Effect of Stockpiling Conditions on the Performance of PPE that Protect Workers from Bloodborne Pathogens & Infectious Airborne Particulates

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National Personal Protective Technology Laboratory

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The National Personal Protective Technology Laboratory was created by NIOSH at the request of Congress in 2001 to...

*Prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies.*
CDC’s Office of Public Health Preparedness and Response funded NPPTL to...

Explore the effect of stockpile conditions such as

- Storage time
- Temperature
- Humidity

on PPE that protects workers from

- Bloodborne Pathogens (i.e., surgical gowns)
- Infectious Airborne Particulates (i.e., respirators)
The impact of stockpile conditions on PPE performance is an important emergency response issue because...

18M HCWs & Public Depend on It
- Supply chain shortages during H1N1 & H7N9*
- Variable resources = variable stockpile conditions → absence of data to ensure PPE remain protective

Shelf Life & Economic Concerns
- When should PPE w/o a shelf life be replaced?*
- Is it necessary to replace PPE that have met its shelf life?—advanced aging methods used to establish shelf life need further development*

*Indicates area of past or current NPPTL research

Photos courtesy: 3M, Kimberly Clark, Moldex
The objective of this project is to provide stockpile facilities, manufacturers, and regulators with...

Evidence-based recommendations for particulate air-purifying respirators (APR) and Level 3 and 4 surgical gowns

- Shelf life
- Storage practices
- Post-market conformity assessment at the point-of-use

Photo courtesy: CDC
The specific aims of this post-market surveillance study are to...

Aim 1: Develop a sampling protocol that may be applied to any hospital, city, county, state, or federal PPE stockpile

Aim 2: Test and evaluate APRs and surgical gowns from stockpile facilities with common U.S. stockpile conditions (includes human subjects testing for APR fit testing)

Aim 3: Analyze and interpret data to determine
   – Performance of APRs and surgical gowns under common U.S. stockpile conditions over time
   – Factors that contribute to PPE degradation over time

To support this effort, NPPTL established a PPE Stockpile Partnership...
Sampling Plan

Developed with input from
1. PPE Stockpile Partnership
2. Federal Register Notice
3. Interviews with stockpile managers
4. Review of environmental and inventory data for numerous facilities
Three facility categories were defined based on the facility’s ability to meet the mfr. recommended temperature and humidity storage conditions.

1. **Meets Recommendations**—Controls environment to meet pre-established storage conditions; demonstrated by available routine monitoring data.

2. **May Meet Recommendations**—Few environmental controls or no controls but local ambient climate generally aligns with mfr. recommended storage conditions; monitoring may or may not exist.

3. **Unlikely to Meet Recommendations**—No environmental controls or monitoring exist, and local ambient climate does not align with mfr. recommended storage conditions.

*Facilities representing each category have been identified by NPPTL.*
Eight stockpile facilities have agreed to collaborate with NPPTL for this study.

- 2 “Meets Recs”
  - Temperature and humidity data provided
  - APR and surgical gown inventories provided

- 2 “May Meet Recs” & 4 “Unlikely to Meet Recs”
  - NPPTL will send data loggers to collect environmental data for 1 year
  - APR and surgical gown inventories provided
Where two production lots exist, the following sampling will be conducted...

Respirators (53 per lot; 8 facilities)

- All APRs that are common to multiple stockpiles—only one size for a single model per stockpile
- All APRs for smaller stockpiles—some models unique to that facility
- Targeted APRs in stockpile for the following time frames
  - 0 to <5 years (None available)
  - 5 to <10 years
  - ≥ 10 years

Surgical Gowns (50 per lot; 5 facilities)

- Selection very limited
- All gown models sampled—more than one size of same model taken
- Targeted gowns in stockpile for the following time frames
  - 0 to <5 years
  - 5 to <10 years
  - ≥ 10 years

# products per lot based on testing plan (described later)
12 APR models sampled in total: 3,710 APRs to be tested, some exceeding mfr.-recommended shelf life.

- 11 N95 filtering facepiece, 1 P95 filter → variety of design approaches important b/c respirators defined by performance, not composition

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>N95 3M 1860</th>
<th>N95 KC Tecnol PFR95 (small)</th>
<th>N95 KC Tecnol PFR95 (regular)</th>
<th>N95 3M 8000</th>
<th>N95 1870</th>
<th>N95 Gerson 1730</th>
<th>N95 3M 9010</th>
<th>N95 Alpha Pro Tech</th>
<th>N95 Sperian ONE-Fit</th>
<th>N95 Willson ONE-Fit</th>
<th>P95 3M 2071</th>
<th>Total Respirators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meets Recs</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
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<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>318</td>
</tr>
<tr>
<td>Meets Recs</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
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<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>424</td>
</tr>
<tr>
<td>May Meet Recs</td>
<td>&gt;10 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
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<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>636</td>
</tr>
<tr>
<td>May Meet Recs</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
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<td>&gt;10 yrs.</td>
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<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>318</td>
</tr>
<tr>
<td>Unlikely to Meet Recs</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>742</td>
</tr>
<tr>
<td>Unlikely to Meet Recs</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>636</td>
</tr>
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<td>&gt;10 yrs.</td>
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<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>424</td>
</tr>
<tr>
<td>Unlikely to Meet Recs</td>
<td>&gt;10 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>&gt;10 yrs.</td>
<td>212</td>
</tr>
</tbody>
</table>

Total 3,710
Level 3 & Level 4 gown models sampled: 900 gowns to be tested.

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Level 3 Medline Proxima</th>
<th>Level 3 Cardinal Health Astound</th>
<th>Level 4 Medline Prevention +</th>
<th>Level 4 Halyard Health Microcool</th>
<th>Total Gowns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meets Recs</td>
<td>0 to &lt;5 yrs.</td>
<td>0 to &lt;5 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td></td>
<td>300</td>
</tr>
<tr>
<td>Meets Recs</td>
<td>5 to &lt;10 yrs.</td>
<td></td>
<td></td>
<td>5 to &lt;10 yrs.</td>
<td>200</td>
</tr>
<tr>
<td>May Meet Recs</td>
<td>≥10 yrs.</td>
<td>5 to &lt;10 yrs.</td>
<td></td>
<td></td>
<td>200</td>
</tr>
<tr>
<td>May Meet Recs</td>
<td>5 to &lt;10 yrs.</td>
<td></td>
<td></td>
<td></td>
<td>100</td>
</tr>
<tr>
<td>Unlikely to Meet Recs</td>
<td>≥10 yrs.</td>
<td></td>
<td></td>
<td></td>
<td>100</td>
</tr>
</tbody>
</table>

Photo courtesy: partsonline.diamedicalusa.com
NPPTL researchers will travel to each facility to collect product samples and note factors that could influence performance based on

- Previous NPPTL research (convenience sample of stockpiled respirators)
- Discussions w/ mfrs. and stockpile managers

First facility sampled in August 2017
Fully Controlled
# 1. Inspect Site/Facility

## SITE INSPECTION CHECKLIST

This form is to be filled out at the facility at the time of collection about the individual boxes.

<table>
<thead>
<tr>
<th>Site</th>
</tr>
</thead>
</table>

| Does the site have potential exposure to **chemicals**? | ☐ YES ☐ NO |
| Please describe. |

| Does the site have potential exposure to **moisture** damage? | ☐ YES ☐ NO |
| Please describe. |

| Does the site have potential exposure to **daily sunlight**? | ☐ YES ☐ NO |
| Please describe. |

| Does the site have potential exposure to **dusty conditions**? | ☐ YES ☐ NO |
| Please describe. |

Photos from Facility #1

Temp/humidity sensor
# 2. Inspect Pallet

## PALLET INSPECTION CHECKLIST

This form is to be filled out at the facility at the time of collection about the individual boxes.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>Manufacturer lot number</th>
</tr>
</thead>
</table>

- **Is the pallet shrink wrapped?**
  - ☐ YES ☐ NO

- **Does the pallet show signs that the respirators are potentially exposed to chemicals?**
  - ☐ YES ☐ NO

- **Please describe.**

- **Does the pallet show signs that the respirators are potentially exposed to moisture damage?**
  - ☐ YES ☐ NO

- **Please describe.**

- **Does the pallet show signs that the respirators are potentially exposed to daily sunlight?**
  - ☐ YES ☐ NO

- **Please describe.**

- **Does the pallet show signs that the respirators are potentially exposed to direct light?**
  - ☐ YES ☐ NO

- **Please describe.**

- **Does the pallet show signs that the respirators are potentially exposed to dusty conditions?**
  - ☐ YES ☐ NO

- **Please describe.**

- **Pallet location on rack/stack**
  - ☐ Top ☐ Middle ☐ Bottom
  - ☐ Exterior ☐ Interior
  - ☐ No weight ☐ Weight

- **Reason to expect localized environmental concern? (10 feet from...)**
  - ☐ YES ☐ NO

- **Exterior edge (floor, ceiling, wall) ☐ Window ☐ Door ☐ □**

- **Ventilation system ☐ Other ☐ □**
3. Inspect Case

**CASE INSPECTION CHECKLIST**
This form is to be filled out at the facility at the time of collection about the individual boxes.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>Manufacturer lot number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Does the case show signs that the respirators are potentially exposed to **chemicals**?  
☐ YES  ☐ NO  
Please describe.

Does the case show signs that the respirators are potentially exposed to **moisture** damage?  
☐ YES  ☐ NO  
Please describe.

Does the case show signs that the respirators are potentially exposed to **daily sunlight**?  
☐ YES  ☐ NO  
Please describe.

Does the case show signs that the respirators are potentially exposed to **direct light**?  
☐ YES  ☐ NO  
Please describe.

Does the case show signs that the respirators are potentially exposed to **dusty conditions**?  
☐ YES  ☐ NO  
Please describe.

Case location on pallet  
☐ Top  ☐ Middle  ☐ Bottom  
☐ Exterior  ☐ Interior  
☐ No weight  ☐ Weight

**Photos from Facility #1**  
Check for damage, dust
4. Inspect Individual Box/Bag

<table>
<thead>
<tr>
<th>BOX INSPECTION CHECKLIST</th>
</tr>
</thead>
<tbody>
<tr>
<td>This form is to be filled out at the facility at the time of collection about the individual boxes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>Lot number</th>
<th>ID Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>01-01-A-Box A</td>
</tr>
</tbody>
</table>

Expiration date ___ / ___ / ___   Manufacturer date ___ / ___ / ___

<table>
<thead>
<tr>
<th>Box location with respect to case:</th>
<th>Top</th>
<th>Middle</th>
<th>Bottom</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Exterior</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[ ] Interior</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[ ] No weight</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[ ] Weight</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Are the respirators stored outside of the original box? [ ] YES [ ] NO

If applicable, is original box faded, discolored, moldy or damaged? [ ] YES [ ] NO [ ] N/A

Please describe.

If applicable, is the plastic layer inside the original box broken, inadvertently opened, cut, or damaged? [ ] YES [ ] NO [ ] N/A

Please describe.

Does the box show signs that the respirators are potentially exposed to chemicals? [ ] YES [ ] NO

Please describe.

Does the box show signs that the respirators are potentially exposed to moisture damage? [ ] YES [ ] NO

Please describe.

Does the box show signs that the respirators are potentially exposed to daily wear-and-tear? [ ] YES [ ] NO

Photo from Facility #1
Respirators—53 tested per production lot

1) Visually inspect: damage, degradation, molding, etc.
2) NIOSH STP 3, 7: Inhalation and Exhalation Resistance
3) NIOSH STP 4: Exhalation Valve Leakage
4) NIOSH STP 59: Particulate Filter Efficiency for N95
5) NIOSH STP 53: Liq. Particulate Filter Efficiency for P95
6) ASTM D412: Rubber/Elastomer Tensile Strength

Level 3 and Level 4 Surgical Gowns—50 tested per production lot

1) Visually inspect
2) AATCC 42: Water Resistance: Impact Penetration—Level 3 and front of Level 4 gowns
3) AATCC 127: Water Resistance: Hydrostatic Pressure Test—Level 3 gowns
4) ASTM F1671: Penetration by Bloodborne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System—Level 4 gowns
5) Sterility—approach still under discussion with FDA
Current Results From Facility #1
Meets Recommendations
## Current data available for Facility #1 (Meets Recs.)

<table>
<thead>
<tr>
<th>Manufacturer &amp; Model</th>
<th>Particulate Filter Efficiency for N95 ≤5% Penetration</th>
<th>Exhalation Resistance &lt;25 mm H₂O Column</th>
<th>Inhalation Resistance &lt;35 mm H₂O Column</th>
<th>Quant. Fit Testing Compare to Control</th>
<th>Rubber/Elastomer Tensile Strength Compare to Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gerson 1730 (Mfr. 2006)</td>
<td>Lot 1: All passed Lot 2: All passed</td>
<td>Lot 1: All passed Lot 2: All passed</td>
<td>Lot 1: All passed Lot 2: All passed</td>
<td>Lot 1: TBD Lot 2: TBD</td>
<td>Lot 1: TBD Lot 2: TBD</td>
</tr>
</tbody>
</table>
Analysis Plan
“Within facility” and “between facility” comparisons are planned to explore the influence on performance and fit (APR only) of factors such as...

- Facility type
- Manufacturer/Model
- Manufacturer date
- Years in storage
- Facepiece vs. filter type
- Strap material, attachment
- Pallet shrink-wrapped
- Exposure to light source, dust, chemicals, UV light

- How do performance results compare to approval/certification requirements?
- Is there evidence to support extending shelf life recommendations?
- Is there evidence to support developing shelf life recommendations where none exist?
- What ‘best practices’ exist for stockpiling?
Timeline

• Respirator testing estimated to be complete for all 8 facilities by November 2018

• Surgical gown testing estimated to be complete for all 5 facilities by January 2019
Potential Considerations
Considerations depending on study findings...

- If data supports extending shelf life, how might NIOSH support voluntary shelf life extension programs for respirators and gowns?

- If data suggests that many stockpiled products may not be protective, how might NIOSH drive the need for change in emergency response planning?
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