

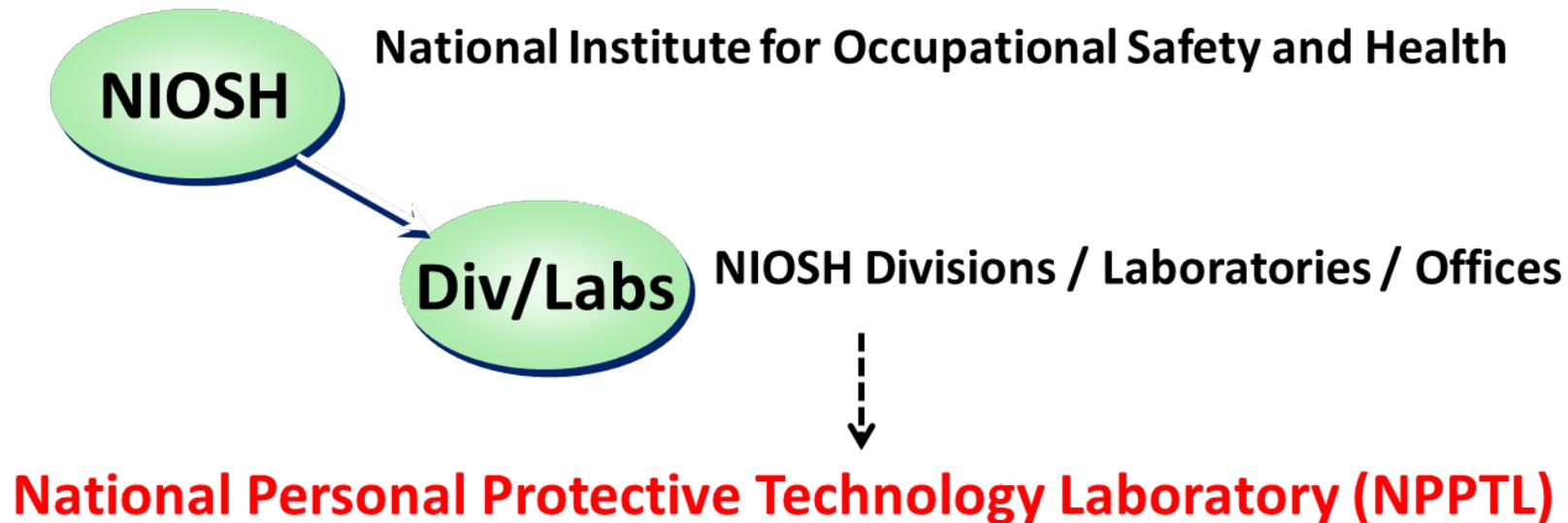
***Effect of Stockpiling Conditions on
the Performance of PPE that Protect Workers from
Bloodborne Pathogens & Infectious Airborne Particulates***

**Presenter: Susan M. Moore, PhD
Project Lead: Lee A. Greenawald, PhD
National Personal Protective Technology Laboratory**

**NIOSH Board of Scientific Counselors Meeting
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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.



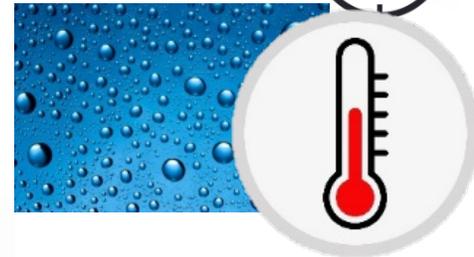
CDC's Office of Public Health Preparedness and Response funded NPPTL to...

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...

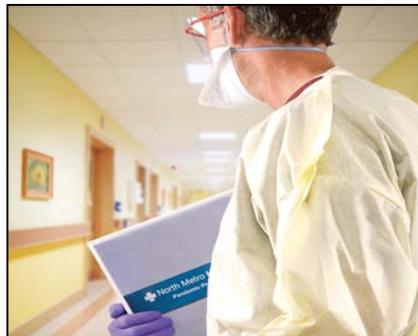
18M HCWs & Public Depend on It

- 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...



Federal Agency and Stockpile



JOHNS HOPKINS MEDICINE

UPMC



Hospital Stockpile



State Stockpile



City Stockpile



County Stockpile



Mfr. & Accreditor Representation

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

NPPTL Announcement

An Opportunity to Influence Study Design for a Research Effort Evaluating Stockpiled PPE

Comment Period

March 24, 2017— April 24, 2017

NIOSH wants your feedback!

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention announces a request for information regarding facilities that stockpile N95 respirators and Level 3 and Level 4 protective surgical gowns.

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



Photos courtesy: Shutterstock

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

Facility Type	N95 3M 1860	N95 KC Tecnol PFR95 (small)	N95 KC Tecnol PFR95 (regular)	N95 3M 8000	N95 3M 1870	N95 Gerson 1730	N95 3M 9010	N95 Alpha Pro Tech	N95 3M 8210	N95 Sperian ONE-Fit	N95 Willson ONE-Fit	P95 3M 2071	Total Respirators
Meets Recs	5 to <10 yrs.	≥10 yrs.		≥10 yrs.									318
Meets Recs	5 to <10 yrs.					5 to <10 yrs.		5 to <10 yrs.					424
May Meet Recs	≥10 yrs.	5 to <10 yrs. ≥10 yrs.			5 to <10 yrs.		≥10 yrs.		≥10 yrs.				636
May Meet Recs	5 to <10 yrs. ≥10 yrs.					5 to <10 yrs.							318
Unlikely to Meet Recs	5 to <10 yrs. ≥10 yrs.	≥10 yrs.			5 to <10 yrs.		≥10 yrs.		≥10 yrs.			≥10 yrs.	742
Unlikely to Meet Recs	5 to <10 yrs. ≥10 yrs.		5 to <10 yrs. ≥10 yrs.		5 to <10 yrs. ≥10 yrs.								636
Unlikely to Meet Recs	5 to <10 yrs. ≥10 yrs.		5 to <10 yrs. ≥10 yrs.										424
Unlikely to Meet Recs										5 to <10 yrs.	5 to <10 yrs.		212
Total												3,710	

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



Photo courtesy: partsonline.diamedicalusa.com

Facility Type	Level 3 Medline Proxima	Level 3 Cardinal Health Astound	Level 4 Medline Prevention +	Level 4 Halyard Health Microcool	Total Gowns
Meets Recs	0 to <5 yrs.	0 to <5 yrs.	5 to <10 yrs.		300
Meets Recs	5 to <10 yrs.			5 to <10 yrs.	200
May Meet Recs	≥10 yrs.	5 to <10 yrs.			200
May Meet Recs	5 to <10 yrs.				100
Unlikely to Meet Recs		≥10 yrs.			100
					900

Sample Collection

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

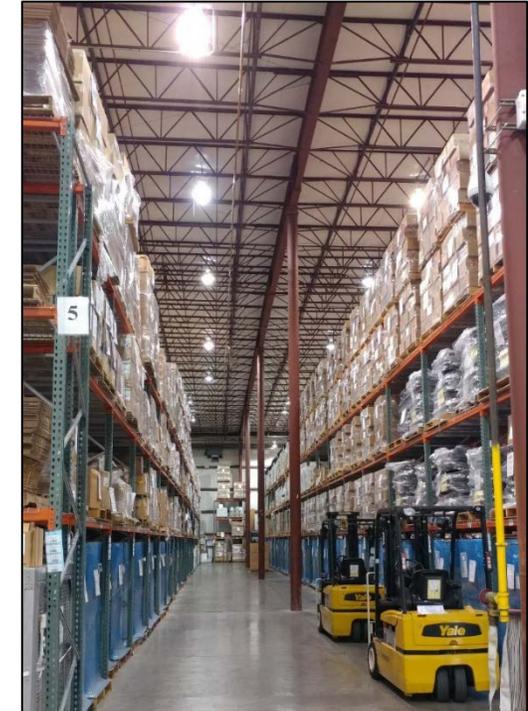
1. Inspect Site/Facility

SITE INSPECTION CHECKLIST

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

Site

Does the site have potential exposure to chemicals ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the site have potential exposure to moisture damage?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the site have potential exposure to daily sunlight ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the site have potential exposure to dusty conditions ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe	



Temp/humidity sensor

2. Inspect Pallet

Photos from Facility #1

PALLET INSPECTION CHECKLIST	
This form is to be filled out at the facility at the time of collection about the individual boxes.	
_____ Manufacturer	_____ Model
_____ Manufacturer lot number	
Is the pallet shrink wrapped ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Does the pallet show signs that the respirators are potentially exposed to chemicals ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the pallet show signs that the respirators are potentially exposed to moisture damage?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the pallet show signs that the respirators are potentially exposed to daily sunlight ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the pallet show signs that the respirators are potentially exposed to direct light ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the pallet show signs that the respirators are potentially exposed to dusty conditions ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Pallet location on rack/stack	<input type="checkbox"/> Top <input type="checkbox"/> Middle <input type="checkbox"/> Bottom <input type="checkbox"/> Exterior <input type="checkbox"/> Interior <input type="checkbox"/> No weight <input type="checkbox"/> Weight
Reason to expect localized environmental concern? (10 feet from...)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Exterior edge (floor, ceiling, wall) <input type="checkbox"/> Window <input type="checkbox"/> Door <input type="checkbox"/>	
Ventilation system <input type="checkbox"/> Other <input type="checkbox"/> _____	



3. Inspect Case

Check for damage, dust

Photos from Facility #1

CASE INSPECTION CHECKLIST	
This form is to be filled out at the facility at the time of collection about the individual boxes.	
_____ Manufacturer	_____ Model
_____ Manufacturer lot number	
Does the case show signs that the respirators are potentially exposed to chemicals ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the case show signs that the respirators are potentially exposed to moisture damage?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the case show signs that the respirators are potentially exposed to daily sunlight ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the case show signs that the respirators are potentially exposed to direct light ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the case show signs that the respirators are potentially exposed to dusty conditions ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Case location on pallet	<input type="checkbox"/> Top <input type="checkbox"/> Middle <input type="checkbox"/> Bottom <input type="checkbox"/> Exterior <input type="checkbox"/> Interior <input type="checkbox"/> No weight <input type="checkbox"/> Weight



4. Inspect Individual Box/Bag

BOX INSPECTION CHECKLIST

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

_____ 01-01-A-Box A
 Manufacturer Model Lot number ID Code
Site-Mfr-Model-Box-Letter
 Expiration date / / Manufacturer date / /

Box location with respect to case:	<input type="checkbox"/> Top <input type="checkbox"/> Middle <input type="checkbox"/> Bottom
<input type="checkbox"/> Exterior <input type="checkbox"/> Interior	<input type="checkbox"/> No weight <input type="checkbox"/> Weight
Are the respirators stored outside of the original box?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If applicable, is original box faded, discolored, moldy or damaged ?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Please describe	
If applicable, is the plastic layer inside the original box broken, inadvertently opened, cut, or damaged ?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Please describe	
Does the box show signs that the respirators are potentially exposed to chemicals ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the box show signs that the respirators are potentially exposed to moisture damage?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Please describe.	
Does the box show signs that the respirators are potentially exposed to daily	

Photo from Facility #1



Testing Plan

NPPTL will test/evaluate respirators and surgical gowns as follows...

Respirator Visual Inspection Checklist

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*
- 7) 29 CFR 1910.134 A: *Quantitative Fit Testing (IRB Pending)*

Take picture if marked "yes".

- | | |
|--|--|
| 1. Does the respirator have an odor ? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 2. Is the respirator deformed in any way ? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 3. Is the nose bridge cracked, corroded, or detached ? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 4. Is the nose foam flaking or appear damaged ? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 5. Does the respirator appear moldy ? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 6. If applicable, are the staples attaching the straps cracked, corroded, or rusty ? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 7. Are the straps detached from the respirator? | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 8. Are the straps damaged in any way? | <input type="checkbox"/> YES <input type="checkbox"/> NO |

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.)

Manufacturer & Model	Particulate Filter Efficiency for N95 ≤5% Penetration	Exhalation Resistance <25 mm H ₂ O Column	Inhalation Resistance <35 mm H ₂ O Column	Quant. Fit Testing Compare to Control	Rubber/Elastomer Tensile Strength Compare to Control
Gerson 1730 (Mfr. 2006) ▪ 6 yrs. in stockpile ▪ 1 vis. insp. concern	Lot 1: All passed Lot 2: All passed	Lot 1: All passed Lot 2: All passed	Lot 1: All passed Lot 2: All passed	Lot 1: TBD Lot 2: TBD	Lot 1: TBD Lot 2: TBD
3M 1860 (Mfr. 2008) ▪ 8 yrs. in stockpile ▪ 0 vis. insp. concern	Lot 1: All passed Lot 2: All passed	Lot 1: All passed Lot 2: All passed	Lot 1: All passed Lot 2: All passed	Lot 1: TBD Lot 2: TBD	Lot 1: TBD Lot 2: TBD
3M 1860 (Mfr. 2009) ▪ 8 yrs. in stockpile ▪ 0 vis. insp. concern	Lot 1: All passed Lot 2: All passed	Lot 1: All passed Lot 2: All passed	Lot 1: All passed Lot 2: All passed	Lot 1: TBD Lot 2: TBD	Lot 1: TBD Lot 2: TBD
Alpha Pro Tech (Mfr. 2008) ▪ 6 yrs. in stockpile ▪ TBD vis. insp. concern	Lot 1: TBD Lot 2: TBD	Lot 1: TBD Lot 2: TBD	Lot 1: TBD Lot 2: TBD	Lot 1: TBD Lot 2: TBD	Lot 1: TBD Lot 2: TBD

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?



Photos courtesy: <http://www.disability-europe.net>

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