PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Testing of Stockpiled ANSI/AAMI PB70 Level 3 Surgical Gowns

To instill confidence in workers that personal protective equipment (PPE) will be effective, leaders in the PPE community develop performance standards and then check to see if the PPE meets these standards (i.e., conforms). This process involves a variety of public and private sector entities contributing expertise in 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 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 did not find evidence that the stockpiled gowns tested no longer met AAMI PB70 Level 3 requirements. However, only the manufacturer can set or extend the shelf life of their products. NIOSH does not recommend the use of these gowns without conducting representative testing of the stockpile and consulting with the manufacturer about the shelf life.

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 the performance of a model of surgical gown held in the SNS beyond the typical shelf life. Specifically, whether this gown model passed the Level 3 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, control gowns, shelf life, ANSI/AAMI PB70

Abbreviations:

ANSI/AAMI: American National Standards Institute/Association for the Advancement of Medical Instrumentation
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

- At the request of the SNS, NIOSH evaluated one model of a Level 3 surgical gown from a single manufacturer to determine if the gown model, which was stockpiled beyond the typical shelf life, met the appropriate performance standards. The manufacturer indicated that the gowns, when originally purchased by the SNS, met ANSI/AAMI *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* (ANSI/AAMI PB70:2012) Level 3 requirements. The test methods used were those specified for ANSI/AAMI PB70 (AAMI PB70 hereafter) Level 3 testing including AATCC 42: *Water Resistance: Impact Penetration* and AATCC 127 *Water Resistance: Hydrostatic Pressure Test*.
    - NIOSH received three sizes (marked on the package as L, XL, and XXL) of SNS stockpiled gowns (hereafter referred to as stockpile gowns) that were manufactured in 2008 and 2010 from three different lots. There was no expiration date provided on the labels, however all the gowns were beyond the typical shelf life (five years). NIOSH obtained a set of gowns manufactured in 2014 from the open market for comparison (hereafter referred to as control gowns). Although this was the same model, visual inspection identified a different seam sealing technique. The stockpile gowns used a smaller weld area for the tie attachment and a welded sleeve seam, while the control gowns used a wide welded area for the tie attachment and fusible interfacing tape to form the sleeve seam.
    - NIOSH funded an accredited third-party testing laboratory to evaluate the gowns using the test methods identified in AAMI PB70: AATCC 42 *Water Resistance: Impact Penetration* on the critical zones and the front of the gown and AATCC 127 *Hydrostatic Water Resistance* on the critical zones. AATCC 42 subjects a test sample to a stream of water and measures the amount that penetrates through the fabric to a blotter paper. Garments that are more protective should have less water penetrating the fabric test sample (i.e., lower levels are better). AATCC 127 applies water under pressure to one side of a fabric sample and determines the pressure at which droplets form on the other side of the sample. Garments that are more protective should be able to withstand higher levels of pressure before droplets form (i.e., higher levels are better).
- 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 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 beneficial. Red is for instances 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 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

NIOSH selected 12 XL gowns and 10 each of the L and XXL gowns for testing at each gown location specified in the AAMI PB70 Level 3 specification. The standard specifies that the AATCC 42 and AATCC 127 testing should be conducted at a location in the critical zones, which include the front of the gown (chest), the sleeve seam, and the points of the attachments. In addition, AATCC 42 should be conducted on the front of the gown, which may be outside of the critical zone chest area.

- AATCC 42: Impact Penetration Test Method
  - All of the stockpile gowns passed AATCC 42 testing in all three critical zones, while one control gown failed at the tie attachment area. A single test failure should not be used to infer that a gown lot does not meet the AAMI PB70 standards, as the standard allows for some gown failures. All of the stockpile and control gowns passed AATCC 42 testing on the front of the gown.
- AATCC 127: Hydrostatic Pressure Test Method
  - All test samples taken from the chest area of stockpile gowns passed the Hydrostatic Pressure Test criterion. At the sleeve seam zone, one stockpile gown failed out of 32 samples tested, while the control gowns (with a difference in sleeve seam design) resulted in 16 out of 32 sample failures. According to the AAMI PB70 Rejectable Quality Limit (RQL), stockpile gowns did not exceed failure rates for any tested zones, while the control gown sleeve seam testing failed at a higher rate than the RQL. In contrast, stockpile gowns showed overall lower resistances for the tie attachment area than the control gowns. All control gowns passed while one stockpile gown failed for the tie attachment area.

Table 2. AAMI Level 3 Gown Lot Information and Results

Set	Date of Manufacture	Size	Sample Source	Quantity Tested	Stoplight Conclusion
Stockpile gown-1	6/2008	XXL	SNS	10	Green
Stockpile gown-2	1/2010	XL	SNS	12	Green
Stockpile gown-3	1/2010	L	SNS	10	Green
2014 control gown-1	8/2014	XXL	Open Market	10	Red
2014 control gown-2	9/2014	XL	Open Market	12	Red
2014 control gown-3	9/2014	L	Open Market	10	Red

CASE Conclusion

NIOSH evaluated one model of SNS stockpiled Level 3 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 AATCC 42 *Water Resistance: Impact Penetration* and AATCC 127 *Hydrostatic Pressure Test*. For AATCC 42 testing, all of the stockpile gowns passed the AAMI PB70 Level 3 criteria, while only one of the control gowns failed in the tie attachment region. During the AATCC 127 testing, the stockpile gowns showed a single failure each in a sleeve seam and in a tie attachment region out of 32 samples. The control gowns performed worse, with 16 out of 32 control gown samples failing the AATCC 127 testing on sleeve seams, while samples from the chest and tie attachment regions passed. Since the SNS stockpiled Level 3 gowns showed failure rates under the RQL, NIOSH gave green results for testing. However, the control gowns failed testing at a rate substantially higher than the RQL, thus NIOSH considered this a red result.

This evaluation was limited to gowns selected from the lots received, so the conclusions cannot be generalized to state the readiness of the broader supply of Level 3 surgical gowns stockpiled in the SNS. In addition, NIOSH did not test other aspects of gown performance, such as tear strength or puncture resistance. NIOSH did not find evidence that the stockpiled gowns tested no longer met AAMI PB70 Level 3 requirements. However, only the manufacturer can set or extend the shelf life of their products. Thus, NIOSH does not recommend the use of these gowns without conducting representative testing of the stockpile and consulting with the manufacturer about the shelf life.

Actions the PPE Community May Take to Further Protect Workers

- The control gowns manufactured in 2014 failed testing at a rate substantially higher than expected. NIOSH provided the results to the manufacturer and recommends additional research by the PPE community related to gown performance to better understand the factors that lead to test failures and the impact of test failures on healthcare worker safety and health.

- 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 premarket 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. Additionally, request the shelf life information and recommended storage conditions.
    - 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; (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; and (3) make a requirement to include storage conditions and shelf life information on labeling or primary packaging.

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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CDC INFO: https://www.cdc.gov/cdc-info/

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