How well are you protected? What healthcare workers need to know about gown standards and selection considerations

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National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory

Photo Credit: CDC PHIL 19199

Minnesota Department of Health
November 20, 2018 11:00AM CT
Outline

CDC’s Ebola PPE recommendations

Current healthcare protective clothing standards

Protective clothing selection process and important considerations

Ongoing NIOSH research projects with gowns
Background

- The 2014 Ebola epidemic in West Africa was the largest in history

2014 Ebola Epidemic Facts:

>28,500 cases
>11,000 deaths

>900 healthcare worker cases
>500 healthcare worker deaths

- In the country most affected, the confirmed Ebola incidence rate was over a hundredfold higher in healthcare workers (HCWs) than the general population

CDC’s Recommended Protective Clothing for Healthcare Workers

- Single-use (disposable) **fluid-resistant gown/coverall**: Recommended while evaluating and managing persons under investigation (PUIs) for Ebola who are clinically stable and do not have bleeding, vomiting, or diarrhea (at a minimum)
- Single-use (disposable) **impermeable gown/coverall**: Recommended when caring for a patient with confirmed Ebola or unstable PUI

<table>
<thead>
<tr>
<th>Table: Specifications for fluid-resistant and impermeable gowns and coveralls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fluid-resistant</strong></td>
</tr>
<tr>
<td>Surgical or isolation* gown that passes:</td>
</tr>
<tr>
<td>• ANSI/AAMI PB70 Level 3 requirements</td>
</tr>
<tr>
<td>or</td>
</tr>
<tr>
<td>• EN 13795 high performance surgical</td>
</tr>
<tr>
<td>gown requirements</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Impermeable</strong></td>
</tr>
<tr>
<td>Surgical or isolation* gown that passes:</td>
</tr>
<tr>
<td>• ANSI/AAMI PB70 Level 4 requirements</td>
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<tr>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

*Testing by an ISO 17025 certified third party laboratory is recommended.

Protective Clothing Selection Process

Conduct Hazard Assessment
• Source
• Modes of transmission
• Pressure and type of contact
• Duration and type of tasks
• Stage of disease
• Severity of symptoms

Identify Standards or Specifications
• HCW gown and coverall classification standards, specifications, test methods
• National, international

Select Appropriate Protective Clothing
• Regulations
• Practices

Photo Credit: CDC PHIL 10816
Microorganisms’ Movement through Protective Clothing Materials

- Pore characteristics (size, volume, geometry, and orientation)
- Repellency
- Thickness
- Thread count (woven)

External Factors
- Shape
- Size
- Morphology
- Polarity
- Motility
- Adaptation to environmental extremes

Characteristics of Microorganisms
- Physical and Chemical Properties of the Fabric
- Characteristics of Carriers

- Surface Tension
- Volume
- Viscosity

- Physical, chemical, and thermal stresses
Bloodborne Pathogen Strikethrough

- Microorganisms are transported by carriers such as body fluids, sloughed skin cells, lint, dust, and respiratory droplets. A significant number of microorganisms can be carried in a very minute volume of blood or body fluids, which may not be visible to the naked eye.

<table>
<thead>
<tr>
<th>Volume of strike-through (1)</th>
<th>100 µL</th>
<th>10 µL</th>
<th>1 µL</th>
<th>0.1 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>size</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td><img src="https://via.placeholder.com/100" alt="Image" /></td>
<td><img src="https://via.placeholder.com/50" alt="Image" /></td>
<td><img src="https://via.placeholder.com/25" alt="Image" /></td>
</tr>
<tr>
<td>Number of bloodborne pathogens (2)</td>
<td>HBV 10,000,000</td>
<td>HCV 100–100,000</td>
<td>HIV 6–700</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,000,000</td>
<td>10–100,000</td>
<td>0.6–70</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100,000</td>
<td>1–1,000</td>
<td>0.06–7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10,000</td>
<td>0.1–100</td>
<td>0.006–0.7</td>
<td></td>
</tr>
</tbody>
</table>

(1) Volume of red 40 dyne/cm synthetic blood delivered to white blotter paper.
(2) Based on documented whole blood concentrations of infected patients.

Terminology

- Fluid-resistant
- Fluid-proof
- Fluid-repellent
- Impervious
- Moisture-proof
- Moisture-resistant
- Impermeable
- Liquid-proof
- Liquid-resistant
Considerations for Protective Clothing Selection

- **Design of protective clothing**
  - No clinical studies have been done to compare the efficacy of gowns vs. coveralls
  - Coveralls: provide 360 degree protection
  - Gowns: relatively easier to put on/remove, and more familiar to HCWs, hence more likely to be used and removed correctly. The level of heat stress generated is also expected to be less compared to coveralls

- **Critical fabric and clothing properties**
  - Strength properties of the fabric and seams (e.g., tensile strength and seam strength)
  - Barrier properties of seams/closures
  - Size of the garment

- **Donning and doffing features of protective clothing**
  - The ease or difficulty with which PPE is put on and removed may affect its effectiveness and the potential for self-contamination

- **Other factors**
  - These include factors such as compliance with regulatory agencies, durability (abrasion resistance), comfort (breathability, air permeability), flammability, electrostatic properties, cost, availability, ergonomics/human factors, and integration with other types of PPE
Current Healthcare Protective Clothing Standards and Specifications
Standards and Specifications for Gowns

- **ANSI/AAMI PB70** - Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities
  - Applies to surgical gowns and isolation gowns

- **EN 13795** - Surgical drapes, gowns, and clean air suits, used as medical devices for patients, clinical staff, and equipment. General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels.
  - Applies to surgical gowns

- **ASTM F2407** - Standard specification for surgical gowns intended for use in healthcare facilities
  - Applies to surgical gowns
<table>
<thead>
<tr>
<th>Level</th>
<th>Test</th>
<th>Liquid Challenge</th>
<th>Result*</th>
<th>Expected Barrier Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AATCC 42</td>
<td>Water</td>
<td>≤ 4.5 g</td>
<td>Minimal water resistance (some resistance to water spray)</td>
</tr>
<tr>
<td></td>
<td>AATCC 127</td>
<td>Water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>AATCC 42</td>
<td>Water</td>
<td>≤ 1.0 g</td>
<td>Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)</td>
</tr>
<tr>
<td></td>
<td>AATCC 127</td>
<td>Water</td>
<td>≥ 20cm</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>AATCC 42</td>
<td>Water</td>
<td>≤ 1.0 g</td>
<td>Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)</td>
</tr>
<tr>
<td></td>
<td>AATCC 127</td>
<td>Water</td>
<td>≥ 50cm</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>ASTM F1670 (for surgical drapes) ASTM F1671 (for surgical gowns and other protective apparel)</td>
<td>Surrogate blood Bacteriophage Phi-X174</td>
<td>Pass Pass</td>
<td>Blood and viral penetration resistance (2 psi)</td>
</tr>
</tbody>
</table>

All have an Acceptance Quality level (AQL) of 4% and Rejectable Quality Level (RQL) of 20%
ANSI/AAMI PB70 Critical Zones for Gowns

Adapted with permission from ANSI/AAMI PB70:2012, “Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities”
## Standard Test Methods to Evaluate the Resistance of Fabrics to Water

<table>
<thead>
<tr>
<th>Barrier Property</th>
<th>AATCC Test Methods</th>
<th>ISO Test Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Resistance – Impact Penetration</td>
<td><strong>AATCC 42</strong></td>
<td><strong>ISO 9073-17</strong></td>
</tr>
<tr>
<td></td>
<td>Determines the ability of a material to resist water penetration under spray impact</td>
<td>Determines the ability of a material to resist water penetration under spray impact</td>
</tr>
<tr>
<td>Water Resistance – Hydrostatic Pressure</td>
<td><strong>AATCC 127</strong></td>
<td><strong>ISO 9073-16</strong></td>
</tr>
<tr>
<td></td>
<td>Determines the ability of a material to resist water penetration under constant contact with increasing pressure</td>
<td>Determines the ability of a material to resist water penetration under constant contact with increasing pressure</td>
</tr>
</tbody>
</table>

Note: These tests are typically conducted on fabrics, but they can be conducted on the garment seams/closures as well.
Barrier Performance Test Methods - Impact Penetration Test

AATCC 42: Water Resistance: Impact Penetration Test

- Used to determine the ability of a material to resist water penetration under single spray contact
- Sample is oriented at a 45 degree angle and clamped in place over a piece of preweighed blotter paper
- Water is released from a funnel
- Blotter is weighed again
- Weight gain \( \downarrow \) resistivity \( \uparrow \)
Barrier Performance Test Methods – Hydrostatic Pressure Test

AATCC 127: Water Resistance: Hydrostatic Pressure Test

- Used to determine the ability of a material to resist water penetration under constant contact with increasing pressure
- Sample is clamped in place horizontally, and the hydrostatic pressure is steadily increased by raising the height of the water column
- Terminated when visible penetration of water droplets occurs
- Hydrostatic pressure \( \uparrow \) resistivity \( \uparrow \)
### Standard Test Methods to Evaluate the Resistance of Fabrics to Synthetic Blood & Virus Penetration

<table>
<thead>
<tr>
<th>Barrier Property</th>
<th>ASTM Test Methods</th>
<th>ISO Test Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synthetic Blood Penetration</td>
<td><strong>ASTM F1670</strong> — Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood</td>
<td><strong>ISO 16603</strong> — Determination of the resistance of protective clothing materials to penetration by blood and body fluids—Test method using synthetic blood</td>
</tr>
<tr>
<td>Viral Penetration</td>
<td><strong>ASTM F1671</strong> — Standard test method for resistance of materials used in protective clothing to penetration by bloodborne pathogens using Phi-X174 bacteriophage penetration as a test system</td>
<td><strong>ISO 16604</strong> — Determination of resistance of protective clothing materials to penetration by bloodborne pathogens—Test method using Phi-X174 bacteriophage</td>
</tr>
</tbody>
</table>

Note: These tests are typically conducted on fabrics, but they can be conducted on the garment seams/closures as well.
Barrier Performance Test Methods – Viral Penetration Test


- Used to determine the ability of a material to resist the penetration by bloodborne pathogens using a surrogate virus under continuous liquid contact
- A specimen is subjected to a nutrient broth containing a virus for a specified time and pressure sequence
- Phi-X174 is used
- Time and temperature are specified at 6 minutes, 2.0 psi for 1 minute, and atmospheric pressure for 54 minutes
- Terminated if visible liquid penetration occurs before or at 60 minutes
- This is a pass/fail test
- Primary bloodborne pathogens included in the test method are Hepatitis B Virus, (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Other microorganisms must be considered on a case-by-case basis

Photo Credit: NIOSH NPPTL
Critical Parameters of Blood and Viral Penetration Resistance Tests

- Virus morphology
- Time of exposure
- Surface tension
- Pressure of the challenge
**Virus Morphology**

- **Phi-X174**: spherical, ~27 nm in diameter
- **HCV**: spherical, ~30 nm in diameter
- **HIV**: spherical, 100-120 nm diameter
- **Ebola Virus**: filamentous, ~80 nm in diameter

Photo Credit: CDC PHIL 8153, 11279, 10815
# Surface Tension of the Challenge Liquid

<table>
<thead>
<tr>
<th>Surface tension values for water, synthetic blood, and human blood and body fluids(1)</th>
<th>Surface Tension (N/m)</th>
<th>Temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Average</strong></td>
<td><strong>Min.</strong></td>
</tr>
<tr>
<td><strong>Water</strong> [Randall and Calman 1954]</td>
<td>0.072</td>
<td>—</td>
</tr>
<tr>
<td><strong>Synthetic Blood</strong></td>
<td>0.042 ± 0.002</td>
<td>—</td>
</tr>
<tr>
<td><strong>Blood</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[Attinger et al. 2013] (review)</td>
<td>—</td>
<td>0.027</td>
</tr>
<tr>
<td>[Hrcncir et al. 1997]</td>
<td>0.056</td>
<td>—</td>
</tr>
<tr>
<td><strong>Saliva</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[Kazakov et al. 2009]</td>
<td>0.042</td>
<td>—</td>
</tr>
<tr>
<td>[Geigy Scientific Tables, 1984]</td>
<td>0.015-0.026</td>
<td>—</td>
</tr>
<tr>
<td><strong>Gastric juices</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[Spychal et al. 1990]</td>
<td>0.047</td>
<td>—</td>
</tr>
<tr>
<td>[Aburub et al. 2008]</td>
<td>—</td>
<td>0.035</td>
</tr>
<tr>
<td><strong>Duodenal and Jejunal fluids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[Fuchs and Dressman 2014]</td>
<td>—</td>
<td>0.028</td>
</tr>
<tr>
<td><strong>Sweat</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[Bothorel et al. 1992]</td>
<td>0.0383</td>
<td>—</td>
</tr>
<tr>
<td>[Bothorel et al. 1992]</td>
<td>0.0418</td>
<td>—</td>
</tr>
<tr>
<td>[Geigy Scientific Tables, 1984]</td>
<td>0.069-0.070</td>
<td>—</td>
</tr>
</tbody>
</table>

(1) Vomit is usually gastric juice, although in extreme cases intestinal juices can be included. Diarrhea is just the opposite—it is predominantly intestinal juices.
Pressure Type and Level

- Pressing and leaning in surgery 1 to 60 psi\(^{(1)}\)
- Leaning against the operating table 0.52 psi\(^{(2)}\)
- Reaching for an instrument <0.70 psi\(^{(2)}\)
- Most pressures applied to the front of surgical gowns <2.9 psi for <15 seconds\(^{(3)}\)
- Representative abdominal pressure during surgical procedures 0.25-2.0 psi\(^{(2)}\)
- ASTM F1670 and ASTM F1671 use 2 psi (13.8 kPa) hydrostatic pressure
- ISO 16603 and ISO 16604 use incremental hydrostatic pressure levels, 0 psi up to 2.9 psi
- Hydrostatic vs. mechanical pressure

Time of exposure to pressurized liquid challenge another factor that might affect the results. This time is now set to one minute in the ASTM F1670 and ASTM F1671 test methods.
Standards and Classifications for Coveralls

- EN 14126—“Performance requirements and test methods for protective clothing against infective agents”
- NFPA 1999—“Standard on Protective Clothing for Emergency Medical Operations”
Ongoing and Completed Research Projects with Gowns and Gloves at National Personal Protective Technology Laboratory (NPPTL)
### Ongoing/Completed Ebola Response Research Projects at NPPTL

<table>
<thead>
<tr>
<th>Category</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing PPE Performance</strong></td>
<td>• Elbow Lean Study&lt;br&gt;• Glove Strength Study&lt;br&gt;• Stockpile Study</td>
</tr>
<tr>
<td><strong>Development of Performance and/or Design Criteria</strong></td>
<td>• Isolation Gown Project&lt;br&gt;• PPE Elements Project (head covers, aprons, footwear covers)</td>
</tr>
<tr>
<td><strong>Development of New Test Methods</strong></td>
<td>• PPE Elements Project (glove/protective clothing interface)&lt;br&gt;• Liquid and Viral Penetration Tests Project</td>
</tr>
</tbody>
</table>
Evaluation of Gowns and Coveralls against Simulated Bodily Fluids Using a Rapid Elbow Lean Test

Objective

To quickly evaluate simulated bodily fluid penetration of protective clothing under mechanical pressure that demonstrates actual use conditions.

Methods

- Elbow Lean Test was used to obtain a visual semi-quantitative measure of the resistance of garments to the fluid penetration.
- Two bodily fluid simulants (colored water and synthetic blood).
- Five gowns and four coveralls, continuous and discontinuous regions, multiple elbow pressure levels (2-44 PSI).

Findings

- No strikethrough at continuous regions of one gown & two coveralls.
- Only the same gown consistently resisted strike-through at discontinuous areas.
- Fluid strikethrough increased with higher applied elbow pressure, was higher for lower fluid surface tension, and was higher for the discontinuous regions of the protective garments (exception of one garment).

Effect of Multiple Alcohol-based Hand Rub Treatments on Tensile Strength and Elongation of Medical Exam Gloves

**Objective**
Provide HCWs with useful information on the selection of medical exam gloves and understand the effect of alcohol based hand rubs (ABHR) on gloves (during doffing of PPE used for protection against the Ebola virus based on the CDC guidance).

**Methods**
- Five Latex and eight nitrile medical gloves
- Ethanol-Based and Isopropanol-Based Hand Rubs (EBHR and IBHR)
- Six applications (similar to CDC PPE doffing recommendations for Ebola)

**Findings**
- Both ABHRs decreased tensile strength while slightly increasing elongation
- Generally, the effect was greater on the nitrile than the latex gloves
- All tested gloves still met NFPA 1999 glove requirements for tensile strength up to six applications, except for two brands of relatively thin nitrile gloves
- Results show that multiple EBHR applications on the latex gloves and some of the nitrile gloves tested should be safe for Ebola PPE doffing based on the CDC guidance. Some of the results are available on CDC website at [http://www.cdc.gov/vhf/ebola/healthcare-us/ppe/faq.html](http://www.cdc.gov/vhf/ebola/healthcare-us/ppe/faq.html)


Photo Credit: NIOSH NPPTL
Effect of Stockpiling Conditions on the Performance of Particulate Air-Purifying Respirators and Surgical Gowns

Objectives
- Provide stockpile facilities, manufacturers, and regulators with evidence-based recommendations for particulate air-purifying respirators (APR) and Level 3 and 4 surgical gowns by evaluating shelf life and storage practices (humidity, temperature, light exposure) and sampling and testing PPE from 10 stockpile facilities with various conditions.

Progress
- 7/10 facility visits complete; 2,488 respirators tested

Next Steps
- Respirator testing (including quantitative fit testing): September 2017 and June 2019
- Surgical gown testing: August 2018 - March 2019

Expected Outputs
- Information to PPE manufacturers and stockpile managers on:
  - Guidance on practical/resource-driven decision-making related to stockpile conditions
  - Tips for inventory sampling to improve quality assurance activities
  - Low cost tips for environmental monitoring

PI: Lee Greenawald ilv1@cdc.gov
Collaborate with ASTM F23 to develop standard specification that defines minimum performance and design requirements for isolation gowns

- 13/22 disposable gown models met AAMI liquid barrier performance standard
- Preliminary findings were incorporated into CDC Ebola PPE guidance and supported FDA’s new guidance document [http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm452804.pdf](http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm452804.pdf)
- 9 models of reusable isolation gowns from 5 manufacturers were evaluated for performance before and after maximum laundering cycles (72-100). 3/9 models met AAMI liquid barrier performance standard
- ASTM draft standard to establish a new isolation gown standard that lists the minimum performance requirements including tensile strength, tear resistance and seam strength

- Evaluate the comfort properties of isolation gowns using benchtop & manikin testing
- Publish findings with disposable and reusable gowns

Determine the minimum performance and design requirements for three PPE elements (head covers, aprons, footwear covers)

Develop a new standardized test method for assessing the liquid penetration through glove/protective clothing interface, and design advanced protective clothing to eliminate/minimize the leakage through glove-protective clothing interface

- Head cover testing ongoing
- Testing procedure was developed and impact of the test parameters on the fluid penetration was analyzed (paper in press)
- Surgical settings and isolation settings were simulated (paper was submitted)

Test the PPE elements and develop minimum performance requirements
- Simulate decontamination settings, conduct testing of several protective clothing + glove combinations and determine the leakage and develop a standard test method to assess the leakage on glove-protective clothing interface

Objectives

- To develop improved test methods for assessing liquid and viral penetration through healthcare worker and emergency medical service protective clothing
- To evaluate the attributes that affect penetration and rank their importance so that test methods reflect the primary factors affecting penetration

Progress

- After research showed that ASTM test methods did not properly characterize the test fluid, we published a paper and the committee amended ASTM F1670 and F1862
- After research showed that test results depended on a loosely specified screen design, we developed an improved prototype and the committee amended ASTM F903

Next Steps

- To continue to amend current liquid penetration test methods by improving the test apparatus, such as replacing manual valves with precise electronic pressure control
- To develop the next generation of liquid and viral penetration testing standards

PI: Lee Portnoff xda3@cdc.gov
Summary

- Several fluid-resistant and impermeable protective clothing options are available in the market place for HCWs.
- A key step in the protective clothing selection process is to understand the relevant standards and test methods.
- Multiple test methods and classification standards exist to determine the barrier effectiveness of gowns and coveralls. There is room for improvement in some of the test methodologies.
- NPPTL plans to continue research to better understand the factors affecting barrier performance of protective clothing materials against bloodborne pathogens and use that information to validate/improve current test methods.
- NPPTL plans to expand its work for determination of the minimum performance requirements for other PPE elements, such as hoods, aprons, footwear covers, and interface regions.
- NPPTL will continue supporting CDC by generating technical documents for all types of PPE used by HCW and emergency responders to protect against microorganisms in blood and body fluids.
Some NIOSH NPPTL Resources

- Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids
  [http://www.cdc.gov/niosh/npptl/topics/protectiveclothing/](http://www.cdc.gov/niosh/npptl/topics/protectiveclothing/)

- Fighting Ebola: A Grand Challenge for Development – How NIOSH is Helping Design Improved Personal Protective Equipment for Healthcare Workers
  [https://blogs.cdc.gov/niosh-science-blog/2015/02/05/ebola-ppe/](https://blogs.cdc.gov/niosh-science-blog/2015/02/05/ebola-ppe/)

- How Well Do You Think You Are Protected? Understanding proper use and disposal of protective gowns for healthcare workers
  [https://blogs.cdc.gov/niosh-science-blog/2014/05/05/gowns/](https://blogs.cdc.gov/niosh-science-blog/2014/05/05/gowns/)

- NIOSH Research Highlights Importance of Rigorous Standards for Gowns Used to Protect Healthcare Workers
Quality Partnerships Enhance Worker Safety & Health

Visit us at: http://www.cdc.gov/niosh/npptl

Photos courtesy of MSA, Kimberly Clark, and North

Disclaimer: The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. Mention of a company or product name does not constitute endorsement by NIOSH.
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