



Standards for Isolation Gowns and Surgical Gowns and Their Medical Applications

ASTM International and Jordan Standards and Metrology Organization Webinar Series

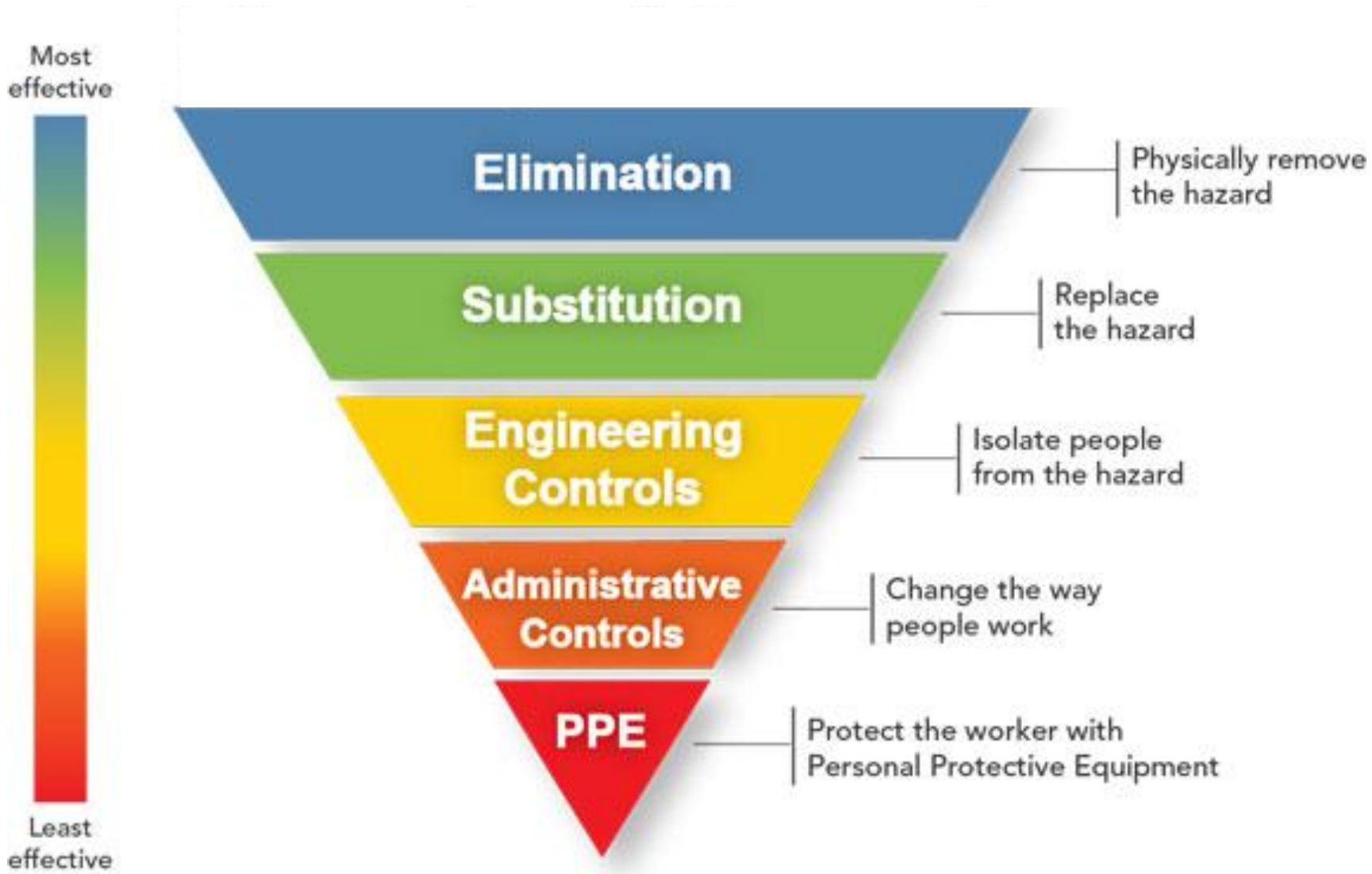
January 19, 2022

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Centers for Disease Control
and Prevention
National Institute for Occupational
Safety and Health

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.

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



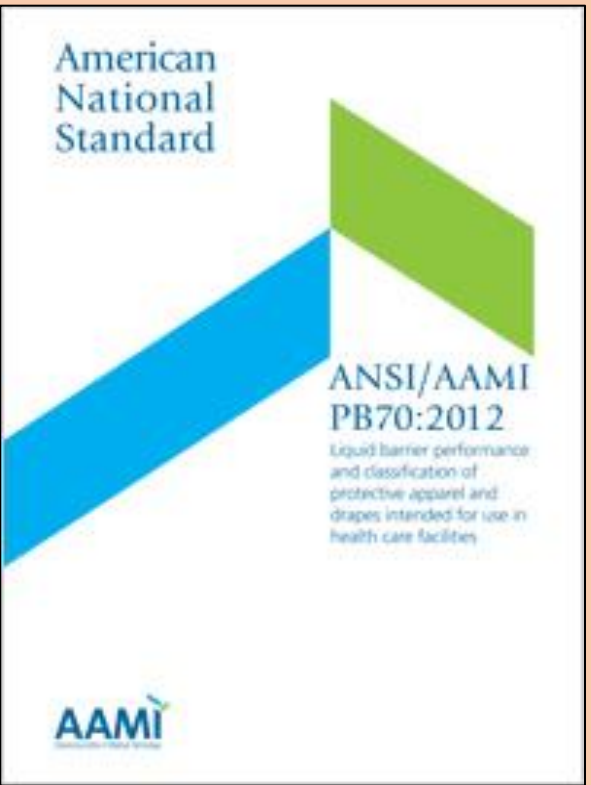
Select Appropriate Protective Clothing

- Regulations
- Practices

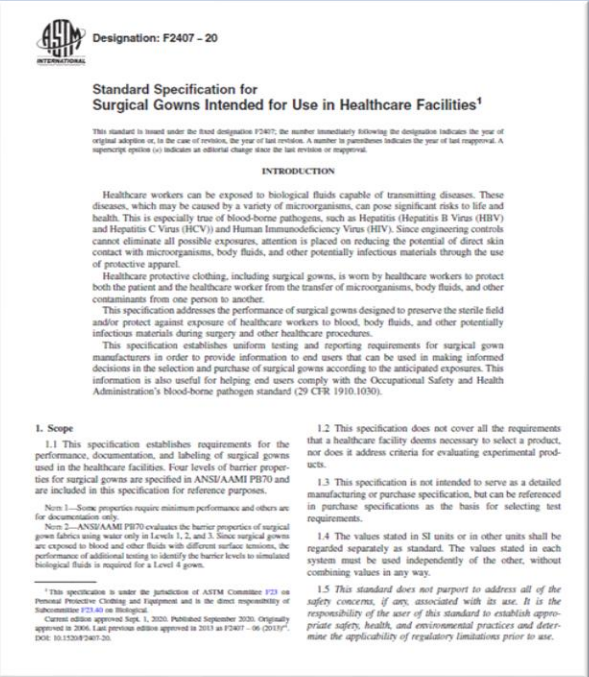


Performance Standards

- **Barrier Performance:**
 - **ANSI/AAMI PB70:2012:** Liquid barrier performance and classification of **protective apparel and drapes** intended for use in healthcare facilities



- **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

1. AAMI-TIR 11 Technical Information Report: Selection of Surgical Gowns and Drapes in Healthcare Facilities. Arlington, VA, USA: Association for the Advancement of Medical Instrumentation; 2005

2. Siegel JD, Rhinehart E, Jackson M, Chiarello L. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in health care settings. *American Journal of Infection Control* 2007; 35(10): S65-S164



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



ASSOCIATION FOR THE ADVANCEMENT
OF MEDICAL INSTRUMENTATION

isolation gown



Photo courtesy of NIOSH EPRO

surgical gown



Photo courtesy of Shutterstock

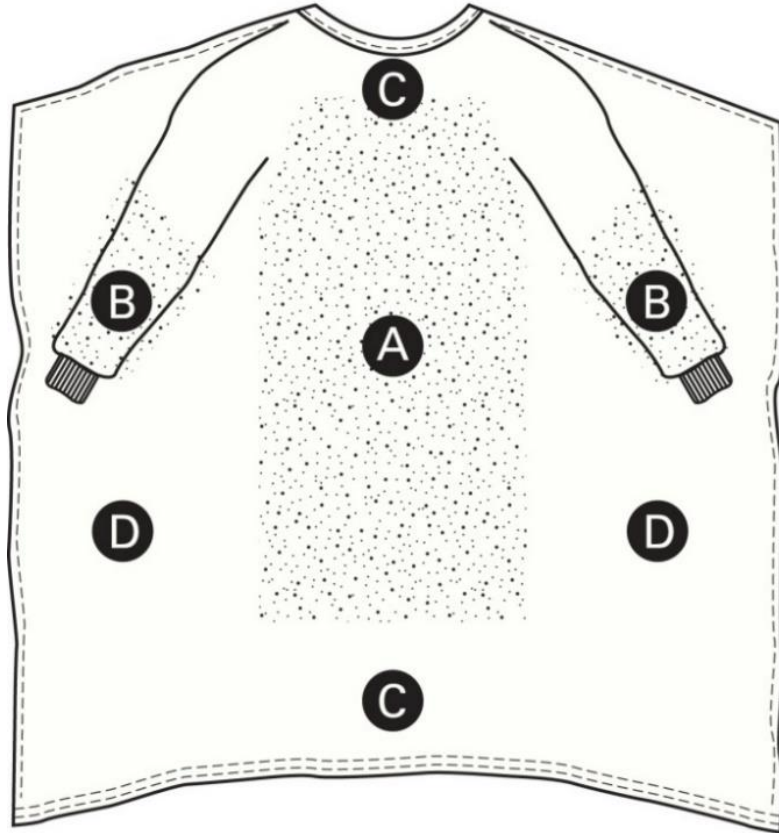
ANSI/AAMI PB70:12 Classification Requirements

Level	Test	Liquid Challenge	Result*	Expected Barrier Effectiveness
1	AATCC 42	Water	≤ 4.5 g	Minimal water resistance (some resistance to water spray)
2	AATCC 42	Water	≤ 1.0 g	Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
	AATCC 127	Water	≥ 20cm	
3	AATCC 42	Water	≤ 1.0 g	Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
	AATCC 127	Water	≥ 50cm	
4	ASTM F1670 (for surgical drapes)	Surrogate blood	Pass	Blood and viral penetration resistance (2 psi)
	ASTM F1671 (for gowns and other protective apparel)	Bacteriophage Phi-X174	Pass	

(* All have an Acceptance Quality level (AQL) of 4% and Rejectable Quality Level (RQL) of 20%

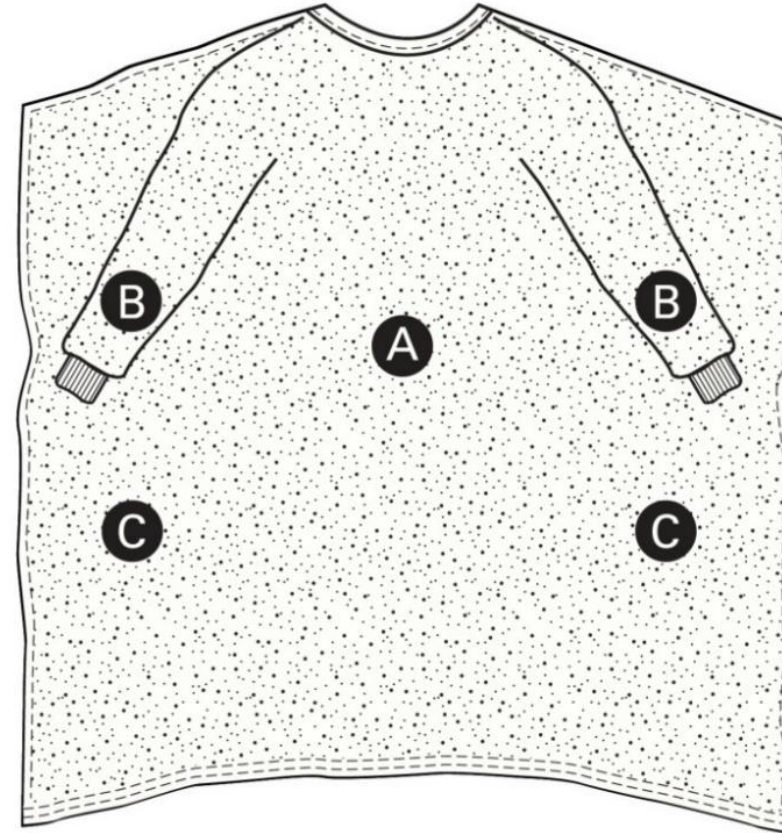
ANSI/AAMI PB70 Critical Zones for Gowns

 Critical zone



Surgical gown

 Critical zone



Isolation gown

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 ↓ water resistivity ↑

AATCC: American Association for Textile Chemists and Colorists



Test Fabric

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

ASTM F1671, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration

- 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

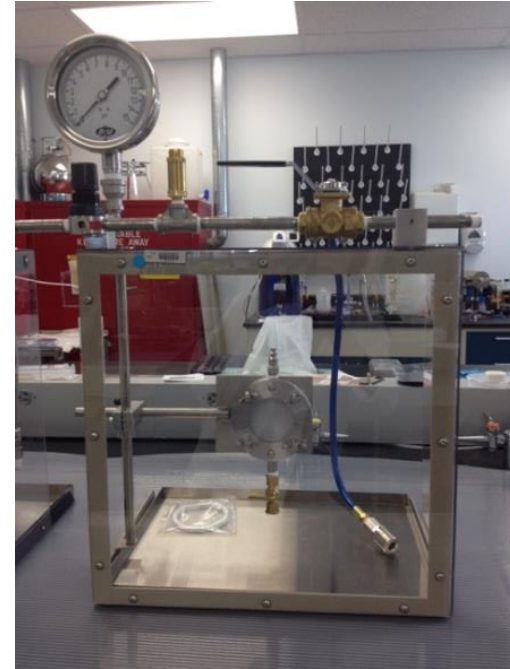


Photo courtesy of NIOSH NPPTL

Standard for Isolation Gowns

- ASTM F3352, published in 2019, that lists minimum performance and design requirements for isolation gowns



Photo courtesy of NIOSH EPRO



Designation: F3352 - 19

Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities¹

This standard is issued under the fixed designation F3352; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last approval. A superscripted quaternary (4) indicates an editorial change since the last revision or approval.

INTRODUCTION

Healthcare personal protective equipment, including isolation gowns, is worn by healthcare workers to protect the patient, the healthcare worker, and visitors from the transfer of microorganisms, blood and other body fluids, and other contaminants.

Healthcare workers and patients can be exposed to body fluids and other potentially infectious materials capable of transmitting diseases. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of bloodborne pathogens, such as Hepatitis (Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)) and Human Immunodeficiency Virus (HIV), as well as other healthcare-associated infections. Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential for direct skin contact with microorganisms, blood or other body fluids, and other potentially infectious materials through the use of protective clothing.

The ASTM F23.40 Biological Subcommittee work group surveyed infection preventionists to determine use/wear issues, familiarity with isolation gown performance standards, and to identify compliance perceptions and problems.² Results of this survey clearly indicated issues with the physical performance of the isolation gowns used in the healthcare settings. Development of this standard, which includes performance and design criteria for isolation gowns, is intended to assist end users in correct gown selection. The minimum criteria in this specification were established based on the findings of a study in collaboration with National Institute for Occupational Safety and Health³ and committee discussions.

This specification addresses the performance of isolation gowns designed to protect the healthcare worker, the patient, and visitors from exposure to blood, body fluids, and other potentially infectious materials during patient care or patient procedures.

This specification establishes uniform testing and reporting requirements for isolation gown manufacturers in order to provide information to end users that can be used in making informed decisions in the evaluation, selection, and purchase of isolation gowns according to the anticipated exposures.

1. Scope

1.1 This specification establishes minimum requirements for the performance and labeling of isolation gowns intended for use by healthcare workers to provide protection for

standard and transmission-based precautions. The intended use of this specification is to ensure the performance properties of isolation gowns for the protection of the wearer. Four levels of barrier properties for isolation gowns are specified in ANSI/AAMI PB 70, and are included in this specification for reference purposes.

1.2 There are other types of gowns that are used in healthcare settings, including: cover gowns, procedure gowns, comfort gowns, precaution gowns, and open-back gowns. All gowns not meeting the definition of isolation gown in 3.1.7 as defined by ANSI/AAMI PB70 are excluded from this standard.

1.3 This specification does not address protective clothing used for surgical applications, such as surgical gowns or decontamination gowns; protective clothing for the hands, such

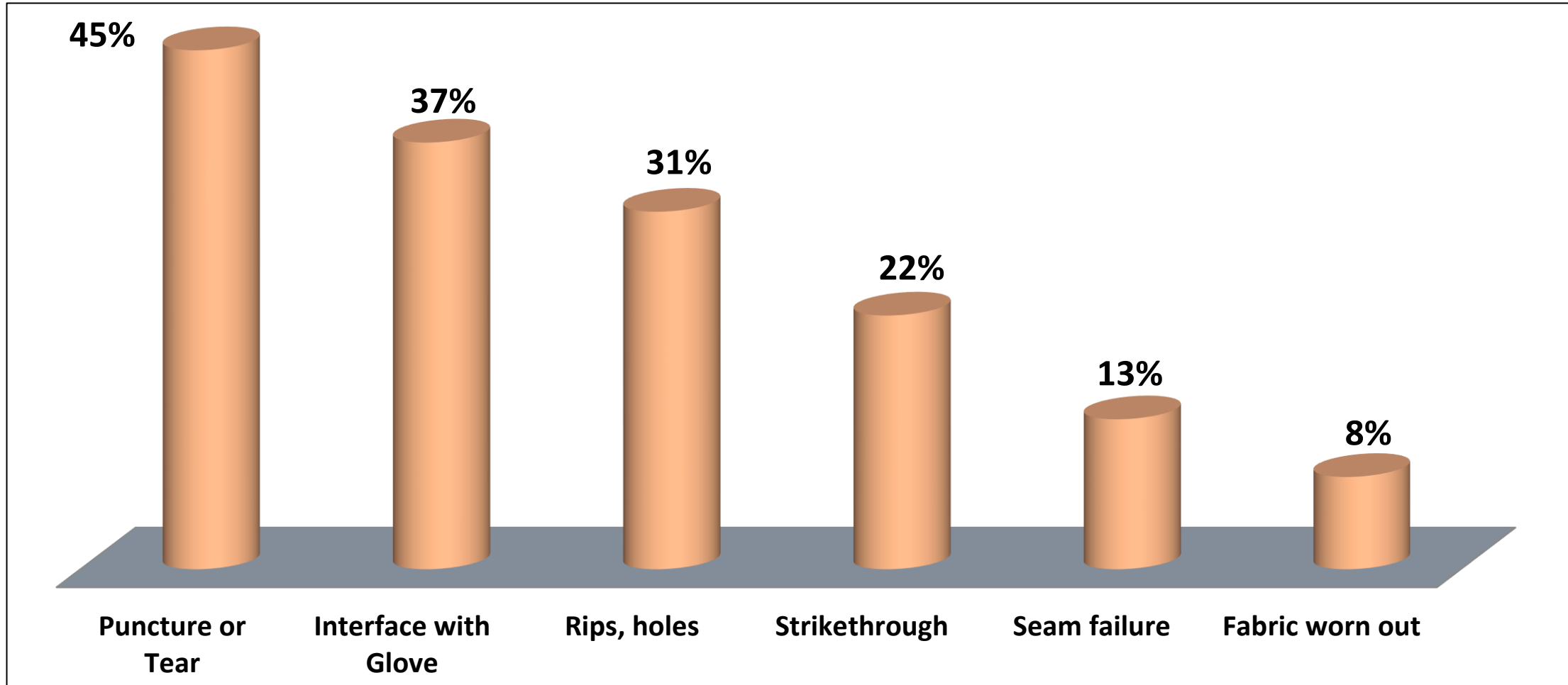
¹ This specification is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.40 on Biological.

Current edition approved June 1, 2019. Published July 2019. Originally approved in 2019. DOI: 10.1520/F3352-19.

² Choud, R., Favret, U. B., Cunningham, T., Daley, J., Harris, L. G., Kilinc-Balci, F. S., and Lewis, J. A., "Isolation Gown Use, Performance and Potential Compliance Issues Identified by Infection Control Professionals," *American Journal of Infection Control*, Vol 40, No. 5, 2012, pp. e74-e75.

³ Kilinc-Balci, F. S., Nweke, J., and Hillam, T., "Evaluation of the Performance of Isolation Gowns," *American Journal of Infection Control*, Vol 43, No. 6, 2015, p. S44.

Gown Failures Encountered by Infection Preventionists



(*) Cloud, Rinn, Uncas B. Favret, Terrell Cunningham, Jacqueline Daley, Linda G. Harris, F. S. Kilinc-Balci, and Janet A. Lewis. "Isolation Gown Use, Performance and Potential Compliance Issues Identified by Infection Control Professionals." *American Journal of Infection Control* 40, no. 5 (2012): e74-e75.

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/marketing the # of processing cycles (multiple-use)
- **Biocompatibility requirements**
 - Non-sensitizing and non-irritating (ISO 10993-10)

FX 3000-IV
HydroTester

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

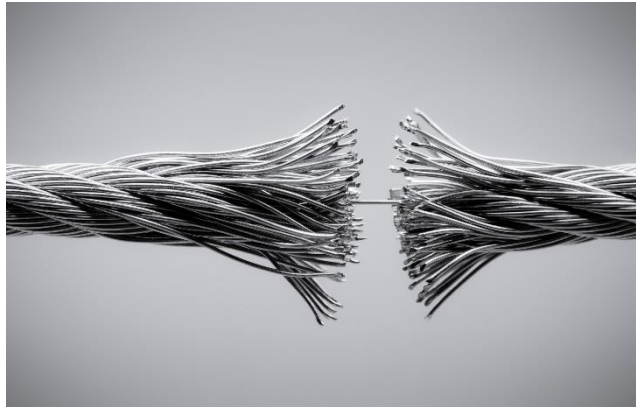


Photo courtesy of NIOSH/NPPTL

Property	Material	Test Method	AAMI PB70 Level 1,2,3,and 4
Tensile Strength	All	ASTM D5034	≥30 N (≥7 lbf)
	Woven textiles	ASTM D5587	≥10 N (≥2.3 lbf)
Tear Strength	Nonwoven textiles, films, nonwoven and film composites	ASTM D5733	≥10 N (≥2.3 lbf)
	All	ASTM D1683/D1683M	≥30 N (≥7 lbf)

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

Standard for Surgical Gowns

- **ASTM F2407** lists suggested performance and design parameters
- It was revised in 2020 to include minimum performance and design criteria



Photo courtesy of Shutterstock



Designation: F2407 – 20

Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities¹

This standard is issued under the fixed designation F2407; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

Healthcare workers can be exposed to biological fluids capable of transmitting diseases. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne pathogens, such as Hepatitis (Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)) and Human Immunodeficiency Virus (HIV). Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential of direct skin contact with microorganisms, body fluids, and other potentially infectious materials through the use of protective apparel.

Healthcare protective clothing, including surgical gowns, is worn by healthcare workers to protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and other contaminants from one person to another.

This specification addresses the performance of surgical gowns designed to preserve the sterile field and/or protect against exposure of healthcare workers to blood, body fluids, and other potentially infectious materials during surgery and other healthcare procedures.

This specification establishes uniform testing and reporting requirements for surgical gown manufacturers in order to provide information to end users that can be used in making informed decisions in the selection and purchase of surgical gowns according to the anticipated exposures. This information is also useful for helping end users comply with the Occupational Safety and Health Administration's blood-borne pathogen standard (29 CFR 1910.1030).

1. Scope

1.1 This specification establishes requirements for the performance, documentation, and labeling of surgical gowns used in the healthcare facilities. Four levels of barrier properties for surgical gowns are specified in ANSI/AAMI PB70 and are included in this specification for reference purposes.

NOTE 1—Some properties require minimum performance and others are for documentation only.

NOTE 2—ANSI/AAMI PB70 evaluates the barrier properties of surgical gown fabrics using water only in Levels 1, 2, and 3. Since surgical gowns are exposed to blood and other fluids with different surface tensions, the performance of additional testing to identify the barrier levels to simulated biological fluids is required for a Level 4 gown.

1.2 This specification does not cover all the requirements that a healthcare facility deems necessary to select a product, nor does it address criteria for evaluating experimental products.

1.3 This specification is not intended to serve as a detailed manufacturing or purchase specification, but can be referenced in purchase specifications as the basis for selecting test requirements.

1.4 The values stated in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

¹ This specification is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.40 on Biological.

Current edition approved Sept. 1, 2020. Published September 2020. Originally approved in 2006. Last previous edition approved in 2013 as F2407 – 06 (2013)¹. DOI: 10.1520/F2407-20.

Scope of ASTM F2407

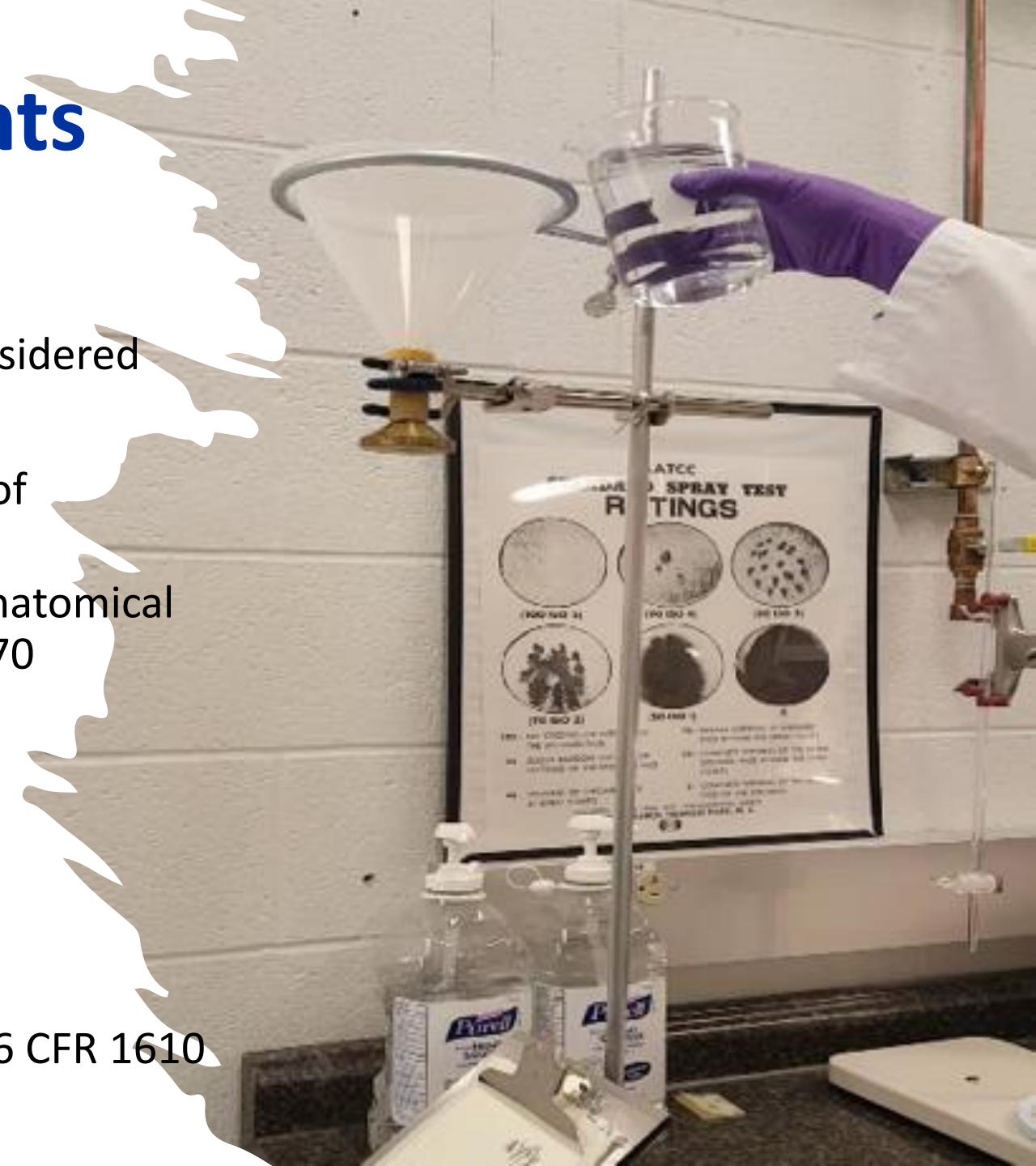
Scope: Single use and multiple use surgical gowns

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/marketing 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
 - Evaporation resistance/water vapor transmission rate
 - Abrasion resistance (Martindale)
 - Flex durability

Physical Property Performance Requirements of Single and Multiple-Use Surgical Gowns



Photo courtesy of NIOSH/NPPTL

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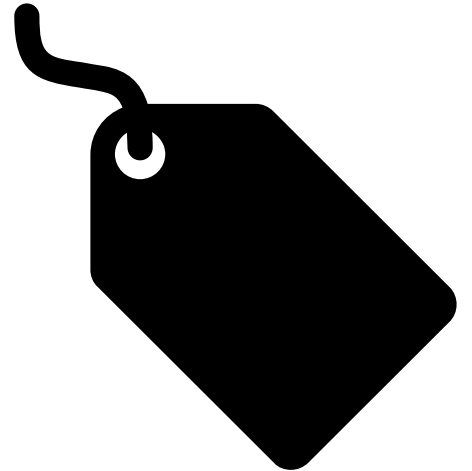
ASTM F2407 Labeling Requirements

- **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



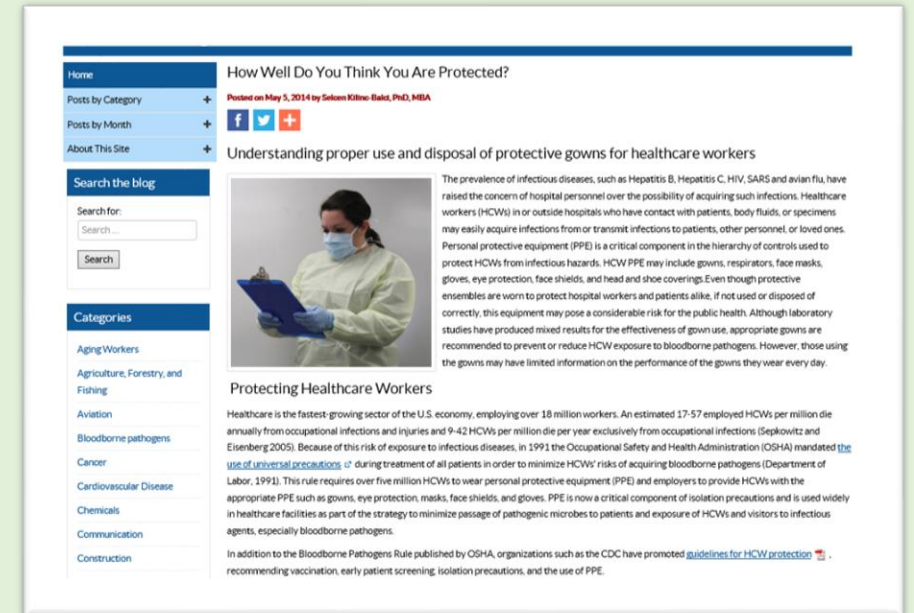
Summary

- 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:
 - 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/>
- 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/>
- 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/>
- NIOSH Research Highlights Importance of Rigorous Standards for Gowns Used to Protect Healthcare Workers
<https://blogs.cdc.gov/niosh-science-blog/2015/07/22/isolation-gowns/>



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How Well Do You Think You Are Protected?

Posted on May 5, 2014 by Selam Kitaw, PhD, MBA

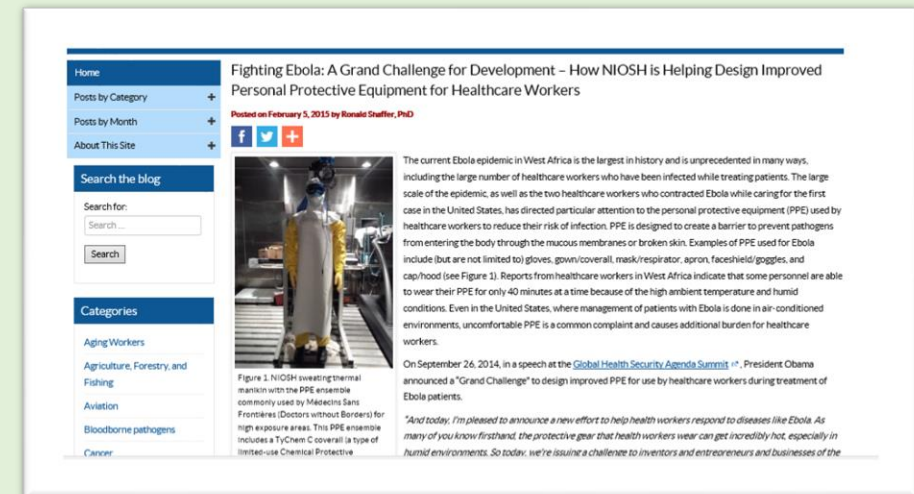
Understanding proper use and disposal of protective gowns for healthcare workers

The prevalence of infectious diseases, such as Hepatitis B, Hepatitis C, HIV, SARS and avian flu, have raised the concern of hospital personnel over the possibility of acquiring such infections. Healthcare workers (HCWs) in or outside hospitals who have contact with patients, body fluids, or specimens may easily acquire infections from or transmit infections to patients, other personnel, or loved ones. Personal protective equipment (PPE) is a critical component in the hierarchy of controls used to protect HCWs from infectious hazards. HCW PPE may include gowns, respirators, face masks, gloves, eye protection, face shields, and head and shoe coverings. Even though protective ensembles are worn to protect hospital workers and patients alike, if not used or disposed of correctly, this equipment may pose a considerable risk for the public health. Although laboratory studies have produced mixed results for the effectiveness of gown use, appropriate gowns are recommended to prevent or reduce HCW exposure to bloodborne pathogens. However, those using the gowns may have limited information on the performance of the gowns they wear every day.

Protecting Healthcare Workers

Healthcare is the fastest-growing sector of the U.S. economy, employing over 18 million workers. An estimated 17-57 employed HCWs per million die annually from occupational infections and injuries and 9-42 HCWs per million die per year exclusively from occupational infections (Sepkowitz and Eisenberg 2005). Because of this risk of exposure to infectious diseases, in 1991 the Occupational Safety and Health Administration (OSHA) mandated the use of universal precautions during treatment of all patients in order to minimize HCWs' risks of acquiring bloodborne pathogens (Department of Labor, 1991). This rule requires over five million HCWs to wear personal protective equipment (PPE) and employers to provide HCWs with the appropriate PPE such as gowns, eye protection, masks, face shields, and gloves. PPE is now a critical component of isolation precautions and is used widely in healthcare facilities as part of the strategy to minimize passage of pathogenic microbes to patients and exposure of HCWs and visitors to infectious agents, especially bloodborne pathogens.

In addition to the Bloodborne Pathogens Rule published by OSHA, organizations such as the CDC have promoted guidelines for HCW protection, recommending vaccination, early patient screening, isolation precautions, and the use of PPE.



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Fighting Ebola: A Grand Challenge for Development – How NIOSH is Helping Design Improved Personal Protective Equipment for Healthcare Workers

Posted on February 5, 2015 by Ronald Stoffer, PhD

The current Ebola epidemic in West Africa is the largest in history and is unprecedented in many ways, including the large number of healthcare workers who have been infected while treating patients. The large scale of the epidemic, as well as the two healthcare workers who contracted Ebola while caring for the first case in the United States, has directed particular attention to the personal protective equipment (PPE) used by healthcare workers to reduce their risk of infection. PPE is designed to create a barrier to prevent pathogens from entering the body through the mucous membranes or broken skin. Examples of PPE used for Ebola include (but are not limited to) gloves, gown/coverall, mask/respirator, apron, faceshield/goggles, and cap/hood (see Figure 1). Reports from healthcare workers in West Africa indicate that some personnel are able to wear their PPE for only 40 minutes at a time because of the high ambient temperature and humid conditions. Even in the United States, where management of patients with Ebola is done in air-conditioned environments, uncomfortable PPE is a common complaint and causes additional burden for healthcare workers.

On September 26, 2014, in a speech at the Global Health Security Agenda Summit, President Obama announced a "Grand Challenge" to design improved PPE for use by healthcare workers during treatment of Ebola patients.

"And today, I'm pleased to announce a new effort to help health workers respond to diseases like Ebola. As many of you know firsthand, the protective gear that health workers wear can get incredibly hot, especially in humid environments. So today, we're issuing a challenge to inventors and entrepreneurs and businesses of the

Figure 1. NIOSH sweating thermal manikin with the PPE ensemble commonly used by Médecins Sans Frontières (Doctors without Borders) for high exposure areas. This PPE ensemble includes a TyChem C coverall (a type of limited-use Chemical Protective

Key References

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- “Isolation Gowns in Health Care Settings: Laboratory Studies, Regulations and Standards, and Potential Barriers of Gown Selection and Use”. Kilinc-Balci FS. *American Journal of Infection Control* 44.1 (2016): 104-111.
- 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.
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<http://blogs.cdc.gov/niosh-science-blog/2015/07/22/isolation-gowns/>
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Thank You!

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