

Next Steps and Challenges in Respirator Design and Engineering

Institute of Medicine

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Agenda

- Present Status Review
- Spectrum of Designs
- Filtration
- Design Needs for Healthcare
- Future Needs
 - **Design**
 - **Anthropometrics**
 - **Characterization of the Aerosol Challenge**
 - **Biocides**
 - **PPE Materials**

Spectrum of Half Mask Respirators

Disposable

Reusable



Maintenance

Respirators are available from many manufacturers in a wide range of certification designations, styles and sizes.

Respirator Filter Media: Historical perspective

- **Results from filtration studies over the last 30 years show similar, repeatable filtration test results for particles 3 to 400 nm in diameter and above.**
- **There is no evidence of “particle bounce” down to 1.5 nm.**
- **Mouth generated aerosols and engineered nanoparticles obey the laws of physics (if they didn’t we would not be able to measure them)**
- **Classical filtration models describe penetration results well down to 3 nm for both mechanical and electrostatic filters.**
- **Data for filtration efficacy for PPE-type filters has shown no surprises from previous NIOSH test data over the last 25 years.**
- **The present 42CFR84 NIOSH Filter Tests are adequate classify filters reproducibly and have strong correlations with other filtration tests at different flows and particles sizes**
- **Approved respirator filters are stable in high humidity and temperatures in normal use and may be made oil repellent with low surface energy treatments, greatly enhancing performance against oily challenges.**

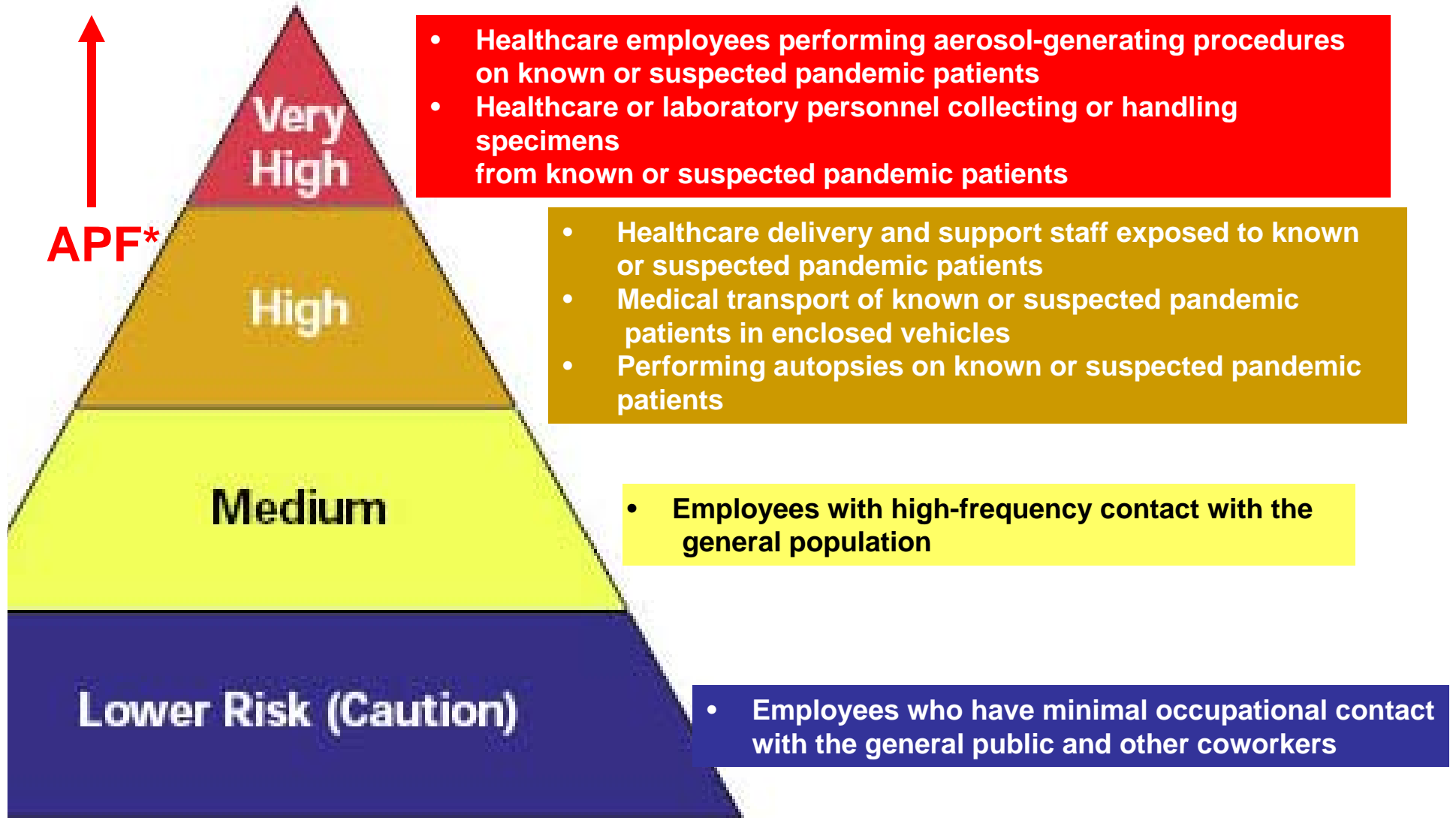
Designing Respiratory PPE- Worker Needs

- A minimum required filtration performance
- Easy to put on and take off
- Comfortable
- Designs available to fit wide range of faces
- Easy to breath through
- Sanitary/hygienic on selection
- Compatible with PPE and other protection equipment
- Maintenance:
 - Convenience of proper disposal
 - Convenience of cleaning and replacement of parts
- Industry-specific needs (e.g. fluid resistance)

PPE equipment selection is based on the hazard and risk

OSHA Occupational Risk Pyramid for Pandemic Influenza

From: Guidance on Preparing Workplaces for an Influenza Pandemic
OSHA 3327-02N 2007



***Consider using APF (Assigned Protection Factor) in selection process**

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Need for Uniform Training Programs:

“Respirators must be used in the context of a comprehensive respiratory protection program”

(see OSHA standard 29 CFR 1910.134)

- PPE can be stock-piled by the millions, but will be used properly only with training.
- It can take time to choose a respirator for employees and then arrange for a qualified trainer to provide training, fit testing, and medical evaluations for employees.
- If employers wait until an influenza pandemic actually arrives, they may be unable to provide an adequate respiratory protection program in a timely manner.
- Evaluate employees to assure they can perform work tasks while wearing a respirator.

Future Needs

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Design / Selection

Considerations for Healthcare

- The demographics of healthcare workers may be different from industry – beards, general healthiness.
- Familiarity with daily use of respirators.
- For long term wearing, materials are needed for comfort and ease of fit.
- PPE design must not interfere with work or other clothing.
- Sensitivity to patients: familiar, non-startling PPE equipment, social factors.
- Communication needs: verbal, facial.
- There may be a need for greater Assigned Protection Factor respirators for **high** risk jobs.

Evaluation of the Hazard and Selection of the Device

- **Evaluation of the Hazard**
 - Research is needed on the viable aerosol challenge which has been generated by a human (sneeze, cough, mouth breathing).
 - What are the workplace concentrations?
 - Is it a 10000 nm sneeze droplet particle or does it evaporate down to a 60 nm spore particle?
 - Are the particles single spores or conglomerates of spores, tissue and mucus?
 - Is one large particle with millions of spores more infective than a million small particles of single spores?
 - Are previous studies correct with respect to new methods of particle analysis?
- **Selection of the device**
 - What are the expectations of the level of filter efficiency?
 - What the air flows are expected?
 - Are antimicrobial treatments necessary?

Different kind of materials for PPE type – What new materials are needed?

- **Comfortable face seal materials**
- **Sweat handling systems**
- **Antifogging respirator-eyewear solutions**
- **Containers for sanitary disposal**
- **Designs which can be used with either industrial accessories and/or with healthcare accessories (gowns, hoods, eyewear)**

Thank You

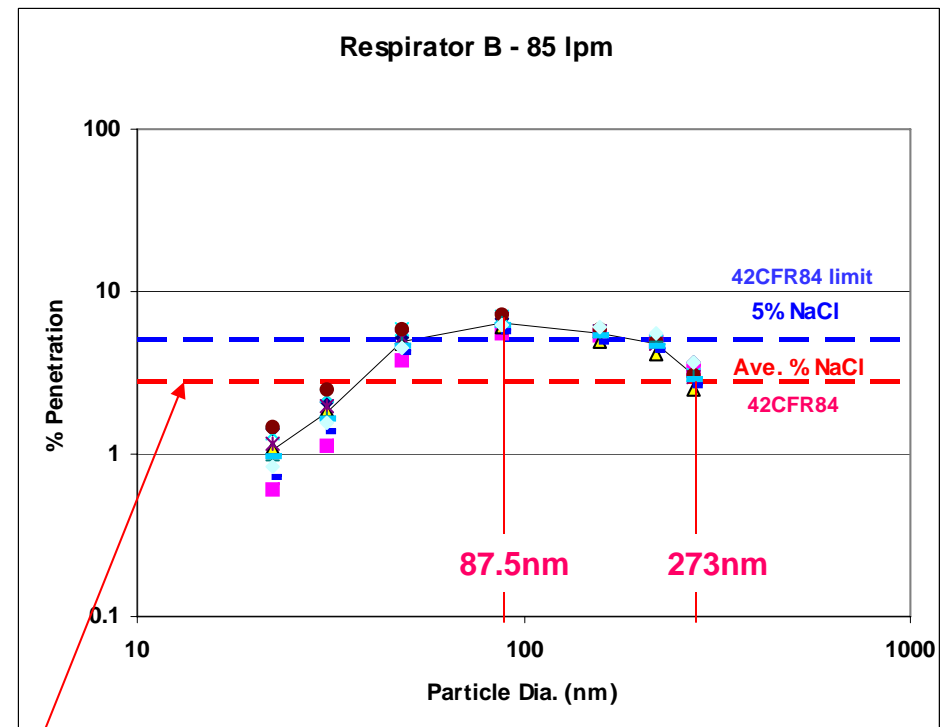
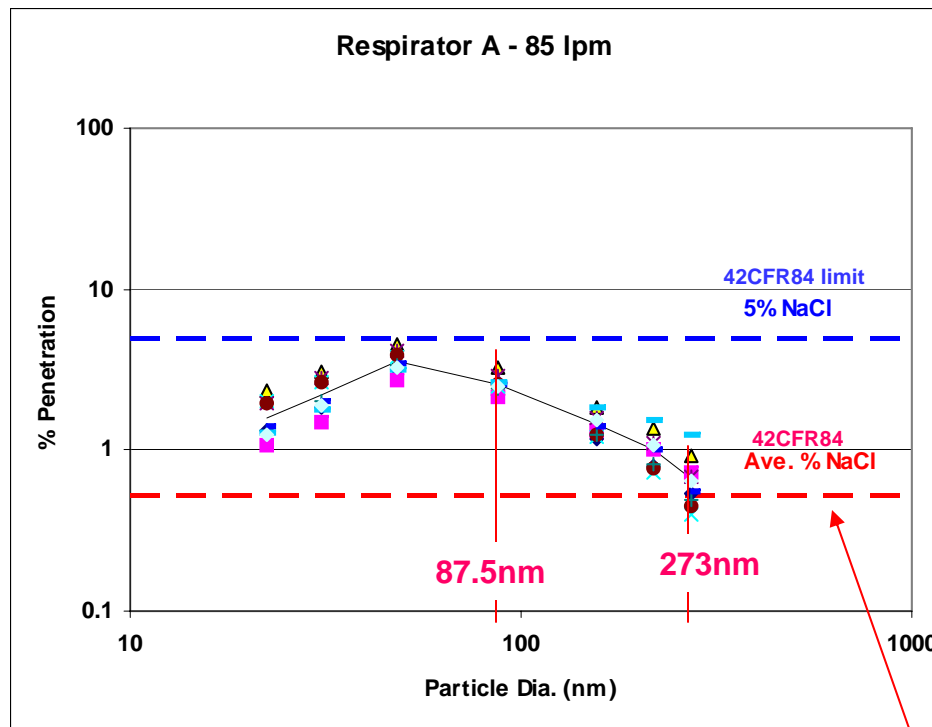
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APPENDIX

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N95 Respirators Work Well Down to Very Small Particle Sizes

42CFR84 Percent NaCl vs. TSI 8160 Penetration at Selected Sizes: Two N95 Respirators from different manufacturers (n=10)*



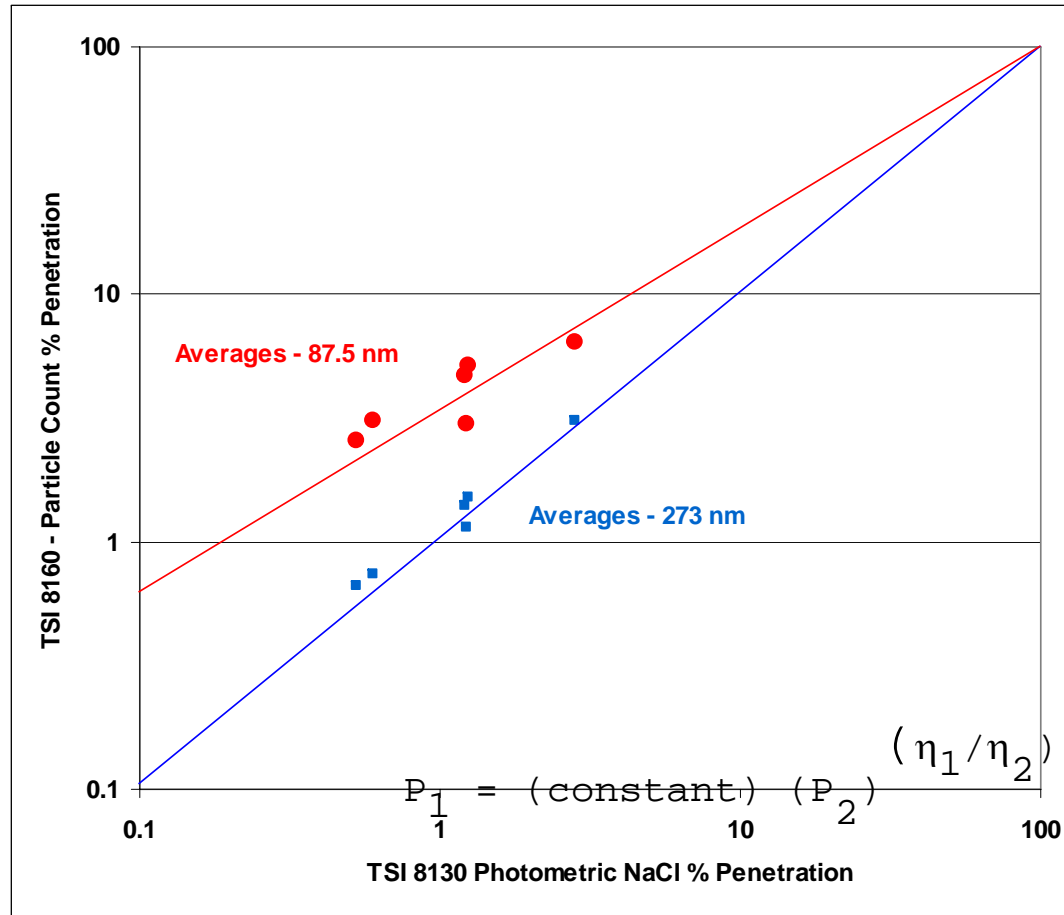
----- NIOSH 42CFR84 Test

*This is one study, and NIOSH is doing further research on engineered nanoparticle filtration.

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NIOSH Certification and Other Single Particle Filter Tests Rank Respirators in a Similar, Predictable manner

Average Percent Penetration: Photometric vs. Count For Six different mfg. of N95 Respirator Models (n=10)



Needed Research Steps on the use of Biocides in RPD

- 1. Develop bioaerosol test system**
 - **Generating and detecting airborne particles in approximate ranges of 0.03 microns to over 1 micron.**
 - **Bioaerosols representative of pathogens encountered in a real world environment.**
- 2. Evaluate and compare the filter efficiency of commercially available respirators and filtration media not containing antimicrobials and those containing antimicrobials against test agents such as viruses and bacteria.**
- 3. If warranted, evaluate approaches to enhance the antimicrobial activity of respirator components, including coverwebs and filter media and develop a prototype new generation respirator that would reduce transmission of infectious agents.**
- 4. Evaluate the health implications for adding a biocide**