

Welcome to the NIOSH NPPTL Meeting for All Respirator Manufacturers

October 22, 2014

AGENDA

| Time | Topic |
|-------------------|---|
| 8:30am – 9:00 am | Registration |
| 9:00am – 9:15 am | Welcome/Meeting Protocols/Logistics |
| 9:15am – 10:15 am | NPPTL Research Activities |
| 10:15am – 10:30am | Break |
| 10:30am – 12:00am | Standard Application Procedure/Standard Application Form |
| 12:00am – 12:45pm | Lunch |
| 12:45pm – 1:00pm | Post-Market Activities |
| 1:00pm – 2:15pm | Workgroups focusing on issues related to changes to the SAF and the draft application checklist |
| 2:15pm – 2:30pm | Break |
| 2:30pm - 3:00pm | Workgroup Debriefing |
| 3:00pm | Adjourn |
| | |

Today's Activity Reminders

- **Rest rooms off the lobby**
- **Escorts required for other movement**
- **Cash Payment for pre-ordered lunches**
- **Restrictions on departing site**
 - Surrender Visitor ID
 - Repeat visitor processing for re-entry
- **TEB personnel available for discussions**

Save the Date

December 2, 2014 – NIOSH/Industry Working Group meeting to discuss ideas for improving respirator approval processing times

- ISEA Headquarters, Arlington, VA
- For more information contact

Jon Szalajda

JSzalajda@cdc.gov

412-386-6627)

NPPTL Research Activities

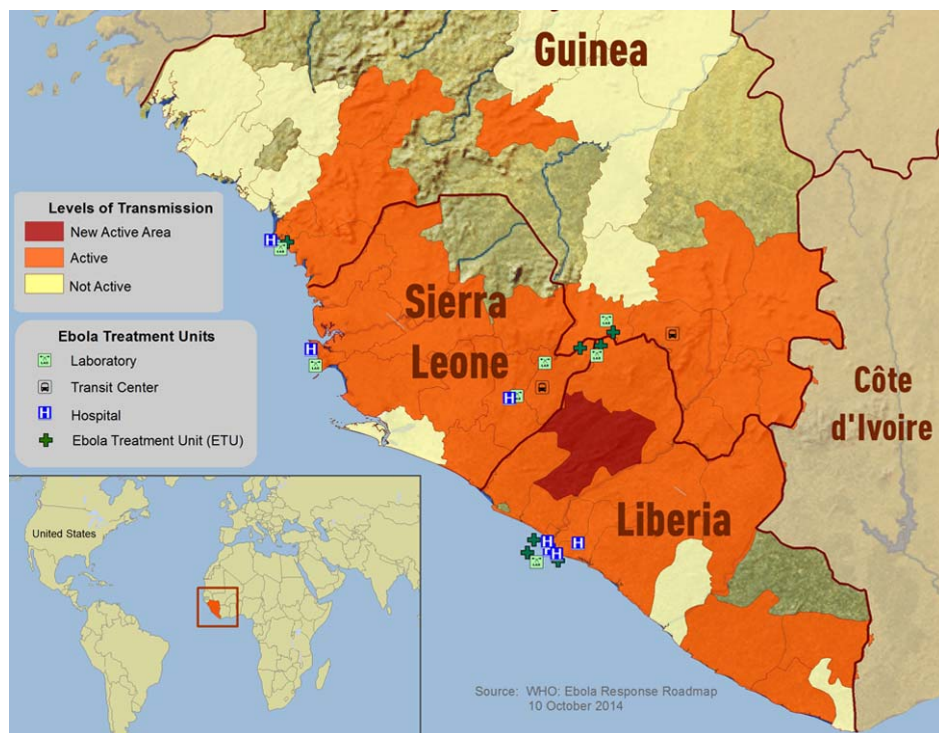
NPPTL Support to CDC's Ebola Response

Ron Shaffer

Branch Chief, Technology Research

NPPTL Respirator Manufacturers Meeting, October 22, 2014

2014 Ebola Outbreak

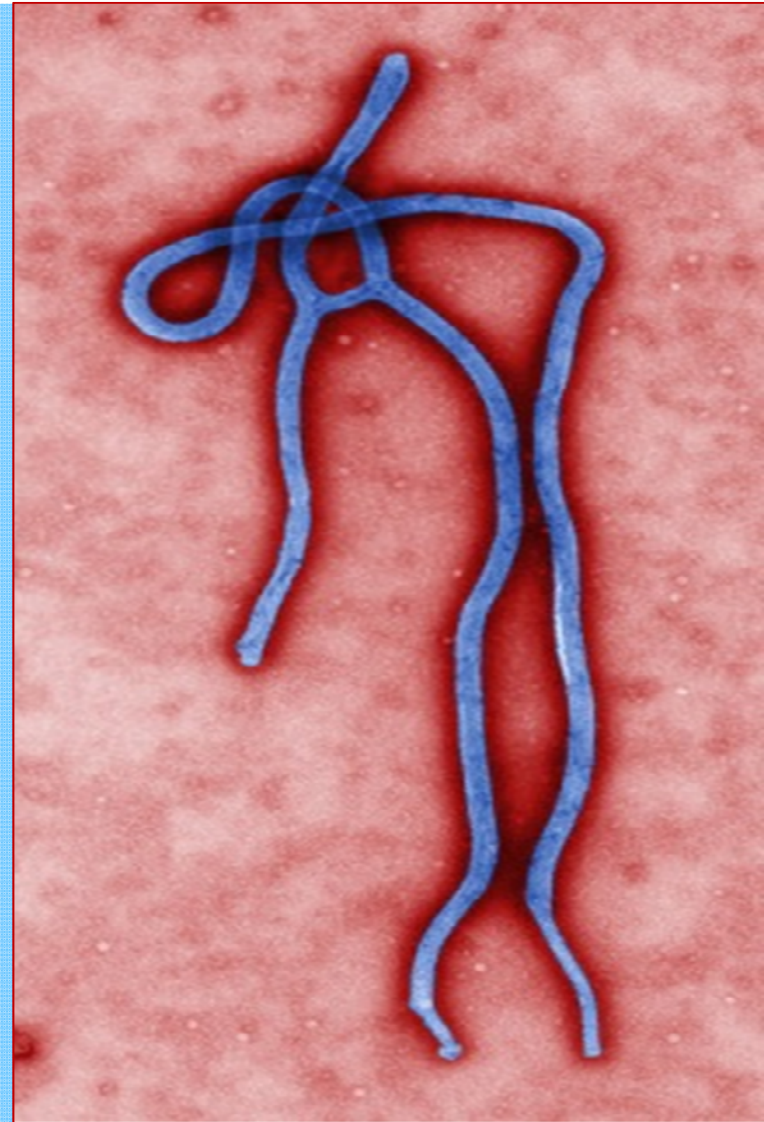


<http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html>

- This is the largest Ebola epidemic in history
- CDC's response to Ebola is the largest international outbreak response in CDC's history

Ebola Virus Disease

- **Previously called Ebola hemorrhagic fever**
- **5 species of *Ebolavirus***
 - *Zaire ebolavirus*
 - *Bundibugyo ebolavirus*
 - *Reston ebolavirus*
 - *Sudan ebolavirus*
 - *Tai Forest ebolavirus*
- **All but *Reston ebolavirus* known to cause disease in humans**
- **Historically, death rates for Ebola range from 50%-90%**



Transmission

- ❑ **Ebola virus is spread through direct contact (through broken skin or unprotected mucous membranes) with:**
 - A sick person's blood or body fluids, including urine, saliva, sweat, feces, vomit, and semen
 - Contaminated objects (like needles and syringes)
 - Infected animals (by contact with their blood, fluids, or infected meat)
- ❑ **Ebola virus has been detected in breast milk, but it is not known if the virus can be transmitted from mothers to infants through breastfeeding**
- ❑ **Mosquitos or other insects cannot transmit Ebola virus**
- ❑ **It is not believed that pets (like dogs and cats) are at significant risk for Ebola**

<http://www.cdc.gov/vhf/ebola/transmission/human-transmission.html>

Risk

- **Health workers caring for Ebola patients and the family and friends in close contact with Ebola patients are at the highest risk of getting sick because they may come in contact with the blood or body fluids of sick patients**
- **Ebola also can be spread through contact with objects (like clothes, bedding, needles/syringes and medical equipment) that have been contaminated with the virus**
- **People also can become sick with Ebola after coming in contact with infected wildlife**
 - In Africa, Ebola may be spread as a result of handling bushmeat (wild animals hunted for food) and contact with infected bats

Example PPE Used in West Africa

WHO-Basic



WHO-HIGH



MSF



WHO = World Health Organization; MSF = Médecins Sans Frontières

NPPTL Roles

- **Subject matter expert review and consultation to the CDC Emergency Operations Center on PPE guidance**
- **Collaborating with U.S. Agency for International Development (USAID), White House Office of Science and Technology Policy (OSTP) and other federal partners on “Fighting Ebola: A Grand Challenge for Development”**
 - To learn more, please visit <http://ebolagrandchallenge.net/>
- **Research**
 - Establish baseline on performance and usability (e.g., heat stress, donning/doffing, decontamination) of existing PPE used in West Africa
 - Continue existing projects that support better PPE for healthcare workers (e.g., transfer of viruses on PPE, physiological evaluations of PAPRs, Project BREATHE, isolation gowns)

NPPTL Roles (2)

□ Communications & Surveillance

- PAPR webpage (in development)
- NIOSH science blog on Ebola PPE (in clearance)
- NIOSH/OSHA Hospital Respiratory Protection Program Toolkit (~Jan 2015)
- Handling inquiries from general public and PPE manufacturers (e.g., CDC-INFO, PPE hotline, x4000 line)
- Twitter / Social media (follow us on twitter @NPPTL, #fightingebola)

N95 Filtering Facepiece Respirator Shelf Life

Dana Rottach

NPPTL Technology Research Branch

Outline

- **Background**
- **Previous Results**
- **Properties of Concern**
- **Proposed Research Project**
- **Proposed Filter Efficiency / Resistance Testing**
- **Effect of Tether Tension Study Results**
- **Proposed Tensile Testing of Tethers**
- **Proposed Fit Test Protocol**
- **Statistical Methods**
- **Proposed Modeling/Simulation**
- **Expected Publications**

Background

- **N95 Filtering Facepiece Respirator (FFR) stockpiling is increasing**
- **No reported problems with performance of stockpiled FFRs**
- **NIOSH has received several questions from stockpile administrators**
 - *Are my respirators still effective?*
 - *What should I do with respirators past the manufacturer's shelf life?*

Previous Study Results

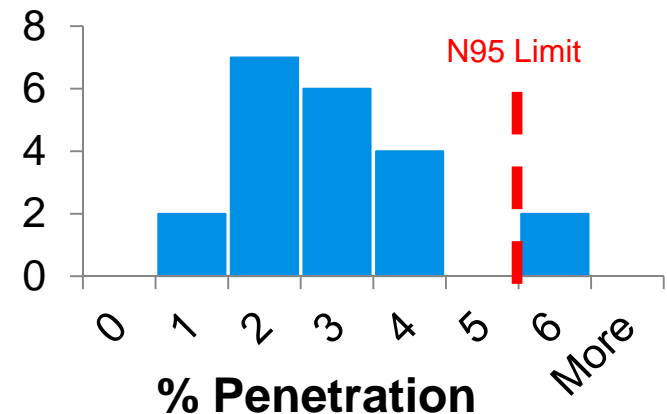
2010 - 2013 Audits of NIOSH Certified FFR

- 378 Stored Respirators Tested
- 27 Approval Failures
- All Failures Due To Penetration
 - Exhalation valve leakage seemed to increase
 - 57 passed valve leakage tests, no failures

21 N95 FFR models tested for filter efficiency & resistance

- Samples of convenience
- Stored in laboratory/office 5-10 years +
- 2 outside specified N95 range

Viscusi, D. J., Bergman, M., Sinkule, E., Shaffer, R. E. (2009).
American journal of infection control, 37(5), 381-386



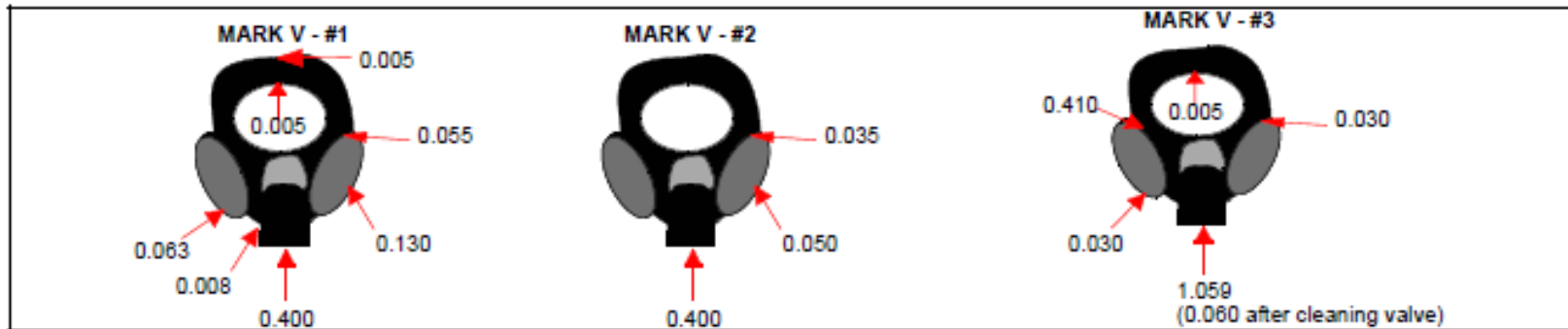
Exhalation Valve



Quick Assessment of the Navy Mark V CBR Respirator After 13 Years in Storage

Ryan J. Felling, Gregory A. Cherry, and Ronald A. Weiss
Survivability/Lethality Analysis Directorate, ARL 2003

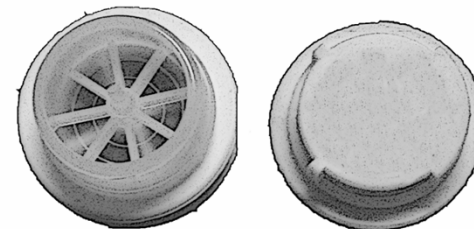
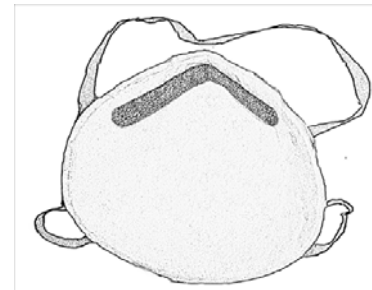
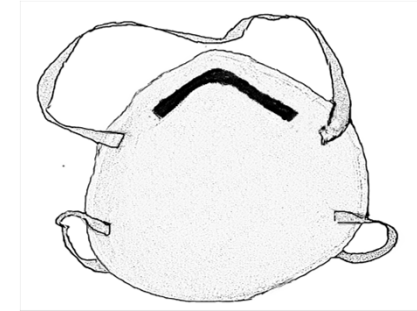
Leaks in tested samples (TDA-99D Mask Leakage Detector)



“The problem with the exhalation valve could be due to ... (A) loss of stiffness with age allowing the valve to prolapse ...”

Changes in N95 FFR Properties

- **Filtration efficiency may degrade**
- **Elastomeric tethers may change**
 - Oxidative degradation
 - Can make FFR fit more or less tight
- **Sealing foam may degrade**
 - Stiffness / Resilience
 - Reduced conformability
 - Foam may disintegrate
- **Exhalation valves may leak**



Occupational Safety and Health Administration (OSHA) requires fit testing to specific models- fit characteristics of aged N95 FFR must be similar to fresh FFR

Tether Tension: FFR Fit Simulation

Sensitivity Analysis of Important Parameters Affecting Contact Pressure Between a Respirator and a Headform, Dai, J., Yang, J., Zhuang, Z. (2011). International Journal of Industrial Ergonomics, 41, 268-279

Tether tension and sealing pressure

| Strap tensions | A Chin | B Nose bridge | C Cheekbone | D Cheekbone |
|----------------|-----------|------------------|----------------|----------------|
| 0.5 | 0.57 | 0.61 | 0.56 | 0.54 |
| 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| 2.0 | 1.6 | 0.87 | 1.6 | 1.5 |



Relationship between tether tension and sealing pressure can be complex

Proposed Research Project

Research Objectives

| | |
|---|-----------|
| <i>New Tests to Assess FFR Aging</i> | 2014-2016 |
| <i>Accelerated Aging Protocols for FFR</i> | 2015-2017 |

Testing

- Filter media: Filtration efficiency/resistance 2015-2016
- Valve: Changes in modulus of gasket 2014-2015
- Strap: Breakage and changes in stiffness 2014-2015
- Attachment: Strap release
- Whole respirator: Fit characteristics 2015

Sample Sources

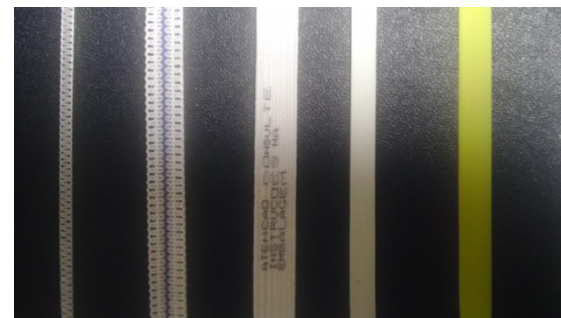
Excess from other NPPTL studies
Not from certification applications



[Strategic National Stockpile](#)

Existing Stockpiles
Federal/State/Other

Artificially Aged FFR
*Elevated heat and humidity /
Substituted components*



Reference to any specific products by name, image, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government.

FFR Component Performance Tests

Filter Efficiency/Breathing Resistance

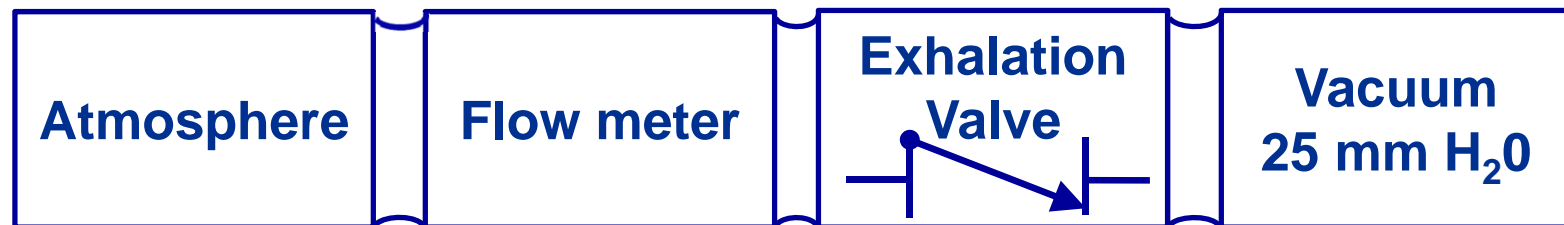
TSI 8130 Automated filter testing machine

- Used for certification (STPs 3,7, 59)
- Measures penetration and resistance

Exhalation Valve Leakage

NPPTL Exhalation Valve Test Assembly (STP 4)

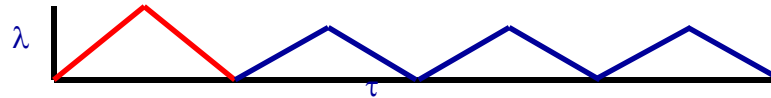
- Low leakage rates (certification max: 30 ml/min)
- Static closed valve testing



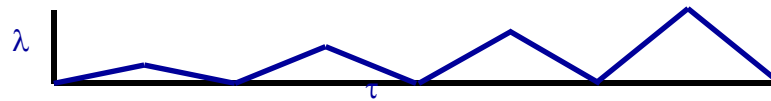
STP List: <http://www.cdc.gov/niosh/npptl/stps/APresp.html>

FFR Respirator Tether Tensile Testing

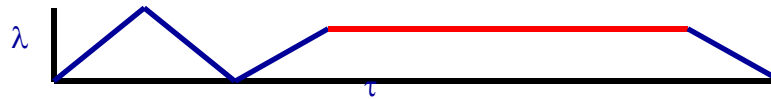
Elastic moduli *Larger first strain peak for Mullins prestretching*



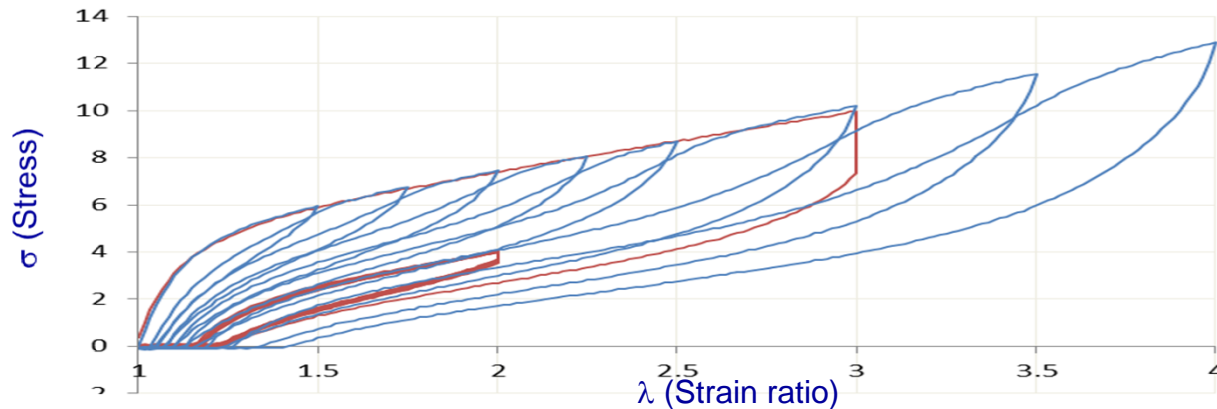
Mullins effect/stress softening *Increasing strain peaks*



Stress relaxation *Strain held as the stress decays*



Example
(Isoprene)



Arbitrarily choose $\lambda=2$ for strain comparisons

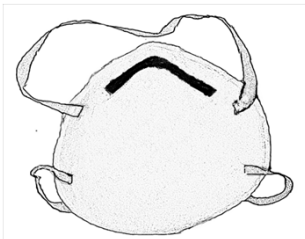
Fit Test Protocol

- OSHA quantitative fit test protocol
- 3 N95 FFR models for healthcare workers
- 25 test subjects
- Test fit on fresh and aged FFR

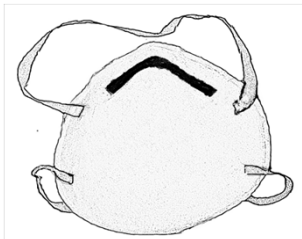
Procedure

- Fit tests: two fresh, three aged at one session

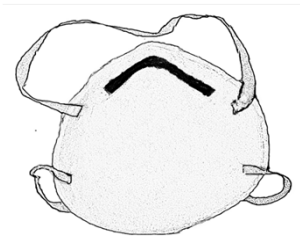
Randomized order- one fresh defined as standard



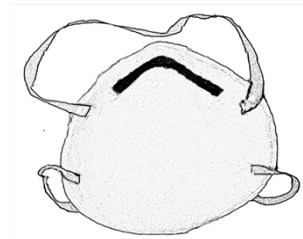
Standard (Fresh)



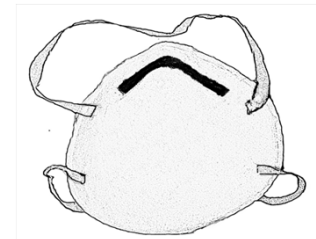
5 Years



Fresh



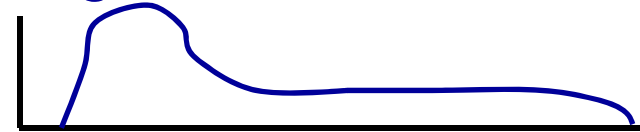
7 Years



3 Years

Statistical Analyses

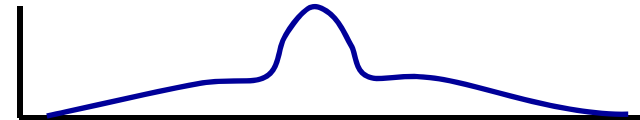
Sign test



Fit test panel, exhalation valve leakage

- Paired, unknown distributions
- Which is higher?
- Magnitude of difference ignored
- 95% confidence: 18/25 or better (19/25 for 95% overall)

Wilcoxon signed-rank test



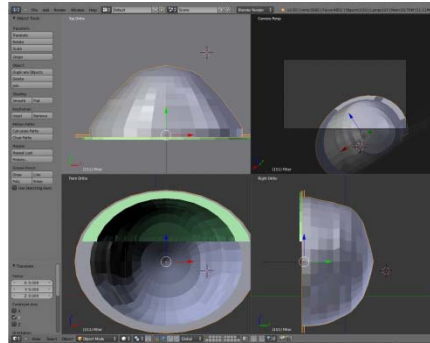
Filtration efficiency, resistance, tether modulus

- Paired, not necessarily gaussian distribution
- Symmetric differences about median(no one-sided long tail)
- Which is higher, and by how much?

Modeling/Simulation

Artificially aged respirators / performance prediction

Computational



Finite Element / Boundary Element Modeling

Headforms

Advanced Static Headform
Robotic Advanced Headform



M Bergman, Z Zhuang, R Shaffer

<http://blogs.cdc.gov/niosh-science-blog/2013/07/25/headforms/>

Planned Manuscript Topics

1. *Impact of time in storage on the elastic properties of the tether materials*
2. *Results of the fit test panel comparing respirators of different ages*
3. *A model of filtration incorporating electrostatic decay*
4. *Effect of aging on exhalation valves*
5. *Computational modeling of aging respirators to allow predictions of the shelf stability of described respirators*
6. *A combination of the previous research with a simple economic model*

Contact Information

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BREAK

Updates to the Standard Application Procedure (SAP)

Robert Stein
General Engineer
NIOSH - NPPTL

Application Guidance

The SAP has been providing application guidance since about 1995

- Greater uniformity to documentation packages
- Provides some more in-depth guidance on certain requirements
- From your point of view -
 - **What need is best or most often addressed through the SAP?**

Application

Don't get lost in the jargon

- **“Application”**

- What is it?
- Among other items, It is the document created by the SAF
- However, it is also the complete documentation package submitted in support of a request for approval under the provisions of 42 CFR, Part 84
- In the instances where they are required, the application is considered to be incomplete without –
 - Form of payment
 - Hardware
- The application may therefore also be thought of as this entire ensemble (paperwork, check, hardware)

We don't want to rehash old news

- **We know we have spent many hours talking about application faults**
- **They haven't gone away**
- **We would rather take this time today to talk about another layer of information.**
 - Characteristics of the approvals being sought

We need to know the nature of the approval

- Let's look at a couple of examples from the CEL to see what we mean
- [Sample Approval URL](#)
- [Sample Approval 2 URL](#)

The next version of the SAF will require this information to be provided

- **SAF V-9 will be a pdf-style form**
- **Some selection logic will be written in to help direct applicants to the correct information choices**
- **Some pieces of information are unique to particular types of respirators (air lines)**
- **Others are not (exhalation valve)**

The assembly matrix will be your guide

- **If the number of approvals is unclear, refer to the assembly matrix/matrices**
- **Each new row on the matrix represents a new approval**
- **Each new approval requires complete descriptive information**

We want to know if it is a surgical mask

- **There currently is no required order for the applications to be submitted**
- **However...**
 - If the respirator is cleared by the FDA as a surgical mask, tell us
 - If it is not yet cleared by the FDA, but you are seeking, or intend to seek clearance, tell us
 - Look for new places to provide these responses in the new SAF

Benefits will result from the investment

- **Time required for processing new approvals into the Certified Equipment List will be reduced**
- **Accuracy will be enhanced**
- **It provides an additional level of guidance to identify the instances in which multiple approvals are necessary**

There are a few more areas that will be receiving more coverage

- **Fees**
- **CBRN**
 - SCBA
 - APR
 - PAPR
 - APER
- **CCER**
- **Please let us know other areas where you would like to see more coverage**

We are compiling general helps for completion.

- **Application checklist**

Application Check List

1. Is the AAR (applicant assigned reference) Number unique to the approval request/application?
2. Have all the applicable sections of the Standard Application Form (SAF) been completed?
3. If hardware is included, are the individual hardware items for evaluation identified with the AAR number and part numbers referenced on the assembly matrix?
4. If hardware is included, is the shipping container marked with the associated AAR number and/or TN number?
5. If hardware is included, does the hardware shipped include a packing slip accurately identifying what was actually shipped?
6. If testing is to be performed, has the fee been sent to NPPTL? Is the fee check dated recently, less than 2 weeks before the application is to be submitted? Does the fee check include your EIN number if you are a US company or a US subsidiary?
7. Does the assembly matrix match what was requested in the Reason for Application section of the SAF? Does the Assembly Matrix and SAF represent the actual configuration of the new or modified approval?
8. Does the reason for application accurately reflect what is being sought in the way of new approvals or modifications to existing approvals?
9. Are all the files included with the application listed in the SAF?
10. Are all the files supplied in the acceptable file formats?
11. Are all the files properly identified/listed in the SAF?
12. Do the revision levels on all drawings match those listed on the assembly matrix?
13. Do the item numbers on the exploded view drawing match the item numbers on the assembly matrix?
14. Do all the part numbers on the approval labels match the part numbers listed in the assembly matrix?
15. Is all the required information present on the sub-component drawings or for filtering facepieces, respirator drawings as indicated on the appropriate checklists?
16. For filtering facepieces, are the abbreviated labels, primary company and private label company, listed and shown on page 2 of the drawing?
17. For all other respirators, are the abbreviated labels, primary company and private label company, listed and shown on page 2 of the subassembly, harness and/or abbreviated label drawing?
18. Are all applicable draft approval labels included with the application, (respirator, cartridges, filters and/or others as required)?
19. Do the assemblies identified on the label match those identified on the matrix (or matrices) with the possible exception of accessories?
20. Are all of the appropriate Caution and Limitation (C&L) statements identified on the individual approvals?
21. Are all of the C&L statements referred to on the approvals spelled out on the label(s)?
22. Do the user's instructions include all the required information, (OSHA 1910.134 statement on fit testing, donning instructions, assembly instructions, additional warnings and cautions, private

Your opinions count.

- **Is the concept of a checklist one that seems correct?**
- **Do you have suggestions for content?**

Contact Information

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LUNCH

NIOSH Approval Holder Site Audits

Vance Kochenderfer

Policy and Standards Development Branch

Purpose of the Site Audit Program

- **To ensure that manufactured respirators provide the level of protection for which they are labeled**
- **Certification testing tells us that you can make one batch of respirators that meets standards**
- **But what about all the respirators you make after that?**
 - Documented systems must be in place to control future production—site audits are how we verify those systems

Documented Quality System

- **Application review is the first step**
- **Site audits are how we verify the system is implemented and effective**
- **Make sure the documents in your application accurately reflect what you are doing!**
 - This is especially important when using outside consultants

Extent of the Site Audit Program

- **88 approval holders, 124 sites (as of March 2014)**
 - Any site where quality system activities take place, including design, purchasing, subcontractors, etc.
- **Audit frequency typically 2 or 4 years**
 - 2 years: production facilities (114)
 - 4 years: corporate offices (10)
- **Audit duration 1 or 2 days**
 - Facility size
 - Number of approvals held
 - Respirator complexity
 - Quality performance/problem history

Why Does NIOSH Care About...

- **...respirators sold outside the U.S.?**
 - Requirements apply to any respirator labeled as NIOSH-approved
- **...respirators that have been out of production?**
 - Tomorrow, you could start manufacturing these by the thousands
 - It is extremely difficult for us to arrange an audit on short notice

Conduct of Site Audits

- **Why we do not rely on third-party registration (e.g., ISO 9001):**
 - Specific requirements in 42 CFR 84 require special training and experience
 - Not all registrars are thorough
- **Audits resemble other types of management system audits**
 - Initiation (pre-audit survey) is done by NIOSH
 - Site visit is done by contracted auditors and/or NIOSH and MSHA employees
 - Follow-up on any nonconformances is done by NIOSH personnel

Questions?

- **Any questions relating to site audits can be directed to site audit coordinator**

Vance Kochenderfer

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- **Reference: Site Audit Q&A Letter to Manufacturers of September 30, 2014**

NIOSH NPPTL website

For Respirator Manufacturers

Additional Resources

Letters to All Manufacturers

Workgroups focusing on issues related to changes to the Standard Application Form and the Draft Application Checklist

BREAK

Workgroup Debriefing

Save the Date

December 2, 2014 – NIOSH/Industry Working Group meeting to discuss ideas for improving respirator approval processing times

- ISEA Headquarters, Arlington, VA
- For more information contact

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Quality Partnerships Enhance Worker Safety & Health



Visit Us at: <http://www.cdc.gov/niosh/npptl>

Disclaimer:

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Thank you