How will ISO's Standardization of Respiratory Protection Devices Effect Respiratory Protection Programs?

Presented by Holli Merchant, CIH CSP
Agenda

- ISO Overview
- TC94 SC15 History & Overview
- SC15 Purpose
- Implementation and Explanation of Respiratory Protective Devices Standards
- Respirator Classification
- Adoption of ISO Standards
- Protection Classes
- Respirator Programs and the New Standards
- Training
- Summary
What is ISO?

- International Organization for Standardization (ISO) began in 1947, it is a non-governmental membership organization and the world’s largest developer of voluntary International Standards.
- ISO’s goal is to facilitate the unification and coordination of industrial standards across the globe.
- ISO is currently headquartered in Geneva, Switzerland and has members from 162 countries and is comprised of over 250 technical committees.
ISO Standards are developed through a consensus process.

Countries have voting rights and vote their opinions on a document at various stages of the lengthy process.

ISO Standards are based on expert opinions from around the globe forming technical committees. All voting member countries are included in standard development.
The technical committee on Personal Safety, Protective Clothing and Equipment (TC94) voted in 2001 to form a sub-committee (SC15) to write standards for “Respiratory Protection Devices.”

Meetings have been held once a year since 2002.

Currently 25 Countries participate as Primary (voting) members, as well as 5 observing countries.

The purpose of the SC 15 sub-committee is to standardize the performance of respiratory devices.

There are multiple documents that have come out of this sub-committee.
Understanding the US Role in ISO/TC94/SC15

- The United States is represented by the American National Standards Institute (ANSI) via a technical advisory group (USTAG).
  - ANSI has assigned NIOSH as the administrator for the TC94 SC15 USTAG.
  - Membership in the USTAG is open and welcomes new members.
Purpose of the Standard

- Countries have their own performance standards and methods for assessing RPD’s.

- Respirator manufacturers around the world may have identical products with very different performance claims.

- Sometimes the filter efficiency requirements for two products might be the same but measured differently.

- The lack of a harmonized standard can cause challenges when trying to make a global recommendation for a common hazard. Such as during the SARS outbreak.
During the SARS Outbreak, health authorities recommended N-95 respirators.

This led to a worldwide shortage of N-95’s.

There were other filtering face-pieces that were adequate for protection, such as the FP2 which meets a European standard.

The FP2 was only allowed after the World Health Organization (WHO) became aware of the product, which was quite a while after the initial recommendation.

The standardization of respirator classifications would allow for a faster response to worldwide health hazards.
Wearer Centric Focus

- ISO requirements focus on human factors and the wearers tolerance and ability.
- Therefore, in the early years the Sub-Committee mostly put out technical specifications that were designed as a reference manual for the standard writers.
- These documents address the issues where an RPD may create an extra burden for the wearer.
ISO Working Structure

- There are three working groups under the Sub Committee.
- Working Group 1- General
- Working Group 2- Filtering Devices- devices dependent on ambient atmosphere
- Working Group 3- Supplied Breathing Gas Devices- devices independent of ambient atmosphere.
Standards in Process

- 32 total documents to come out of this Sub-Committee
- Four different types: General, Technical Specifications, Performance Standards, and Test Methods
- General
  - Terms and Definitions- Published
  - Classification- Out for Voting
  - Marking and Information- Published
  - Selection, Maintenance and Use- Three parts of this standard
Technical Specifications

- 8 different technical specifications.
- Used as education tools for standards writers.
- Subjects include: Metabolic rates, anthropometrics, oxygen and carbon dioxide, work of breathing, thermal effects, psycho-physiological, hearing and speech, ergonomics.
- These are sometimes converted to performance standards after they have been published as a technical specification.
Test Methods

- Test methods
- These are the methods that manufacturer’s will have to adhere to.
- There are 14 of them.
- They include: Inward leakage, resistance, particle filter efficiency, gas filter capacity, tools, mechanical resistance, practical performance, air flow rate, carbon dioxide, flame and heat, field of vision, work of breathing, closed circuit gasses, and noise level.
Performance Standards

- There are two performance standards, filtering RPD’s and supplied breathable gas.
- The filtering RPD performance standard is the one that will change respiratory protection substantially.
- The supplied breathable gas performance standard indicates that Self Contained Breathing Apparatus will be marked by the volume of the tank.
Both standards set the performance requirements for all respiratory protection which have now given rise to one classification standard.

The performance centric approach classifies a respirator based on its performance and not its design. These classifications could result in a big change for respirators.

The standard ISO 16973 is currently out for voting as a Draft ISO Standard.
Respirator Classification

- Right now in the United States, RPDs are classified by type. Such as Half Face- Piece dust respirator. This type determines which NIOSH requirements need to be met and what the assigned protection factor would be.
- Under the ISO framework classification becomes much more complicated.
- Factors such as work rate, particle filter efficiency, respiratory interface and the ISO protection class it tests into determine what classification it receives.
- The new classification system is alphabetic, such as PC$_4$W$_1$bTF$_4$. That means it has a Protection Class of 4, a work rate of 1 and an F4 particle filter.
Classification

- Work Rate
- Respiratory Interface
- Protection Class
- Filter Efficiency
- Special Circumstances
## Protection Class Table

<table>
<thead>
<tr>
<th>TIL% (max)</th>
<th>( \frac{1}{TIL_{\text{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>
## Classification Comparison

<table>
<thead>
<tr>
<th>Basic Classification</th>
<th>Today</th>
<th>ISO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work Rates</td>
<td>Not classified – some validation e.g. fire fighting SCBA</td>
<td>4 Work Rate Classes</td>
</tr>
<tr>
<td>Particle Filters</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>Gas and Vapor</td>
<td>Classified by capacity</td>
<td>Classified by capacity and work rate</td>
</tr>
<tr>
<td>Selection and Use</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>
Work Rates

- Work rates are a key factor in the classification of respirators.
- This chart indicates what work rate a respirator is designed for.
Respiratory Interface Class
# Filters

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

<table>
<thead>
<tr>
<th>Filters</th>
<th>OX</th>
<th>MB</th>
<th>CO</th>
</tr>
</thead>
<tbody>
<tr>
<td>F4</td>
<td>Organic Gases</td>
<td>Methyl Bromide</td>
<td>Carbon Monoxide</td>
</tr>
<tr>
<td>99.9</td>
<td>n/a</td>
<td>1 2 3</td>
<td>20 60 180</td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th>Filters</th>
<th>Minimum Particle Filter Efficiency [%]</th>
<th>Group Gas Filter Type</th>
<th>Specific Gas Filter Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>F5</td>
<td>HG</td>
<td>Mercury</td>
<td>n/a</td>
</tr>
<tr>
<td>99.99</td>
<td>PH</td>
<td>Phosphine</td>
<td>1 2 3</td>
</tr>
</tbody>
</table>

**Filtration**
In addition to the classification methods mentioned above, there are special classifications for

- Mining
- CBRN
- Fire Fighting
Classification Example & Notes on Classification

**EXAMPLE:**

- Same ‘type of” respirators may have different classification.
  - 3 full face masks may all have different classification.
  - They may look different but be classified the same.
  - Half Face, Full Face, PAPR.
  - A PAPR could be classified lower than a half-face.
- This is a very different approach than what the US has in place today.
### Classification Example

#### 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>
Program Considerations

- Part 2 of the Selection, Maintenance and Use Standard is a condensed guide for companies developing respiratory protection programs.
- This guideline will be fantastic for countries where no respirator use guideline is available.
- It is a little complicated in the United States where there is already respirator use. This standard uses significantly different language. And is a bit complicated.
Fit Testing

- Part 3 of the Respirator, Selection and Use is fit testing procedures.
- Key items to note:
  - No annual fit test.
  - No Irritant smoke as an option.
Protection Factor

- Many countries use an APF or another protection factor to describe the protection level provided by an RPD. They are 10 for half face, 50 for full face, etc. In the United States.
- These protection factors went through extensive rulemaking to be developed.
- Under the new standard, the protection class will be based on Total Inward Leakage (TIL) which is a laboratory test.
- The TIL has been used in Europe for years. Three different test methods have been proposed and ISO will have to work through the logistics of that.
Adoption of ISO Respiratory Protection Standards?

- Lots of countries have existing national regulations for RPD performance.
- In the US, these standards are established by NIOSH.
- Some countries have existing selection and use standards, in the United States those are found in 29 CFR 1910.134 in the form of protection factors.
- NIOSH is already reviewing the options for adoption of the new ISO standards.
- Since it changed its respiratory protection standard as recently as 2006, is OSHA likely to change its standard?
Ramifications of the New Standards

- If adopted in the United States, the ISO guidance will replace the RPD classification and terminology used by NIOSH.
- This would standardize the performance requirements for RPD users.
- Create a more “wearer centric” set of standards than the existing documentation.
ISO Standard Adoption

Once the standards have been completed and adoption is forthcoming, there are still challenges.

- How will protection levels be determined?
- The complexity of the classification system..
- What will we call respirators? Will they still be half faces?

Instead of an N95 respirator it will now be a

PC$_3$W$_1$bTF$_2$ RPD
Challenges for Multi-National Corporations

- For multi-national corporations there is a whole new set of options. Do we adopt the ISO standard? What do we do if Europe adopts it and the United States doesn’t?
- What does two different classifications systems do to a respiratory protection program?
- How does the new Program guideline in ISO effect respirator programs?
Training to the New Standard

- There is significant new language in this standard.
- No longer will we use half mask, full face, etc.. Now they would be called by Protection Class.
- Selection becomes somewhat difficult for the layperson so there would be significant training around that.
- The new respirator guideline addresses how to select respirators when no Occupational Exposure Limit (OEL) exists. This would be a form of control banding. This will be very different from the current system of selection.
Positives

- The new standard uses a much more rigorous and scientific method to determine classes of respirators.
- Which will ultimately lead to a more scientific way of developing protection factors.
- It attempts to address the issue of how to select respirators when no OEL exists.
- It standardizes the way manufacturers have to classify respirators.
- And it will make worldwide response to a health crisis easier.
How Soon

- Best guess. Completely finished in 2 years.
- Adoption by the United States.. Who knows?
In order to standardize respiratory protection classification and testing, Sub Committee 15 was formed.

- The Sub Committee had developed 32 documents that are in various stages of approval.
- The Sub Committee has determined that they will take a wearer centric focus.
- In order to do that, there is a significant process to classify respirators. Respirators will no longer be classified by types.
- Respirators will be classified by their tested performance class, work rates, interface class and filter performance.
Summary 2

- Based on the TIL results, then a protection factor would be developed. This would be completely different than the currently APF that OSHA has.

- Some respirators that we are used to having a low protection factor could suddenly have a higher protection factor than say a full face.

- Adoption of the standard is not assured, the US may not want to adopt this standard because it is rather complicated.

- If the US does not adopt, this could be very difficult for multinational companies.

- Hide and watch, we will see what happens.
References