Standards for Isolation Gowns and Surgical Gowns and Their Medical Applications

ASTM International and Jordan Standards and Metrology Organization Webinar Series
January 19, 2022

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Hierarchy of Controls

Source: https://www.cdc.gov/niosh/topics/hierarchy/default.html
Personal Protective Equipment (PPE)

Specialized clothing or equipment worn by workers for protection against health and safety hazards. For healthcare workers (HCWs), PPE may include:

- Respirators
- Medical face masks
- Gloves
- Gowns
- Goggles
- Face shields
- Head and shoe coverings
Standard Precautions

- Used for all patient care
- Based on a risk assessment
- Make use of common-sense practices and PPE to protect HCW from infection and prevent the spread of infection from patient to patient

Wear a gown that is appropriate to the task, to protect skin and prevent soiling or contamination of clothing when contact with blood, body fluids, secretions, or excretions is anticipated.

https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html
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 courtesy of CDC PHIL 10816
Performance Standards

- **Barrier Performance:**

- **Physical Performance:**
  - ASTM F3352: Standard specification for isolation gowns intended for use in healthcare facilities
  - ASTM F2407: Standard specification for surgical gowns intended for use in healthcare facilities
Isolation Gowns

- “Protective apparel used to protect HCWs and patients from the transfer of microorganisms and body fluids in patient isolation situations”¹

- “Worn to protect the HCW’s arms and exposed body areas during procedures and patient care activities when anticipating contact with clothing, blood, body fluids, secretions, and excretions”²

Surgical Gowns

- “Type of devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate matter” (21 CFR 878.4040)
AAMI PB70 Level

1
2
3
4

PROTECTION

isolation gown

surgical gown

Photo courtesy of NIOSH EPRO
Photo courtesy of Shutterstock
## ANSI/AAMI PB70:12 Classification Requirements

<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>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)</td>
<td>Surrogate blood</td>
<td>Pass</td>
<td>Blood and viral penetration resistance (2 psi)</td>
</tr>
<tr>
<td></td>
<td>ASTM F1671 (for gowns and other protective apparel)</td>
<td>Bacteriophage Phi-X174</td>
<td>Pass</td>
<td></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”
Barrier Performance Test Methods - Impact Penetration Test

AATCC 42: Water Resistance: Impact Penetration Test

- Used to determine the material’s ability 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 paper is weighed again
- Weight gain \( \downarrow \) water resistivity \( \uparrow \)

AATCC: American Association for Textile Chemists and Colorists

Video courtesy of NIOSH NPPTL
Barrier Performance Test Methods - Hydrostatic Pressure Test

AATCC 127: Water Resistance: Hydrostatic Pressure Test

- Used to determine the material’s ability 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 occur

Hydrostatic pressure ↑ water resistivity ↑
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 surrogate virus (Phi-X174) for a specified time and pressure sequence
- 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 considered 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 courtesy of NIOSH NPPTL
Standard for Isolation Gowns

- ASTM F3352, published in 2019, that lists minimum performance and design requirements for isolation gowns.
Puncture or Tear
Interface with Glove
Rips, holes
Strikethrough
Seam failure
Fabric worn out

Gown Failures Encountered by Infection Preventionists

45%
37%
31%
22%
13%
8%

Scope of ASTM F3352

**Scope:** Single use and multiple use isolation gowns

**isolation gown,** n—item of protective clothing/apparel used to protect healthcare personnel, visitors, and patients from the transfer of microorganisms and body fluids in patient isolation situations

**Exclusions:** Other types of gowns that are used in healthcare settings, including: cover gowns, procedure gowns, comfort gowns, precaution gowns, surgical gowns, decontamination gowns, and open-back gowns and other PPE items
ASTM F3352 Requirements

▪ **Barrier performance:** ANSI/AAMI PB70

▪ **Single use and multiple use gowns**
  — Anticipated care and maintenance were considered

▪ **Design requirements**
  — 360° coverage
  — Means or area for recording/marking the # of processing cycles (multiple-use)

▪ **Biocompatibility requirements**
  — Non-sensitizing and non-irritating (ISO 10993-10)
ASTM F3352 Requirements-cont’d

- **Performance requirements** *(considers both material and seams)*
  - Tensile strength
  - Tear resistance
  - Seam strength

- **Additional gown properties for reporting only** *(optional)*
  - Lint generation
  - Evaporation resistance/water vapor transmission rate
  - Abrasion resistance (Martindale)
  - Flex durability
Physical Property Performance Requirements of Single and Multiple-Use Isolation Gowns

<table>
<thead>
<tr>
<th>Property</th>
<th>Material</th>
<th>Test Method</th>
<th>AAMI PB70 Level 1,2,3,and 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile Strength</td>
<td>All</td>
<td>ASTM D5034</td>
<td>≥30 N (≥7 lbf)</td>
</tr>
<tr>
<td>Tear Strength</td>
<td>Woven textiles</td>
<td>ASTM D5587</td>
<td>≥10 N (≥2.3 lbf)</td>
</tr>
<tr>
<td></td>
<td>Nonwoven textiles, films, nonwoven and</td>
<td>ASTM D5733</td>
<td>≥10 N (≥2.3 lbf)</td>
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<tr>
<td></td>
<td>film composites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seam Strength</td>
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Determine the seam strength of isolation gown knit or stretch woven materials as specified in ASTM D751, using the tension testing machine with ring clamp.

- **Barrier performance** is determined according to ANSI/AAMI PB70 with 4% acceptable quality level (AQL), 20% rejectable quality level (RQL).
ASTM F3352 Labeling Requirements

- **Product labeling**
  - Product or style name
  - Barrier performance level
  - Product lot or serial number
  - Size

- **Package labeling**
  - Manufacturer name
  - Product or style name
  - Barrier performance level
  - Product lot or serial number
  - Size
  - Meets requirements of Specification ASTM F3352
  - Use-by date
  - Manufacturer address and phone number
  - For multiple-use products, processing instructions including the # max processing cycles
  - A caution statement if contains natural rubber latex
**ASTM F2407** lists suggested performance and design parameters

It was revised in 2020 to include minimum performance and design criteria.
Scope of ASTM F2407

Scope: Single use and multiple use surgical gowns

surgical gown, n—protective clothing that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate matter

Exclusions: Other types of gowns that are used in healthcare settings, including: isolation gowns, decontamination gowns, surgical masks, operating room shoes, shoe covers, and other PPE items
ASTM F2407 Requirements

- **Barrier performance**: ANSI/AAMI PB70
- **Single use and multiple use gowns**
  - Anticipated care and maintenance were considered
- **Design requirements**
  - Means or area for recording/marking the # of processing cycles (multiple-use)
  - The sizes of the critical zone(s) defined by anatomical reference in accordance with ANSI/AAMI PB70
- **Biocompatibility requirements**
  - Pass AAMI BE78 or ISO 10993-10
- **Sterility assurance level requirements**
  - At least 10^-6 (moist heat, EtO, Gamma)
- **Flame spread**
  - Class 1 Normal Flammability according to 16 CFR 1610 before and after conditioning
ASTM F2407 Requirements-cont’d

- **Performance requirements** *(considers both material and seams)*
  - Tensile strength
  - Tear resistance
  - Seam strength

- **Additional gown properties for reporting only** *(optional)*
  - Lint generation
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  - Abrasion resistance (Martindale)
  - Flex durability
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ASTM F2407 Labeling Requirements

- **Product labeling**
  - Manufacturer name
  - Product or style name
  - Barrier performance level
  - Product lot or serial number
  - Size
  - Integral tracking mechanism (for multiple-use products)

- **Package labeling**
  - Manufacturer name
  - Product or style name
  - Barrier performance level
  - Product lot or serial number
  - Size
  - Meets requirements of Specification ASTM F2407
  - Use-by date
  - Manufacturer address and phone number
  - For multiple-use products, processing instructions including the max # processing cycles
  - Label as “sterile” if sold sterilized
  - A caution statement if contains natural rubber latex
Several protective clothing options are available in the marketplace for healthcare workers.

A key step in the protective clothing selection process is to understand hazards, exposures, the relevant standards, test methods and their intended use.

Multiple test methods and classification standards exist to determine the barrier effectiveness and physical performance of gowns.

NIOSH will continue supporting ASTM International by:

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- generating technical information for different types of PPE used by healthcare workers and emergency responders to protect against microorganisms in blood and body fluids, and
- participating in consensus standard development process
Some NIOSH Sources

- 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
**Key References**


- Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids. NIOSH/The National Personal Protective Technology Laboratory Topic Page. [http://www.cdc.gov/niosh/npptl/topics/ProtectiveClothing/default.html](http://www.cdc.gov/niosh/npptl/topics/ProtectiveClothing/default.html)


Key References


Visit NPPTL’s Website:
• [https://www.cdc.gov/niosh/npptl/default.html](https://www.cdc.gov/niosh/npptl/default.html)

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Thank You!

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