tr>
<tr>
<td><strong>Gas and Vapor</strong></td>
<td>Classified by capacity</td>
<td>Classified by capacity and work rate</td>
</tr>
<tr>
<td><strong>Selection and Use</strong></td>
<td>Varies by region but generally based on Protection Factors</td>
<td>Based on ISO Classification - Protection level linked to TIL - Work Rates</td>
</tr>
</tbody>
</table>
ISO Classification - TIL

- Total inward leakage test is the basis of ISO Classification
- ISO Respiratory Protective Devices (RPD) are not defined by ‘type’
  - PAPR could be classified same or lower than half mask respirator
- No design related limits on class
  - a respirator can achieve the highest or lowest PC class regardless of what ‘type’ it is

<table>
<thead>
<tr>
<th>TIL% (max)</th>
<th>$\frac{1}{TIL_{MAX}}$</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.001</td>
<td>100000</td>
<td>PC 6</td>
</tr>
<tr>
<td>0.01</td>
<td>10000</td>
<td>PC 5</td>
</tr>
<tr>
<td>0.1</td>
<td>1000</td>
<td>PC 4</td>
</tr>
<tr>
<td>1</td>
<td>100</td>
<td>PC 3</td>
</tr>
<tr>
<td>5</td>
<td>20</td>
<td>PC 2</td>
</tr>
<tr>
<td>20</td>
<td>5</td>
<td>PC 1</td>
</tr>
</tbody>
</table>
Work Rates

• Work rate classification
  – Four classifications W1 – W4
• Manufacturer determines what class to certify to
• Work rate class drives performance requirement flow rates
• Selection and use standard directs user to what work rate is needed
• W1 would cover approximately 90% of industrial work places
Respiratory Interface Class

BARRIER

Body
Head
Face
Mouth and nose
Mouth only
Nose only
Barrier lines
Type (tight) (loose)

Respiratory Interface Class
Filters

- Filters classified by performance, work rate class and ‘single shift’ or ‘reusable’
- These requirements result in a lot of filter options to end user (40 particulate filter classes)
  - i.e. 9 NIOSH particle filter categories today – 2 filters (N95, P100) are the primary filters used
- Wider capacity range of Gas and Vapor Filters - Chemical cartridge capacity may be better matched to exposure levels (e.g., small capacity cartridge for short or low level exposures

<table>
<thead>
<tr>
<th>Minimum Particle Filter Efficiency [%]</th>
<th>Group Gas Filter Type</th>
<th>Specific Gas Filter Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class</td>
<td>Class</td>
<td>Class</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F5</th>
<th>NOX</th>
<th>FM</th>
<th>ETO</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.99</td>
<td>Nitrous oxides</td>
<td>Formaldehyde</td>
<td>Ethylene Oxide</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F4</th>
<th>OG</th>
<th>MB</th>
<th>CO</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.9</td>
<td>Organic Gases</td>
<td>Methyl Bromide</td>
<td>Carbon Nonoxide</td>
</tr>
<tr>
<td>n/a</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F3</th>
<th>AC</th>
<th>HCN</th>
<th>CD</th>
</tr>
</thead>
<tbody>
<tr>
<td>99</td>
<td>Acidic</td>
<td>Hydrogen Cyanide</td>
<td>Chlorine Dioxide</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F2</th>
<th>BC</th>
<th>OZ</th>
<th>HF</th>
</tr>
</thead>
<tbody>
<tr>
<td>95</td>
<td>Basic</td>
<td>Ozone</td>
<td>Hydrogen Flouride</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F1</th>
<th>OV</th>
<th>NO2</th>
<th>AH</th>
</tr>
</thead>
<tbody>
<tr>
<td>80</td>
<td>Organic Vapours</td>
<td>Nitrogen Dioxide</td>
<td>Arsine</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Special Applications

• In addition to basic requirements, additional testing is required to meet certain classes
  – Examples include:
    • Fire fighting
    • Mining operations
    • CBRN
Classification Summary

• Similar looking “PAPRs” may have different classifications

• Different looking devices may be classified the same
  – PAPR, Full Face and Half Mask
## Classification Examples

<table>
<thead>
<tr>
<th>Basic Performance Characteristic</th>
<th>Full Face Assisted</th>
<th>Full Face Unassisted</th>
<th>Half Mask Assisted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protection Class</td>
<td>PC4</td>
<td>PC4</td>
<td>PC4</td>
</tr>
<tr>
<td>Respiratory Inlet</td>
<td>cT</td>
<td>cT</td>
<td>bT</td>
</tr>
<tr>
<td>Work Rate</td>
<td>W1</td>
<td>W1</td>
<td>W1</td>
</tr>
<tr>
<td>Particle Filter Efficiency</td>
<td>F2</td>
<td>F3</td>
<td>F4</td>
</tr>
</tbody>
</table>
Other Requirements specific to Assisted RPD

• Noise level when motor is running (80 dBA)
• Strength of connections test - e.g.,
  – Hoses
  – Filters
• Practical performance tests
  – Subject wearing the RPD
• Warning indicators
  – Low flow
  – Low battery
Summary

• Classification is based on Laboratory Performance and not Type of RPD
  – Similar looking devices can have different levels of protection classes
• Protection Level Classification scheme utilizes a TIL laboratory test method
• Work rate classification adds complexity that some users may not know how to address
• May offer a broader breadth of performance criteria
  – Protection Level of Powered Air Purifying Respirator (PAPR) may be better matched to environmental exposures and work rates (e.g., low protection level PAPR for low hazard ratio work tasks)
• Special Application Classification
  – Additional performance requirements designed to help meet unique demands
Top 3 barriers to, or opportunities to improve, effective usage of PAPRs in health care settings

1) Level of protection needed
2) Training
3) Maintenance
Top 3 ideas to improve NPPTL certification

For HC PAPRs

Important knowledge gaps
- PAPR air flow needed

Techniques to evaluate product
- Elimination of the silica dust loading test

Approach or content of certification standards
- Performance oriented vs. specification