PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Testing of Stockpiled ANSI/AAMI PB70 Level 4 Surgical Gowns

To instill confidence in workers that personal protective equipment (PPE) will be protective, leaders in the PPE community develop performance standards and then check to see if the PPE meets these standards (i.e., conforms). This process includes a variety of public and private sector entities depending on their expertise involving the particular PPE and hazards. To bring greater oversight and coordination to these activities, the National Institute for Occupational Safety and Health (NIOSH) developed the *National Framework for Personal Protective Equipment – A Conformity Assessment Infrastructure.*

The Framework assists leaders of the PPE community in developing activities that are appropriate given the risk posed to the worker. NIOSH works with public and private sector entities to assess and improve upon conformity assessment activities by collecting PPE from the marketplace or at the point of use. NIOSH then evaluates the PPE against established standards and uses the test results to provide leaders in the PPE community guidance on post-market sampling strategies, evidence-based criteria for PPE acceptance or rejection, and potential performance requirement updates.

NIOSH determined that existing surgical gown test methods require greater clarification to ensure consistent evaluations and conclusions. Additionally, NIOSH recommends that a post-market conformity standard be developed.

This report relates to work conducted at the request of the Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS). The SNS asked NIOSH to evaluate a specific surgical gown model that was in the process of being purchased for the SNS to determine if that gown model met CDC recommendations for use while providing care to patients with Ebola. Specifically, whether this gown model passed the Level 4 requirements of American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) PB70:2012, "Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities."

Keywords: PPE, surgical gowns, stockpile, ASTM, ANSI/AAMI PB70

Abbreviations:
ANSI/AAMI: American National Standards Institute/Association for the Advancement of Medical Instrumentation
ASTM: American Society for Testing Materials
AATCC: American Association of Textile Chemists and Colorists
ASQ: American Society for Quality
SNS: Strategic National Stockpile
RQL: Rejectable Quality Level

What NIOSH Did to Protect the Worker

- NIOSH evaluated one model of a Level 4 surgical gown from a single manufacturer at the request of the SNS to determine if the gown model met the appropriate performance standards. The manufacturer indicated the gowns meet ANSI/AAMI *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* (ANSI/AAMI PB70:2012) Level 4 requirements. The test methods used were those specified for ANSI/AAMI PB70 (AAMI PB70 hereafter) Level 4 testing including ASTM F1671: *Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System* and AATCC 42: *Water Resistance: Impact Penetration*.
    - NIOSH received two cases (30 gowns in each case and each case from a different lot manufactured in 2014) of the gowns purchased by the SNS, but sent to NIOSH's National Personal Protective Technology Laboratory (NPPTL) to conduct the evaluation. Several months after receiving the gowns for the SNS, NIOSH NPPTL acquired two additional cases of gowns from the open market to be used as control gowns. Manufactured in 2015, these gowns had visibly different seam sealing than the gowns manufactured in 2014.
    - NIOSH funded an accredited third party testing laboratory to evaluate each gown at the three critical zones identified by AAMI PB70 (sleeve seams, tie attachments, and chest area) using ASTM F1671 and AATCC 42 test methods. The ASTM F1671 test methodology provides procedures for testing material both using a supporting screen and without a screen. The third party testing lab performed both variations.
- The AAMI PB70 standard requires manufacturers to implement a quality system that rejects lots with a failure rate greater than or equal to 20% at least 90% of the time. This is known as the rejectable quality level (RQL). NIOSH NPPTL created a red/yellow/green stoplight analogy based on the RQL and levels of concern. Green is for instances where the failure rate of testing is below the RQL. Yellow is for intermediate failure rates, where more testing would likely be needed. Red is where failure rates are significantly higher than the RQL and indicates the gowns may not provide the expected level of protection.

For an evaluation of 32 gowns, NIOSH NPPTL considered 0-6 failures as green, 7-9 failures as yellow, and 10 or more failures as red.

Table 1. Red/Yellow/Green Criteria for Sets of 32 Samples at 20% RQL

	Interpretation	Sample Failure Rate	Number of Failures
Red	Lot likely exceeds RQL	Significantly higher than RQL	10 or more
Yellow	Insufficient for determination	Slightly higher than RQL	7-9
Green	Lot likely below RQL	At RQL or lower	0-6

What NIOSH Found Through Testing and Evaluation

- AATCC 42: Water Resistance Test Method
  - NIOSH NPPTL tested 32 gowns (16 from each gown lot manufactured in 2014) at the noncritical zones on the front (i.e., outside of the critical zones). All of the 2014-manufactured gown samples tested met AAMI PB70 AATCC 42 testing criteria.
- ASTM F1671 Test Method
  - Without screen test methodology (**Table 2, Procedure A**)—For the surgical gowns received from the SNS (ASTM F1671 testing of 32 samples from sleeve seams, 32 samples from chests, and 32 from tie attachments), the results yielded four failures on the sleeve seams —three failures from one lot and one failure from the second lot. With four failures found out of the 32 tested samples, NIOSH NPPTL considered this a green result. On the control samples, the third party testing lab only tested ASTM F1671 at the sleeve seam. One control sample failed out of 32 on the sleeve seams with the ASTM F1671 test method.
  - With screen test methodology (**Table 2, Procedure B**)—The manufacturer provided a custom-made flat, stainless steel screen that meets the ASTM F1671 requirements. NIOSH used the same gown sleeves at different locations for ASTM F1671 Procedure B testing and the results yielded two failures on one lot from the 2014-manufactured samples and one failure on the control samples. None of the failures occurred on the gowns that failed the testing without the screen. The ASTM F1671 method specifies the use of a screen when testing elastomeric or extensible materials if any distortion of the test material is suspected of causing a failure; however, testing without a screen is expected to give worst-case scenario. With only two out of 32 gown samples failing the ASTM F1671 test, NIOSH NPPTL considered this a green result.

Table 2. ASTM F1671 Test Results

Year of Manufacture	Lot	Critical Zone	Quantity Tested	Procedure A (No Screen) Failures	Procedure B (With Screen) Failures	Procedure A & B Failures on same sleeve
2014	A - SNS	Sleeve	16	3	0	0
2014	B - SNS	Sleeve	16	1	2	0
2015	C - Open Market	Sleeve	32	1	1	0
2014	A - SNS	Tie	16	0	Not Tested	Not Tested
2014	B - SNS	Tie	16	0	Not Tested	Not Tested
2014	A - SNS	Chest	16	0	Not Tested	Not Tested
2014	B - SNS	Chest	16	0	Not Tested	Not Tested

CASE Conclusion

NIOSH NPPTL evaluated one model of SNS stockpiled Level 4 surgical gowns according to the requirements of AAMI PB70 liquid barrier classification standard for verification of adequate barrier performance in specified regions of the gown. Tests included ASTM F1671 (Viral Penetration Resistance) and AATCC 42 (Water Resistance: Impact Penetration). For ASTM F1671, results were inconsistent both when testing with the stainless steel screen (which reportedly masks up to 42% of the material surface) and testing done without the screen. All testing results showed failure rates under the RQL, thus NIOSH NPPTL gave green results for all sets of testing. However, this evaluation was limited to gowns selected from two lots. Therefore, the conclusions cannot be generalized to state that the majority of the gowns provided by the SNS were consistent with the CDC recommendations for use while providing care to patients with Ebola. In addition, the findings were limited to the samples received as there was no attempt at random sampling to select gowns for testing. NIOSH NPPTL concludes that there is not sufficient evidence to challenge the manufacturer's claim of the gowns manufactured in 2014 being compliant with the requirements of Level 4 of the AAMI PB70 standard.

Actions the PPE Community May Take to Further Protect Workers

- The ASTM F1671 test method does not provide objective criteria for use of the supporting screen, nor does it provide sufficient detail to construct consistently similar screens. The design and specifications of the screen should be clarified in order to receive consistent test results from labs.
- AAMI PB70 was the only conformity-related classification standard that could be identified for surgical gowns in the United States. However, this standard is designed for pre-market conformity considerations. While the AAMI PB70 standard is not sufficient to identify pass or fail criteria for third party post-market product audits, it may provide a foundation for such a standard. For use as a post-market standard, NIOSH makes the following recommendations:
    - PPE Community: Request that the manufacturing process for surgical gowns meet existing quality standards.
    - Standards Development Body: (1) Require full implementation of a standards compliant sampling plan, such the ASQ Z1.9 and Military (MIL)-STD-1916 currently mentioned in the AAMI PB70, to determine sampling plans and (2) develop a consensus-based standard for post-market conformity verification—i.e., for products on the market and being used by workers—taking into account time in storage and other factors likely to affect protection.

Actions the PPE Users, Selectors, and Purchasers May Take to Further Protect Themselves and Others from Hazards

- Sign up for NPPTL's Listserv at https://www.cdc.gov/niosh/npptl/sub-NPPTL.html to receive email notifications relevant to PPE.

For more information related to personal protective equipment, visit the NPPTL website https://www.cdc.gov/niosh/npptl

To receive documents or other information about occupational safety and health topics, contact NIOSH:

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TTY: 1–888–232–6348
CDC INFO: https://www.cdc.gov/cdc-info/

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Suggested Citation

NIOSH [2017]. PPE CASE: testing of stockpiled ANSI/AAMI PB70 level 4 surgical gowns. By Rottach D, Fries M, Kilinc-Balci FS, Moore S, Shaffer R. Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, NPPTL Report Number P2017-0102.