Technical Guidance: **Isolation Gowns**

Updated June 5, 2020

U.S. FDA reference info:
Classification: Class I
Product code: LYU (accessory, surgical apparel)

Overview

The purpose of this technical guidance document is to provide the following information:

- Section 1: An overview of single-use vs. multiple-use isolation gowns, typical materials used, and common methods of reinforcement
- Section 2: A concise introduction to the key design features of isolation gowns, including a brief explanation of why each feature is important and how it is tested
- Section 3: Guidelines for proper use, reuse, and associated risks

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2) Technical Design and Test Criteria

This section provides a concise introduction to the key design features of isolation gowns, including a brief explanation of why each feature is important and how it is tested (as applicable). Collectively, this set of technical features and test criteria are what ensure the safety and effectiveness of the isolation gowns.

Barrier Effectiveness

The most important characteristic of an isolation gown is its effectiveness in providing the appropriate level of penetration resistance [1]. The ANSI/AAMI PB70:2012 standard includes tests to characterize the effectiveness of the gown material's penetration resistance. The four levels of resistance are (in order of increasing protection) [2]:

Level	Description	Example uses
1 (minimal risk)	Minimal water resistance (some resistance to water spray)	Basic care, standard isolation, cover gown for visitors, standard medical unit [3]
2 (low risk)	Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)	During blood draw, suturing, Intensive Care Unit (ICU), pathology lab [3]
3 (moderate risk)	Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)	During arterial blood draw, inserting IV line, Emergency Room (ER), trauma cases [3]
4 (high risk)	Blood and viral penetration resistance (blood and viral penetration resistance, 2 psi)	During long / fluid intense procedures, surgery, pathogen resistance is needed, non-airborne infectious disease is suspected [3]

Test methods

AATCC 42, Water Resistance: Impact Penetration Test
video: https://www.youtube.com/watch?v=OQ6eF0EJrlM

AATCC 127, Water Resistance: Hydrostatic Pressure Test
video: https://www.youtube.com/watch?v=uZ2RsRbx0hM

ASTM F1671, Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

Level	Test Procedure	Pass Criteria
1	AATCC 42	≤ 4.5 g of water gained by the blotter [4]
2	AATCC 42	≤ 1.0 g of water gained by the blotter [4]
	AATCC 127	≥ 20 cm hydrostatic pressure required to penetrate the fabric [4]
3	AATCC 42	≤ 1.0 g of water gained by the blotter [4]
	AATCC 127	≥ 50 cm hydrostatic pressure required to penetrate the fabric [4]
4	ASTM F1671	Fabric exhibits no detectable (<1 PFU/mL) Phi-X174 in the assay titer [4]

AATCC 42 test method approximation:
If blotter paper that meets the specifications of ANSI/AAMI PB70:2012 is not available, use any similarly absorbent medium. The important characteristics are for the medium to be able to quickly absorb any water that leaks through the fabric; it is essential to obtain a meaningful measurement when weighing the absorbent medium before and after the test.

AATCC 127 test method approximation:

Equipment needed:

- Rigid pipe that is at least 60 cm in length and at least 5 cm in diameter
- Duct tape (or equivalent) to secure the fabric specimen to one end of the pipe
- Hose (~5m or longer)
- 1m ruler

Setup:

1. Cut a fabric specimen that is approximately 200 mm x 200 mm.
2. Apply the fabric specimen over one end of the pipe, with the surface to be tested facing the pipe.
3. Secure the fabric to the pipe using duct tape or similar clamping mechanism.
4. Rotate the pipe so that the open end is facing up and the fabric-covered end is facing down.
5. Secure (or hold) the pipe vertically and off the ground.
6. Run the hose from the water source into the pipe. Place the end of the hose as close as possible to the fabric end, without touching the fabric.

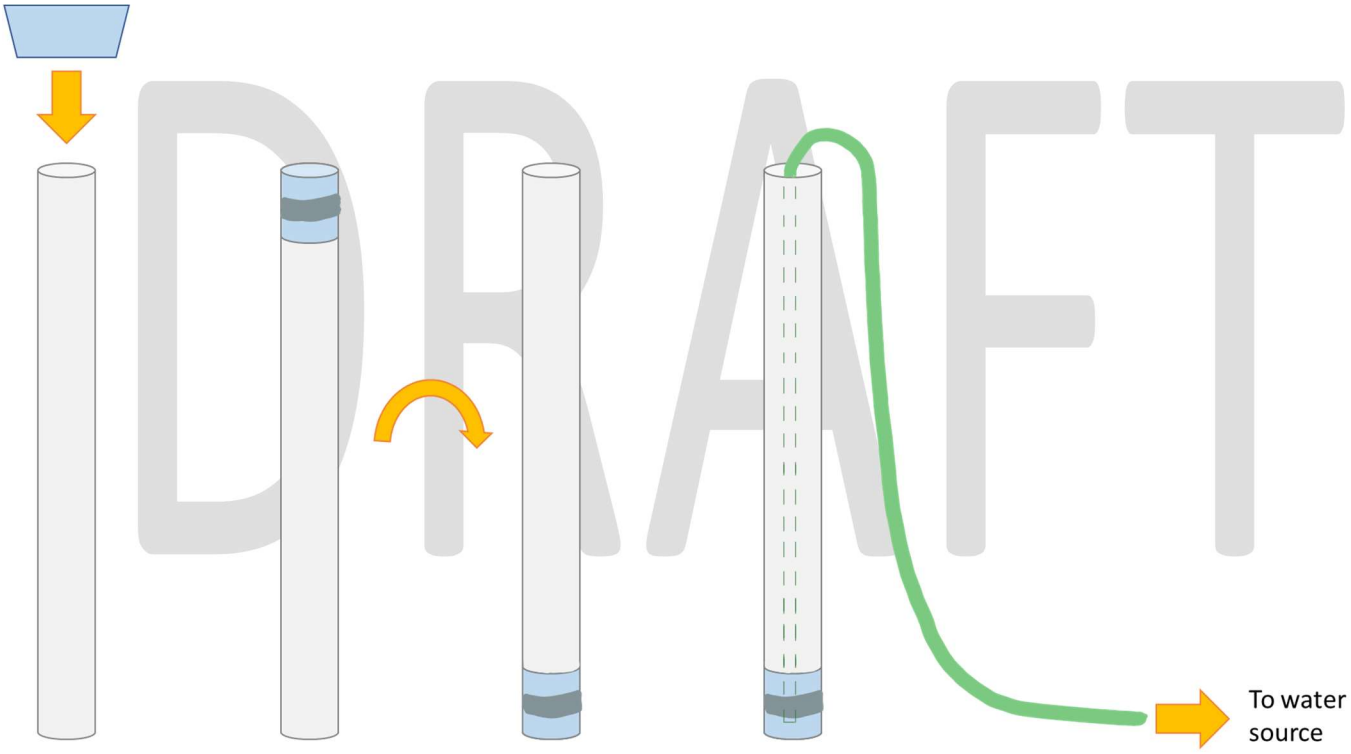

Figure 1 - Setup for AATCC 127 approximation

Procedure:

1. Carefully turn on the water at a very slow rate until the water level has surpassed the end of the hose.
2. Maintain the water flow at a moderately slow rate while observing the exposed surface of the fabric specimen (bottom end of the pipe). Be prepared to quickly turn off the water source.
3. As soon as water droplets are observed to emerge through the fabric specimen, immediately turn off the water source. It may be desirable to lower the pipe to the floor at this point (to maintain the current water level in the pipe).
4. Measure the height of the water level within the pipe. If the pipe is not transparent, it may be best to insert the 1m ruler into the pipe to measure the water level.

Acceptance Criteria:

- For a Level 2 isolation gown, verify that the measured water level (from step 4) is at least 20 cm.
- For a Level 3 isolation gown, verify that the measured water level (from step 4) is at least 50 cm.

Fabric and Seam Strength

If the fabric or seams are not durable enough to withstand typical wear (e.g. kneeling, reaching, bending), the gown may tear during use and become ineffective [5]. The following set of tests may be performed to assess the fabric and construction durability. The tests are organized in order of decreasing importance.

Tensile Strength

Test method (preferred) [3]: ASTM D5034-09, Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)

Test method (approximation):

Conditioning: (If the gown is intended to be multiple-use) Launder the fabric sample according to the manufacturer's recommended washing and drying procedures. Repeat the washing and drying cycles to match the maximum total number of use cycles specified in the manufacturer's claims.

Procedure:

1. Cut a fabric specimen to 100 mm wide by at least 150 mm long. Do not include any seams in this specimen.
2. Pull on the ends of the fabric with an amount of force that is appropriate for foreseeable use (bending, reaching)

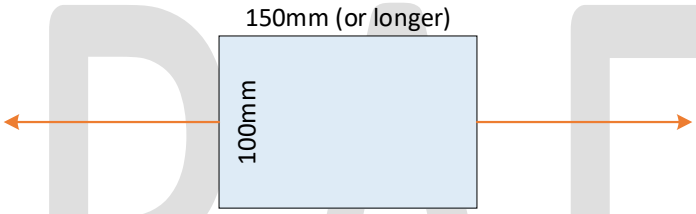

Figure 2 - Tensile Strength Test (approximation)

Acceptance Criteria:

- Verify that the fabric does not fail (fabric remains intact)
- Recommendation: verify that the Barrier Effectiveness (for the specified protection level) still passes for this fabric specimen

Seam Strength

Test method (preferred) [3]:

- For woven or non-woven fabrics: ASTM D1683/D1683M-17, Standard Test Method for Failure in Sewn Seams of Woven Fabrics
- For knit or stretch woven fabrics: ASTM D751-19, Standard Test Method for Coated Fabrics

ASTM D1683/D1683M-17 test method (approximation):

Conditioning: (If the gown is intended to be multiple-use) Launder the fabric sample according to the manufacturer's recommended washing and drying procedures. Repeat the washing and drying cycles to match the maximum total number of use cycles specified in the manufacturer's claims.

Procedure:

1. Fold the fabric along a seam and cut a fabric specimen to 100 mm wide by at least 150 mm long.

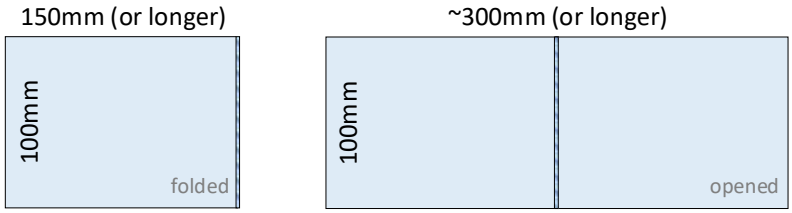

Figure 3 – ASTM D1683/D1683M-17 Seam Strength Test Setup (approximation)

2. Pull on the ends of the fabric with an amount of force that is appropriate for foreseeable use (bending, reaching)

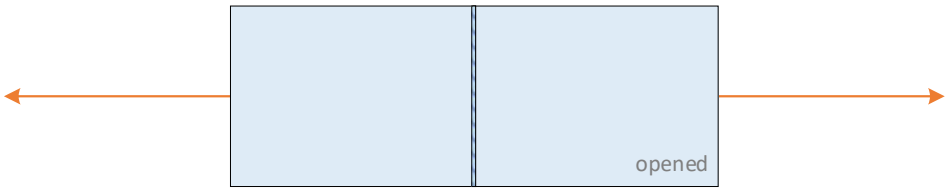

Figure 4 - ASTM D1683/D1683M-17 Seam Strength Test (approximation)

3. Inspect the seam for displacement of one or more fabric yarns from their original position (which may cause differences in alignment and/or spacing).

Acceptance Criteria:

- Verify that the seam does not fail (seam remains intact)

ASTM D751-19 test method (approximation):
Conditioning: (If the gown is intended to be multiple-use) Launder the fabric sample according to the manufacturer's recommended washing and drying procedures. Repeat the washing and drying cycles to match the maximum total number of use cycles specified in the manufacturer's claims.

Procedure:

1. Fold the fabric along a seam and cut a fabric specimen to 50 mm wide by at least 100 mm long.

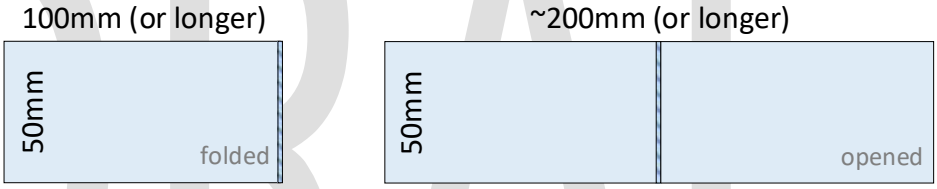

Figure 5 - ASTM D751-19 Seam Strength Test Setup (approximation)

2. Pull on the ends of the fabric with an amount of force that is appropriate for foreseeable use (bending, reaching)

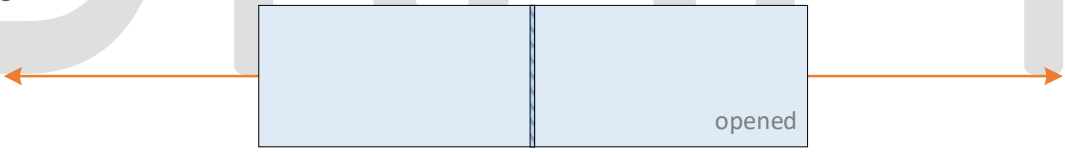

Figure 6 - ASTM D751-19 Seam Strength Test (approximation)

3. Inspect the seam for displacement of one or more fabric yarns from their original position (which may cause differences in alignment and/or spacing).

Acceptance Criteria:

- Verify that the seam does not fail (seam remains intact)

Lint Generation
Test method (preferred) [3]: ISO 9073 Part 1
Test method (approximation):

Tear Resistance
Test methods (preferred) [3]: ASTM D5587-15, Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure

Coverage and Fit

The safety and effectiveness of an isolation gown depends not only on the material properties from which it is constructed, but it also depends on the design of the gown [1]. Important design aspects pertaining to the coverage and fit of the gown include the following:

- Size: If the gown is too large/loose, it will be more likely to be snagged and potentially torn. If the gown is too small, it may restrict freedom of movement and/or cause an opening at the back of the gown [2]. Ensure that the range of sizes available is appropriate for the population.
- Waist tie: One way to help ensure appropriate fit is for a gown to have a waist tie. However, if the gown is not tied properly or not tied at all, it can dangle and cause other hazards [2].
- Cuff style: It is important to ensure that the cuff is appropriately designed such that its interface with gloves can maintain the necessary protection barrier. Gowns may have knit cuffs, elastic cuffs, or thumb loops. Any cuff style is acceptable as long as it allows the glove to fit and stay over the cuff (avoid "sleeve slide").
- Neck closure: There are various styles of neck closures available, including over-the-head, tape tab, tie, and hook & loop. Hook & loop closures are designed for adjustability, whereas tape tab closures are designed to reduce the time for donning and doffing [2]. When choosing a style, it is important to consider the ease of donning and doffing as well as the ability to avoid self-contamination during doffing of the contaminated gown [5].
- Back style: …

Critical Zone

For isolation gowns, the critical zone is the entire gown, including the seams but excluding the cuffs, hems, and bindings [4].

Breathability

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Test method [3]: **ASTM 1868 Part B or -17**, **ASTM D6701-16**, ASTM D737-75

Tracking Mechanism

Isolation gowns intended for multiple use should have a tracking mechanism to record the number of use cycles [4]. A simple strategy is to use a permanent marker to count (tally) the use cycles.

Flame-Resistance

If the respirator is to be used in an environment where fire is foreseeable hazard (e.g. during surgery), then it is recommended that the respirator can pass a flammability test [6].

Test method: Test the flammability per an industry standard such as 16 CFR 1610, Standard for the Flammability of Clothing Textiles

Biocompatibility

Isolation gowns may be in contact with intact skin for a duration of ≤24 hours. To ensure biocompatibility, the U.S. FDA recommends evaluating the gown material for potential adverse reactions [3]. This may not be necessary for gowns made of cotton or other textiles that are typically used for clothing.

Cytotoxicity

Cytotoxicity is the quality of being toxic to cells. Cytotoxicity test methods are designed to evaluate the acute adverse biological effects of extractables from materials; cells exposed to test or control materials are observed for visible signs of toxicity (such as a change in the size or appearance of cellular components or a disruption in their configuration) [7].

Test method [3]: ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

Sensitization

Sensitization or hypersensitivity reactions may occur in response to repeated or prolonged exposure to a chemical substance [8].

Test method [3]: ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Irritation or Intracutaneous Reactivity

The chemicals leached from materials may produce skin irritation, which is a tissue response characterized by inflammation, redness, swelling, and sometimes accompanied by heat and pain [9].

Test method [3]: ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Natural Rubber Latex

Due to reports of allergic reactions, some medical device manufacturers started labeling products as "latex-free," "does not contain natural rubber latex," or "does not contain latex." However, it is not possible to reliably assure the complete absence of the allergens associated with the reactions to natural rubber latex. Therefore, the U.S. FDA advises manufacturers who want to indicate that natural rubber latex was not used in the manufacturing of their product to "inform users that a product, product container, or product packaging was not made with natural rubber latex [10]."

3) Use and Reuse Guidance

Proper use

Isolation gowns are personal protective equipment (PPE) that are intended to help protect the wearer against the spread of inspection if they are exposed to potentially infectious liquid or solid material; they are one aspect of an overall infection-control strategy [3].

Donning

…

Doffing

…

Reuse

Isolation gowns are typically classified as disposable/single-use or reusable/multi-use. Disposable isolation gowns are designed to be discarded after a single use. Reusable isolation gowns are designed to be laundered after each use; such gowns are typically made of 100% cotton, 100% polyester, or polyester/cotton blends. Although reusable, there may be a limit on the maximum number of laundering/drying cycles [2].

Risks

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References

[1] AAMI TIR11:2005/(R)2015, "Selection and use of protective apparel and surgical drapes in health care facilities".

[2] F. S. Kilinc, "A Review of Isolation Gowns in Healthcare: Fabric and Gown Properties," *Journal of engineered fibers and fabrics,* vol. 10, no. 3, pp. 180-190, 2015.

[3] US FDA, "Medical Gowns," 11 March 2020. [Online]. Available: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns#g3. [Accessed 29 May 2020].

[4] ANSI/AAMI PB70:2012, "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities".

[5] NIOSH, "Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids," 9 April 2020. [Online]. Available: https://www.cdc.gov/niosh/npptl/topics/protectiveclothing/#references. [Accessed 29 May 2020].

[6] S. Rengasamy, G. Niezgoda and R. Shaffer, "Flammability of Respirators and other Head and Facial Personal Protective Equipment," *Journal of the International Society for Respiratory Protection,* vol. 35, no. 1, pp. 1-13, 2018.

[7] R. F. Wallin, "A Practical Guide to ISO 10993-5: Cytotoxicity," Medical Device and Diagnostic Industry, 1 April 1998. [Online]. Available: https://www.mddionline.com/practical-guide-iso-10993-5-cytotoxicity. [Accessed 29 May 2020].

[8] R. F. Wallin, "A Practical Guide to ISO 10993-10: Sensitization," Medical Device and Diagnostics Industry, 1 May 1009. [Online]. Available: https://www.mddionline.com/practical-guide-iso-10993-10-sensitization. [Accessed 29 May 2020].

[9] R. F. Wallin, "A Practical Guide to 10993-10: Irritation," Medical Device and Diagnostic Industry, 1 June 1998. [Online]. Available: https://www.mddionline.com/practical-guide-iso-10993-10-irritation. [Accessed 29 May 2020].

[10] FDA, "Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex," 24 August 2018. [Online]. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-labeling-medical-products-inform-users-product-or-product-container-not-made-natural. [Accessed 28 May 2020].

[11] F. S. Kilinc, "Isolation gowns in health care settings: Laboratory studies, regulations and standards, and potential barriers of gown selection and use," *American Journal of Infection Control,* vol. 44, pp. 104-111, 2016.