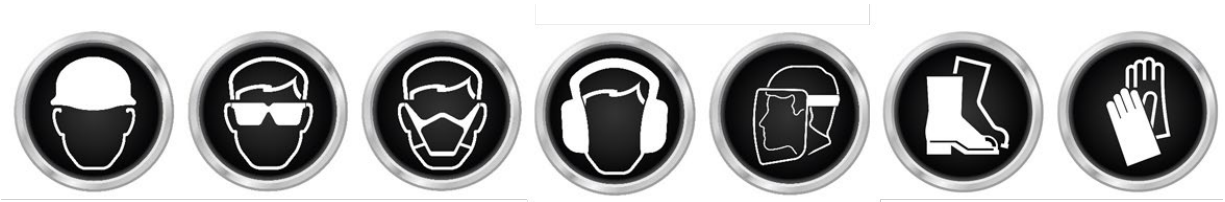
PPE CASE



Personal Protective Equipment Conformity Assessment Studies and Evaluations

Performance of Stockpiled Level 3 Surgical Gowns Sampled from Six Stockpile Facilities

National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
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This report details the results for spray impact and hydrostatic resistance performance for 1,040 Level 3 surgical gowns collected from six U.S. stockpile facilities, including one federal stockpile and five state stockpiles. Performance for stockpiled air-purifying respirators sampled from these same stockpile facilities can be found on NIOSH's PPE CASE Reports website.

End user protections will be enhanced by revisions to AAMI PB70 to define minimum critical zone boundaries and include guidance for post-market quality assurance sampling and data interpretation for third party entities.

In the event of a national emergency, eighteen million U.S. healthcare workers may face high-consequence infectious disease exposures [NIOSH 2017a]. The use of personal protective equipment (PPE), such as gowns, gloves, goggles, and respirators, is an important measure within the infection prevention hierarchy of controls. Recent outbreaks—even those that occurred without extensive impact on US operations (e.g., 2009 H1N1 pandemic, 2016 Ebola outbreak)—caused respirator shortages; when the first US fatality was reported during the Ebola outbreak, the PPE orders increased 10-200 fold [CDC 2021; DHHS 2012; NIOSH 2018]. To prepare for these surge demands, emergency planners stockpile large quantities of PPE at federal and state levels to support local supplies [Patel et al. 2017].

Due to the decision to stockpile PPE, stockpile personnel and decision makers have sought to explore the effectiveness of PPE after long-term storage (e.g., over five years). Use of gowns or other types of PPE past their designated shelf life is not recommended but has been observed in the US where there are surges in demand and the use of PPE past its shelf life is needed. Over the past decade the Strategic National Stockpile (SNS) and state and local stockpile personnel asked NIOSH to evaluate the performance of stockpiled PPE as well as to better understand storage conditions in U.S. stockpile facilities that store PPE; however, until recently this testing did not include respirators and was performed on only a small number of samples for face shields and gowns [NIOSH 2017b; NIOSH 2018].

In 2017, NIOSH established a PPE Stockpile Partnership consisting of 1) federal agencies and the SNS; 2) state, county, and city stockpiles; 3) hospital-related stockpile entities; and 4) a manufacturer trade association to inform the design and execution of an empirical study to evaluate stockpiled air-purifying respirators (APR) and

surgical gowns from ten US stockpile facilities, where this study was conducted in accordance with the study design outlined in Greenawald et al. 2021. The APR performance results can be found on NIOSH's ***PPE CASE Reports website***. This report summarizes the performance testing results of two stockpiled Level 3 surgical gowns models including Medline Proxima Aurora and Cardinal Health Astound. **A total of 1,040 Level 3 surgical gowns were sampled from six facilities.** Being one level out of four (Level 1 being the least protective to Level 4 being the most protective), Level 3 surgical gowns are worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate matter [FDA 2021].

How NIOSH Evaluated Surgical Gowns and Storage Conditions

Description of the Six Facilities

- From 2017 to 2019, NIOSH researchers visited six stockpile facilities, geographically dispersed across the US. These facilities included one federal stockpile and five state stockpiles. These facilities were in the Department of Health and Human Services (HHS) Regions 1, 2, 6, 9, and 10, and are shown in **Figure 1**. These facilities were selected based on their inventories and availability of Level 3 surgical gowns, disparate storage conditions, and type of facility. This methodology is further described in Greenawald et. al 2021.

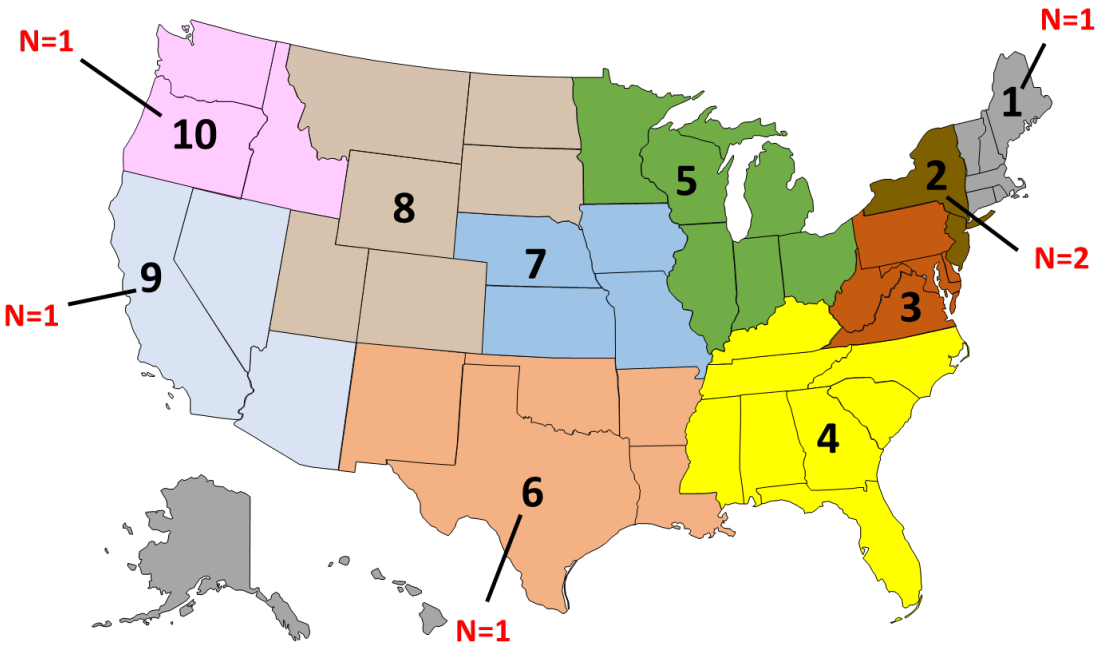

Figure 1. Locations of the six collaborating stockpile facilities by HHS national regions.

Assessment of Storage Conditions

- NIOSH, in conjunction with the PPE Partnership members, developed checklists to document site and packaging (i.e., pallet and case) conditions that may impact surgical gown performance. Example checklists can be found in Greenawald et al 2021.
- NIOSH documented site storage conditions, including the presence of: 1) dust, moisture, fans, windows, doors, and ventilations systems; and 2) chemicals such as cleaning products, vermin traps, and pesticide treatment schedules—no indication of PPE product exposure was identified.

- NIOSH documented PPE pallet-specific storage conditions including: 1) the presence of dust, shrink-wrapping around the pallet, and moisture on the exterior packaging; 2) exposure to sunlight and direct light; 3) proximity to fans, windows, doors, and ventilation systems; 4) damage to shrink wrapping; and 5) location of pallet on storage rack (e.g., top, bottom).
- NIOSH documented PPE case-specific storage conditions including: 1) the presence of dust and moisture; 2) exposure to sunlight and direct light; 3) proximity to fans, windows, doors, and ventilation systems; 4) damage to the case; and 5) location of case within the pallet (e.g., top/not load-bearing, bottom/load-bearing).

For stockpiles where temperature and percent relative humidity (%RH) were monitored, NIOSH reviewed data that were provided by the facility stockpile managers. Where data were not available, NIOSH collected temperature and %RH data by placing data loggers in the facility, collecting temperature and %RH data for eight to 12 months (specifics provided in a later section). The temperature and %RH data were collected within two years of the surgical gowns being tested.

Collection of Surgical Gown Samples

- Surgical gowns classified as Level 3 per the standard ANSI/AAMI PB70:2012 *Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities* (herein referred to as AAMI PB70)—were collected from six stockpile facilities in 2019. Specifically, two models were selected, because they were the only Level 3 surgical gown models available for sampling by these six facilities: 1) Medline Proxima Aurora model and 2) Cardinal Health Astound model.[1]
- The gowns collected were from 16 production lots, which were all manufactured in 2008. Of these 16 sampled lots, 4 lots had shelf lives designated by Cardinal Health Astound on the product packaging at the time of testing—all of these lots exceeded their five-year shelf lives. No storage condition recommendations were on the product packaging.
- Where possible, at least two production lots were sampled for each gown model within a facility. These two lots (designated Lot A and Lot B) were sampled to evaluate and attempt to account for possible inter-lot variation. One lot (designated Lot A) was sampled when there was only one lot available for sampling.
- NIOSH researchers visited each facility and collected gown products which were shipped to the NIOSH facility overnight to reduce exposure to non-climate-controlled conditions during transport. NIOSH tested the gowns at its facility or had them tested by a third-party laboratory accredited to run the test method.
- A minimum of 64 gowns were sampled and tested from each production lot to cover the tests required by the AAMI PB70 standard for Level 3 surgical gowns.
- Non-stockpiled (used as a control) surgical gowns of the same model as those collected from the six facilities were purchased from the open market. Two lots of each non-stockpiled model were purchased. The Medline Proxima Aurora non-stockpiled gowns did not have expiration date or storage condition information on the packaging; all non-stockpiled gowns were manufactured in 2018.[2] The Cardinal Health Astound had five-year expiration dates on the packaging; no Cardinal Health-recommended storage condition information was on the product packaging.

[1] Level 4 surgical gowns were also collected, and results will be published in a separate report.
[2] Medline stated that it does not provide specific shelf life recommendations for this model [Medline 2020].

Characteristics of Sampled Surgical Gowns

- **Table 1** provides a summary of the Level 3 surgical gown models sampled from the six facilities. The table also includes relevant shelf life status information. Surgical gowns are cleared by the Food and Drug Administration (FDA). The FDA does not require manufacturers to designate a shelf life, although some may choose to do so.
- Testing for the stockpiled gowns was completed in 2019 and samples were tested within one year of collection.

Table 1. Characteristics of the Level 3 surgical gowns sampled from six of the ten collaborating stockpile facilities—the other four facilities participated in the APR testing but did not stockpile Level 3 surgical gowns.

Stockpile Facility #[3]	Model	Lot #[4]	Mfr. Year	# of Gowns Tested	Gown Age at Time of Testing (2019, years)	Shelf Life Status on Packaging[5]
1	Medline Proxima Aurora	A	2008	64	11	Not designated (ND)
		B	2008	64	11	ND
	Cardinal Health Astound	A	2008	64	11	Exp. 11/2013; past 5-year shelf life
		B	2008	64	11	Exp. 11/2013; past 5-year shelf life
2	Medline Proxima Aurora	A	2008	50[6]	11	ND
		B	2008	64	11	ND
4	Medline Proxima Aurora	A	2008	64	11	ND
		B	2008	64	11	ND
	Cardinal Health Astound	A	2008	64	11	ND
		B	2008	64	11	ND
6	Medline Proxima Aurora	A	2008	64	11	ND
		B	2008	64	11	ND
	Cardinal Health Astound	A	2008	80[7]	11	Exp. 04/2013; past 5-year shelf life
7	Cardinal Health Astound	A	2008	78[7]	11	Exp. 12/2013; past 5-year shelf life
10	Medline Proxima Aurora	A	2008	64	11	ND
		B	2008	64	11	ND

Evaluation of Spray Impact Penetration and Hydrostatic Water Resistance Performance

- NIOSH followed the required testing as outlined in AAMI PB70 for both non-stockpiled and stockpiled gowns (**Table 2**). AAMI PB70 is a standard that defines liquid barrier performance and classification of protective apparel used in healthcare facilities [ANSI/AAMI PB70 2012]. This includes test methods from the American Association of Textile Chemists and Colorists (AATCC) and the American Society for Testing and Materials (ASTM), as outlined in **Table 2**. AAMI PB70 defines the critical zone of a surgical gown

[3] Stockpile facility numbering reflects the numbering used for all ten stockpile facilities in NIOSH's research study: https://www.cdc.gov/niosh/npptl/ppecase.html

[4] Where possible, at least two production lots were sampled for each gown model within a facility. Gowns sampled from "Lot A" came from one production lot; gowns sampled from "Lot B" came from a second production lot.

[5] Testing was completed in 2019. ND=expiration date not designated on the product packaging.

[6] Not enough gown units were available for sampling.

[7] More than 64 gowns were tested from Lot A as only one lot was available for sampling; sample size was based on available gowns within the cases collected samples. More tie samples were tested for hydrostatic resistance as this was the more stringent test to evaluate performance compared to spray impact.

shall, at a minimum, comprise the front area of the gown from chest to knees and the sleeves from the cuff to above the elbow. Cardinal Health identified the sleeve seam, chest area, and point of attachments in the front of the gown (e.g., tie attachment) as the critical zones for surgical gowns in this study. Medline identified the chest and sleeve seams as critical zones (CZ), but the tie attachments are NOT designated by this manufacturer as a CZ. However, the tie attachments were evaluated as an exploratory effort as the tie attachment area has the potential to move into the front gown area CZ based on the size of the healthcare personnel; the tie attachments are herein referred to as "tie attachment samples" and the results of these Medline tie attachment samples are presented in separate tables.

- Spray Impact (AATCC 42) indicates how well the fabric resists strikethrough when fluids splash or spray onto the fabric, whereas Hydrostatic Resistance (AATCC 127) indicates how well the fabric will resist strikethrough when water pressure is applied to the surface of the fabric.

Table 2. Minimum performance requirements as outlined in AAMI PB70 used to evaluate Level 3 surgical gown performance[8]

Test Method	AAMI PB70 Pass/Fail Criteria for Critical Zones[9] of the Level 3 Surgical Gowns
AATCC 42: Spray Impact Penetration	Blotter weight $\leq$ 1.0 g H_2O
AATCC 127: Hydrostatic Pressure	Resistance $\geq$ 50 cm H_2O

Evaluation of Non-stockpiled Surgical Gowns

- A summary of the non-stockpiled gown testing that was performed is shown in **Table 3**. Testing for the non-stockpiled gowns was completed from 2018 to 2019. The non-stockpiled gowns were also tested in accordance with performance requirements outlined in AAMI PB70.
- **Table 3** displays the number of samples tested for each critical zone (CZ) and tie attachment samples tested from each lot.

Table 3: Summary of the Critical Zones (CZs) Tested from the Non-stockpiled Surgical Gowns

Non-stockpiled Model	Lot # (Mfr. Year)	Total # of Gowns Tested	Total Number of CZ Samples Tested for Spray Impact[10]	Total Number of CZ Samples Tested for Hydrostatic Resistance
Medline Proxima Aurora	A (2018)	64	64	64
	B (2018)	64	64	64
Cardinal Health Astound	A (2018)	64	96	96
	B (2018)	64	96	96

[8] Testing the entire front of the gown and the areas of sleeve outside of the critical zones to evaluate conformance to Level 1 was not included in the described test plan except for the Medline Proxima Aurora gowns, where Medline stated the tie attachments were not considered critical zones, and therefor Spray Impact was evaluated against the tie attachments to confirm Level 1 requirements were meant and hydrostatic resistance was not evaluated.

[9] These pass/fail criteria were also used when evaluating the Medline tie attachment samples.

[10] 32 gowns were evaluated per test, per production lot. For Spray Impact, three critical zones were tested per gown for a total of 96 critical zones evaluated per lot (i.e., 32 chest, 32 tie attachment, 32 sleeve seam). For Hydrostatic Resistance, three critical zones were tested per gown for a total of 96 critical zones evaluated per lot (i.e., 32 chest, 32 tie attachment, 32 sleeve seam) for the Cardinal Health Astound model, while two critical zones were tested per gown for a total of 64 critical zones evaluated per lot (i.e., 32 chest, 32 sleeve seam) and 32 tie attachment samples for the Medline Proxima Aurora Model.

Table 4: Summary of the Tie Attachment Samples (non-Critical Zones) Tested from the Non-stockpiled Surgical Gowns

Non-stockpiled Model	Lot # (Mfr. Year)	Total # of Gowns Tested	Total Number of Tie Attachment Samples Tested for Spray Impact[11]	Total Number of Tie Attachment Samples Tested for Hydrostatic Resistance
Medline Proxima Aurora	A (2018)	32	32	32
	B (2018)	32	32	32

Evaluation of Stockpiled Surgical Gowns

A summary of the stockpiled gown testing for the Medline and Cardinal Health **critical zones** that was performed is shown in **Table 5.** A summary of the stockpiled gown testing for the Medline **tie attachment samples** that was performed is shown in **Table 6.**

[11] 32 gowns were evaluated per test, per production lot. For Spray Impact, three critical zones were tested per gown for a total of 96 critical zones evaluated per lot (i.e., 32 chest, 32 tie attachment, 32 sleeve seam). For Hydrostatic Resistance, three critical zones were tested per gown for a total of 96 critical zones evaluated per lot (i.e., 32 chest, 32 tie attachment, 32 sleeve seam) for the Cardinal Health Astound model, while two critical zones were tested per gown for a total of 64 critical zones evaluated per lot (i.e., 32 chest, 32 sleeve seam) and 32 tie attachment samples for the Medline Proxima Aurora Model.

Table 5: Summary of the Testing Conducted on the Stockpiled Level 3 Surgical Gown Critical Zones.

Stockpile Facility #[12]	Model	Lot #	Mfr. Year	Total # of Gowns Tested	Notes on CZ[13] Sample Size for each Production Lot
1	Medline Proxima Aurora	A	2008	64	Spray Impact CZs 32 chest, 32 sleeve seam Hydrostatic CZs 32 chest, 32 sleeve seam
		B	2008	64	
	Cardinal Health Astound	A	2008	64	Spray Impact CZs 32 chest, 32 tie attachment, 32 sleeve seam Hydrostatic CZs 32 chest, 32 tie attachments, 32 sleeve seam
		B	2008	64	
2	Medline Proxima Aurora	A	2008	50[14]	Stockpile did not have a sufficient number of gown samples to support the test plan. Testing for Hydrostatic Resistance is more stringent and prioritized over Spray Impact testing. Spray Impact CZs 64 (32 chest, 32 sleeve seam) Hydrostatic CZs 32 chest, 32 sleeve seam
		B	2008	64	Spray Impact CZs 32 chest, 32 sleeve seam Hydrostatic CZs 32 chest, 32 sleeve seam
4	Medline Proxima Aurora	A	2008	64	Spray Impact CZs 32 chest, 32 sleeve seam Hydrostatic CZs 32 chest, 32 sleeve seam
		B	2008	64	
	Cardinal Health Astound	A	2008	64	Spray Impact CZs 32 chest, 32 tie attachments, 32 sleeve seam Hydrostatic CZs 32 chest, 32 tie attachments, 32 sleeve seam
		B	2008	64	
6	Medline Proxima Aurora	A	2008	64	Spray Impact CZs 32 chest, 32 sleeve seam Hydrostatic CZs 32 chest, 32 sleeve seam
		B	2008	64	
	Cardinal Health Astound	A	2008	80	Stockpile only had one production lot available for sampling; therefore, additional samples were tested from this single production lot. Spray Impact CZs 128 (48 chest, 32 tie attachment, 48 sleeve seam) Hydrostatic CZs 144 (48 chest, 48 tie attachment, 48 sleeve seam)
7	Cardinal Health Astound	A	2008	78	Stockpile only had one production lot available for sampling; therefore, additional samples were tested from this single production lot. Spray Impact CZs 124 (46 chest, 32 tie attachment, 46 sleeve seam) Hydrostatic CZs 138 (46 chest, 46 tie attachment, 46 sleeve seam)
10	Medline Proxima Aurora	A	2008	64	Spray Impact CZs 32 chest, 32 sleeve seam Hydrostatic CZs 32 chest, 32 sleeve seam
		B	2008	64	

[12] Stockpile facility numbering reflects the numbering used for all ten stockpile facilities in NIOSH's research study. https://www.cdc.gov/niosh/npptl/ppecase.html

[13] Medline does not consider the tie attachments as critical zones.

[14] Not enough product cases were available for sampling.

Table 6: Summary of the Testing Conducted on the Stockpiled Medline Proxima Aurora Surgical Gown Tie Attachment Samples.

Stockpile Facility #[15]	Model	Lot #	Mfr. Year	Total # of Gowns Tested	Notes on Tie Attachment Sample Size for each Production Lot
1	Medline Proxima Aurora	A	2008	64	Spray Impact 32 tie attachments Hydrostatic 32 tie attachments
		B	2008	64	
2	Medline Proxima Aurora	A	2008	50[16]	Stockpile did not have a sufficient number of gown samples to support the test plan. Testing for Hydrostatic Resistance is more stringent and prioritized over Spray Impact testing. Spray Impact[17] 18 tie attachment Hydrostatic 32 tie attachments
		B	2008	64	Spray Impact 32 tie attachments Hydrostatic 32 tie attachments
4	Medline Proxima Aurora	A	2008	64	Spray Impact 32 tie attachments Hydrostatic 32 tie attachments
		B	2008	64	
		B	2008	64	
6	Medline Proxima Aurora	A	2008	64	Spray Impact 32 tie attachments Hydrostatic 32 tie attachments
		B	2008	64	
10	Medline Proxima Aurora	A	2008	64	Spray Impact 32 tie attachments Hydrostatic 32 tie attachments

What NIOSH Found Through Inspection, Testing, and Evaluation

Storage Conditions

- Facility-specific findings—such as site and pallet storage conditions—can be found in the series of individual PPE CASE Reports developed to document the APR testing results for each of the six facilities [Greenawald et al. 2020a-f].
- A brief synopsis of storage conditions found at each of the six facilities where surgical gowns were sampled is presented in **Table 5**. PPE manufacturers may recommend temperature and %RH storage recommendations over the life of the product to minimize loss of performance.

[15] Stockpile facility numbering reflects the numbering used for all ten stockpile facilities in NIOSH's research study. https://www.cdc.gov/niosh/npptl/ppecase.html

[16] Not enough cases were available for sampling.

[17] Since only one tie attachment sample is available per gown, conducting hydrostatic resistance testing for tie attachments was prioritized over conducting spray impact testing for tie attachments.

- Temperature and %RH data were available/obtained for the following lengths of time for each facility:
    - Facility 1: 2 years 11 months (facility-generated data; 2014 - 2017)
    - Facility 2: 2 years 11 months (facility-generated data; 2014 - 2017)
    - Facility 4: 1 year (NIOSH data logger-generated data; 2017 - 2018)
    - Facility 6: 3 years 10 months (facility-generated data; 2013 - 2017)
    - Facility 7: 1 year (NIOSH data logger-generated data; 2017 - 2018)
    - Facility 10: 5 years (facility-generated data; 2014 - 2019)
- **Figures 2** and **3** show the minimum, maximum, and average temperature and %RH, respectively, for each of the six collaborating stockpiles across the specified time frame. Facility-specific temperature and %RH data plots over time can be found in the series of six PPE CASE reports that were completed for the APRs tested from these facilities [Greenawald et al. 2020a-f].

Table 7: Summary of the Storage Characteristics at the Six Stockpile Ffacilities.

Stockpile Facility	Level 3 Gown Models	Storage Characteristics	Environmental Controls and Monitoring	Visual Inspection Concerns for Cases or Gowns
1	Medline Proxima Aurora Cardinal Health Astound	Lighting off when unoccupied; no evidence of excess moisture or chemical spills; no windows allowing sunlight; pallets shrink wrapped on pallet sides but not top or bottom; some pallets were stacked two pallets high on the topmost rack, causing some weight to be applied to the bottom pallet	Temperature controlled; temperature and %RH monitored	Cases: 4 cases with slight crushing, puncture, or tears Gowns: None
2	Medline Proxima Aurora	Warehouse shared with another entity; lighting off when unoccupied; no evidence of excess moisture or chemical spills; no windows allowing sunlight; pallets shrink wrapped on pallet sides but not top or bottom; pallets separated by metal rack	Temperature controlled; temperature and %RH monitored	Cases: 1 case with 2 small punctures/tears Gowns: None
4	Medline Proxima Aurora Cardinal Health Astound	Lighting off when unoccupied; small ceiling vents allowed sunlight to enter facility; no evidence of excess moisture or chemical spills; pallets shrink wrapped on pallet sides but not top or bottom; some pallets were stacked two pallets high on the top most rack, causing some weight to be applied to the bottom pallet	Temperature controlled; temperature and %RH not monitored	Cases: 8 cases with slight to moderate tears/punctures Gowns: None
6	Medline Proxima Aurora Cardinal Health Astound	Lighting off when unoccupied; no evidence of excess moisture or chemical spills; no windows allowing sunlight; ceiling fans circulated air; pallets shrink wrapped on pallets sides and the top; pallets separated by metal rack	Temperature and %RH controlled; temperature and %RH intermittently monitored	Cases: 2 cases with slight to large tears/punctures Gowns: None
7	Cardinal Health Astound	Lighting off when unoccupied; no evidence of chemical spills; evidence of mitigated moisture damage on facilities walls; some windows allowed indirect sunlight; pallets shrink wrapped on sides and a plastic covering was placed on the top; pallets separated by metal rack	No controls or monitoring	Cases: 2 cases with slight crushing on one side Gowns: None
10	Medline Proxima Aurora	Lighting off when unoccupied; no evidence of excess moisture or chemical spills; no windows allowing sunlight; pallets shrink wrapped on sides but not top or bottom; pallets separated by metal rack	Temperature controlled; temperature and %RH monitored	Cases: 3 cases with slight tear/puncture to side and crushing to corner Gowns: None

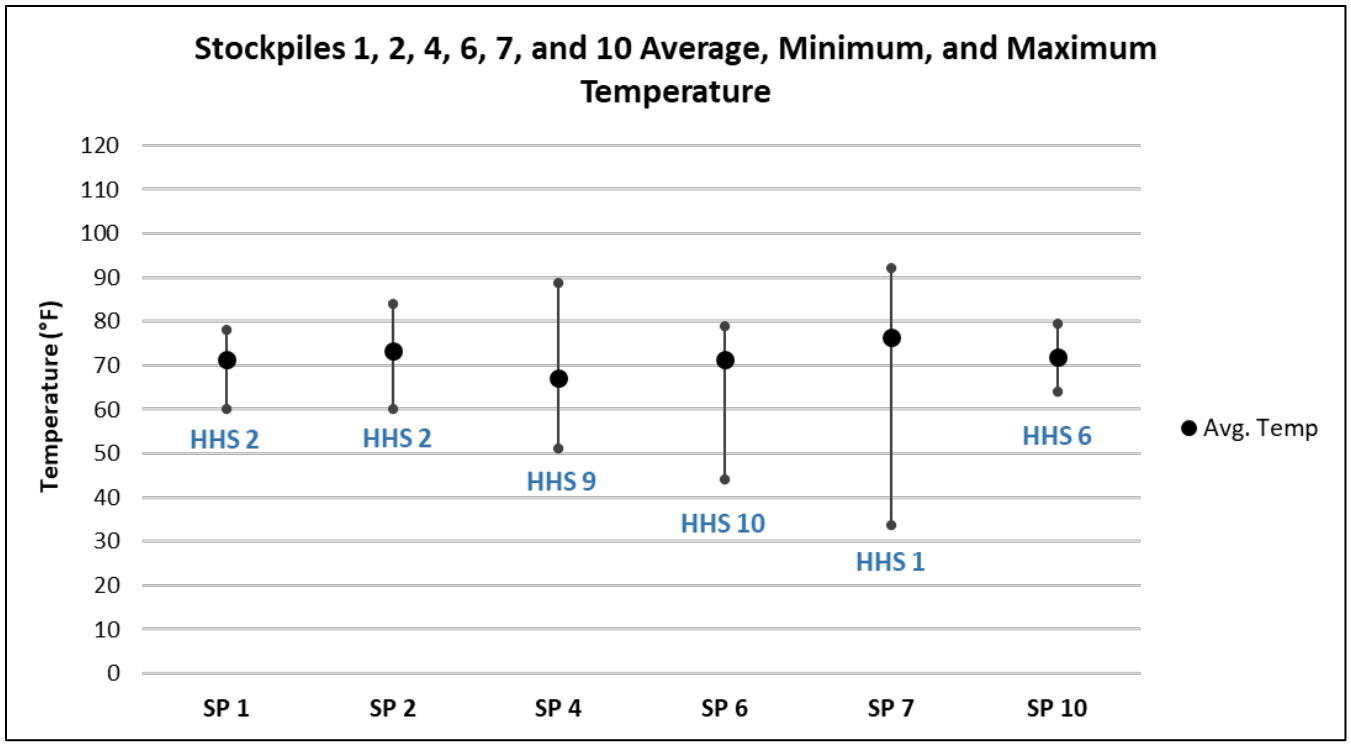

Figure 2: Average, minimum, and maximum temperature for the six stockpile facilities visited in this study. HHS regions for each facility are also depicted; refer to Figure 1 for the HHS region locations.

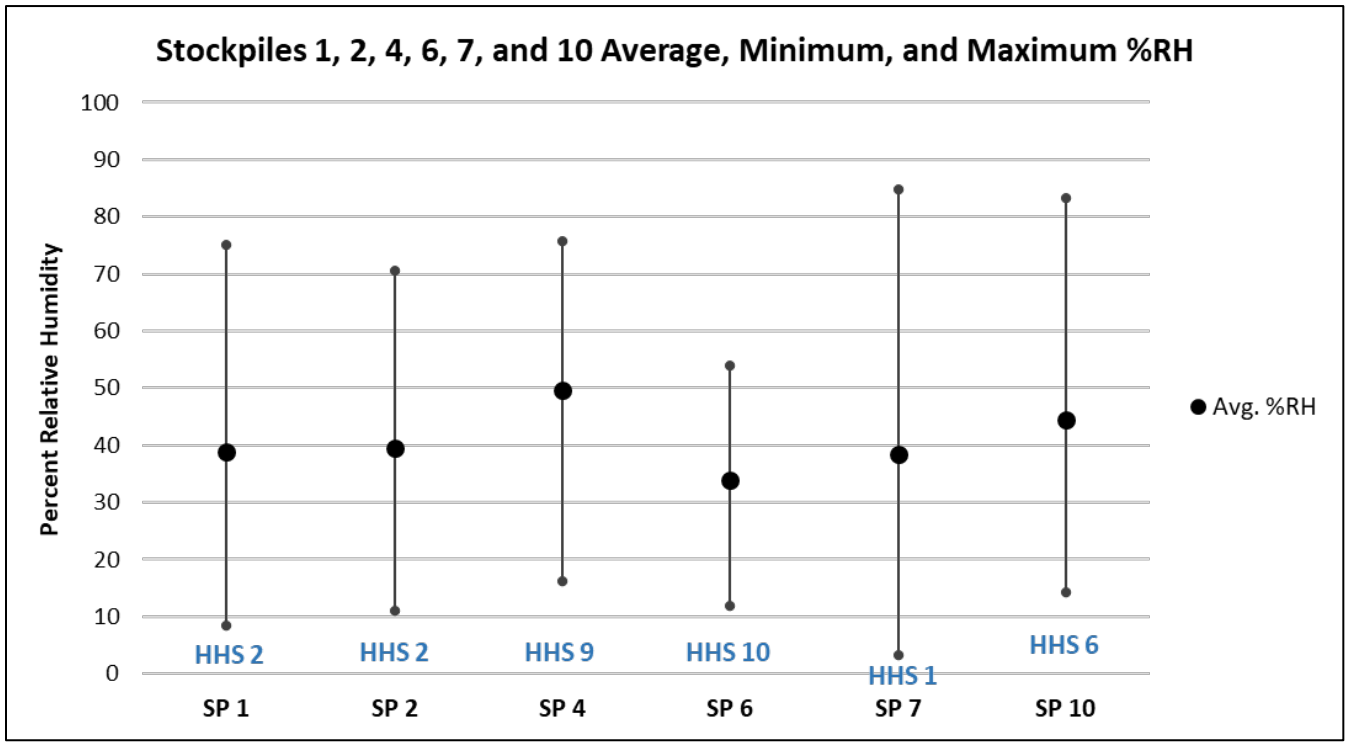

Figure 3: Average, minimum, and maximum %RH for the six stockpile facilities visited in this study. HHS regions for each facility are also depicted; refer to Figure 1 for the HHS region locations.

- Case and Gown Visual Inspections—Visual inspection concerns were recorded for factors that may affect surgical gown performance. These included damage to the gown case (e.g., crushing, open cases) and damage to the gown, such as rips, tears, or cuts to the gown, as well as any appearance of mold and odor. Examples of visual inspection concerns to the product cases are shown in **Figure 4**. Overall, 1,040 stockpiled Level 3 gowns were sampled from 48 cases; 20 cases (41.7%) showed some level of damage (e.g., crushing, tearing). A summary of these results can be seen in **Table 5**. As part of the visual inspection, seal leak detection of the packaging was evaluated using ASTM F1929: *Detecting Seal Leaks in Porous Medical Packing by Dye Penetration*. Method B (*Edge Dip Method*) was used. A pictorial example of this method is shown in **Figure 5**. No individual gown visual inspection concerns were noted (e.g., odor, holes), nor any gown packaging/seal leak issues.

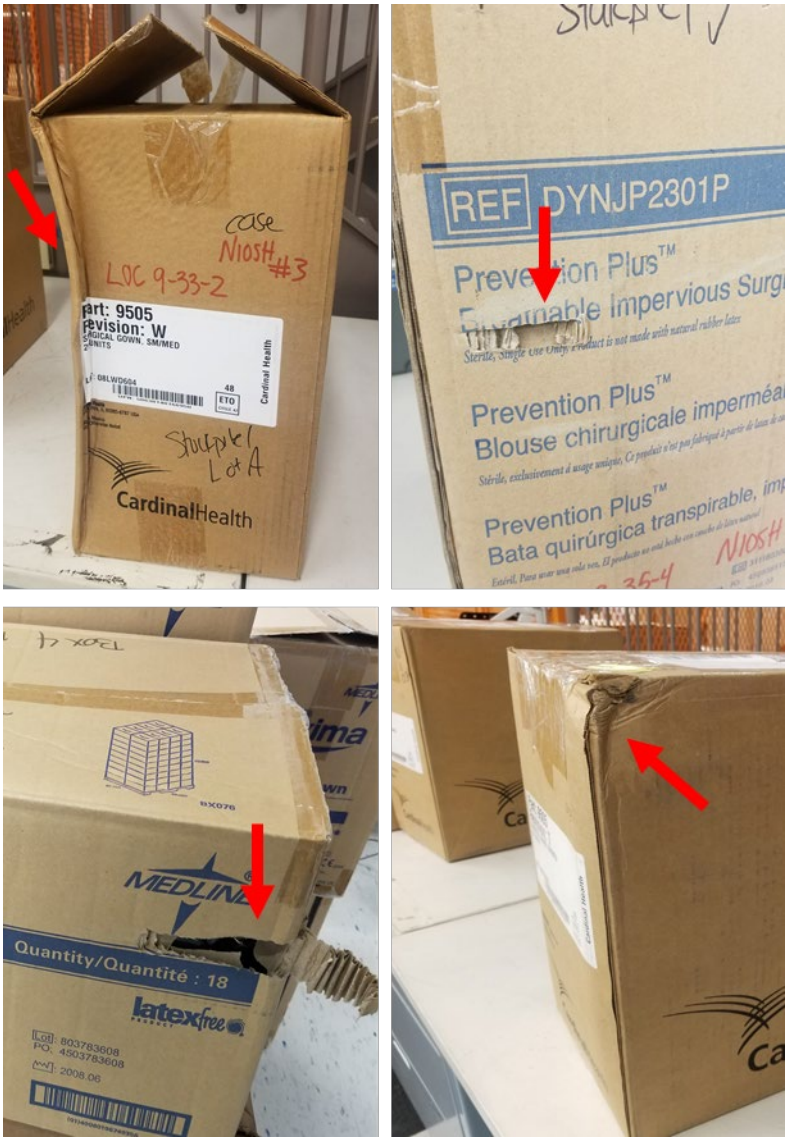

Figure 4: Examples of visual inspection concerns to the surgical gown cases including crushing and ripping to the product packaging.

Figure 5: Example of the ASTM F1929 seal leak test conducted for each non-stockpiled and stockpiled surgical gown.

As part of an exploratory effort, a total of 320 Medline Proxima Aurora tie attachment samples were evaluated. Medline did not consider the tie attachment to be in the critical zone, but were evaluated by NIOSH in the event these attachments moved to the front area of the gown if incorrectly sized or improper size selection occurred These results will be presented in the subsequent section.

Level 3 Surgical Gown Performance by Critical Zone (Medline Proxima Aurora and Cardinal Health Astound)

- In total, 1,040 stockpiled Level 3 gowns were sampled. A total of 2,888 critical zones were tested from these gowns for spray impact and hydrostatic resistance. 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 (β=0.10). This is known as the rejectable quality level (RQL), which defines the fraction defective of a lot that will have a small probability of being accepted [ANSI/AAMI PB70 2012]. When using the sample size example provided in the standard of 32 gowns tested per production lot per test, the allowable failure rate must be adjusted to give a 90% confidence interval. With a 90% confidence interval, a lot with 20% or more of failures has up to a 10% chance of being accepted. With that condition, a maximum of 3 failures out of 32 tests (i.e., 9.4%) are permitted within a critical zone.
- AAMI PB70 is primarily designed to be used by device manufacturers in qualifying, classifying, and labeling the performance of their products so healthcare personnel "can make informed decisions when selecting the appropriate product for the anticipated task at hand", and quality assurance (e.g., to verify production lot quality when received) is specifically an exclusion of this standard [ANSI/AAMI PB70 2012]. This standard allows a manufacturer to evaluate production quality in a continuous manner. Production lot size was not available. Therefore, the data in this study cannot be used to definitively determine whether the production lots evaluated should be "rejected" or "accepted." The data in this study may only be used to determine whether evidence supports that a quality issue may exist and warrants further exploration by the manufacturer. Therefore, AAMI PB70 was used as a general guide to interpret the findings within each critical zone type (i.e., chest, tie, and seam) of the set of 32 critical zone samples tested (i.e., one set of critical zones per gown sampled).

- To simplify the interpretation, NIOSH created a red/yellow/green "stoplight analogy" based on the RQL and levels of concern, which is shown in **Table 8** [adapted from NIOSH 2017b; NIOSH 2018]. Green is for critical zones that have failure rates well below the RQL; yellow is an intermediate status where additional testing may be advisable; and red is for a failure rate potentially higher than the RQL, indicating the gowns may not provide the expected level of protection. This analogy was applied to samples within a critical zone type. For an evaluation of 32 samples within a critical zone (e.g., chest area), NIOSH considered 0-2 failures (i.e., failure rate $\leq$6.3%) as green, 3 failures (i.e., failure rate=9.4%) as yellow, and $\geq$4 failures (i.e., failure rate $\geq$12.5%) as red.
- For several test groups, more than 32 samples were tested within a critical zone. The number of failures corresponding to each color in the stoplight analogy was adjusted based on the total samples tested.

Table 8: Red/yellow/green criteria selected for sets of 32 critical zones (CZ) at 20% RQL per AATCC test method

	CZ Failure Rate	# of Failures within a Single CZ Type	CZ Interpretation
Red	Potentially higher than RQL, β=0.1 (i.e., sample failure rate $\geq$12.5%)	$\geq$4 of 32 CZ	**STRONGLY INDICATES QUALITY ISSUES MAY EXIST AND RESAMPLING MAY BE NECESSARY**
Yellow	Intermediate condition (i.e., sample failure rate=9.4%)	3 of 32 CZ	**INDICATES QUALITY ISSUES MAY EXIST AND RESAMPLING MAY BE BENEFICIAL**
Green	Significantly lower than RQL β=0.1 (i.e., sample failure rate ≤6.25%)	0-2 of 32 CZ	**DOES NOT INDICATE QUALITY ISSUES**

- Spray Impact (AATCC 42)
  - Non-stockpiled gowns—A summary of the spray impact testing results for the non-stockpiled Level 3 surgical gowns can be seen in **Table 9**. A total of 128 chest, 64 tie attachments, and 128 sleeve seam non-stockpiled critical zone samples were tested.
    - **All sample sets from each of the four non-stockpiled gown production lots met the AAMI PB70 performance requirements—i.e., no more than three critical zone samples failed within each critical zone type and within each production lot.**

Table 9: Summary of Spray Impact (AATCC 42) Test Results for Non-stockpiled (Control) Level 3 Surgical Gowns by Critical Zone (CZ)

Spray Impact: Non-stockpiled Gowns (Controls)				
Gown Model	**CZ**	**Total Tested**	**# CZ Failing Test Criteria in Table 2**	**CZ Interpretation Based on # of CZ Failures**
Medline Proxima Aurora Lot A (Mfr. 01/2018)	Chest	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora Lot B (Mfr. 03/2018)	Chest	32	0	Green
	Seam	32	0	Green
Cardinal Health Astound Lot A (Mfr. 04/2018)	Chest	32	0	Green
	Tie	32	2	Green
	Seam	32	0	Green
Cardinal Health Astound Lot B (Mfr. 05/2018)	Chest	32	0	Green
	Tie	32	0	Green
	Seam	32	0	Green

- Stockpiled Gowns—A summary of the spray impact testing results for the stockpiled Level 3 surgical gowns can be seen in **Table 10**.
  - A total of 542 chest, 192 tie attachments[18], and 542 sleeve seam critical zones were tested.
  - **No quality issues were indicated among the sample sets tested from the 16 stockpiled production lots—i.e., no more than three failures within each critical zone type occurred within each production lot. However, the results for AATCC 127 (hydrostatic resistance, data provided below) must be considered in the final determination for the production lot.**

[18] Since only one tie attachment is available per gown, conducting hydrostatic resistance testing for tie attachments was prioritized over conducting spray impact testing for tie attachments.

Table 10: Summary of Spray Impact (AATCC 42) Test Results for Stockpiled Level 3 Surgical Gowns by Critical Zone (CZ).

Spray Impact: Stockpiled Gowns				
Stockpile/Gown Model	**CZ**	**Total Tested**	**# CZ Samples Failing Test Criteria in Table 2**	**CZ Interpretation Based on # of CZ Failures**
Medline Proxima Aurora SP 1 Lot A (Mfr. 11/2008)	Chest	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 1 Lot B (Mfr. 08/2008)	Chest	32	1	Green
	Seam	32	0	Green
Cardinal Health Astound SP 1 Lot A (Mfr. 2008)	Chest	32	0	Green
	Tie	32	0	Green
	Seam	32	0	Green
Cardinal Health Astound SP 1 Lot B (Mfr. 2008)	Chest	32	0	Green
	Tie	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 2 Lot A (Mfr. 11/2008)	Chest	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 2 Lot B (Mfr. 07/2008)	Chest	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 4 Lot A (Mfr. 2008)	Chest	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 4 Lot B (Mfr. 2008)	Chest	32	0	Green
	Seam	32	0	Green
Cardinal Health Astound SP 4 Lot A (Mfr. 2008)	Chest	32	0	Green
	Tie	32	1	Green
	Seam	32	0	Green
Cardinal Health Astound SP 4 Lot B (Mfr. 2008)	Chest	32	0	Green
	Tie	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 6 Lot A (Mfr. 06/2008)	Chest	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 6 Lot B (Mfr. 2008)	Chest	32	0	Green
	Seam	32	0	Green
Cardinal Health Astound SP 6 Lot A (Mfr. 2008)	Chest	48	0	Green
	Tie	32	0	Green
	Seam	48	0	Green
Cardinal Health Astound SP 7 Lot A (Mfr. 2008)	Chest	46	0	Green
	Tie	32	0	Green
	Seam	46	0	Green
Medline Proxima Aurora SP 10 Lot A (Mfr. 2008)	Chest	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 10 Lot B (Mfr. 2008)	Chest	32	0	Green
	Seam	32	0	Green

- Hydrostatic Resistance (AATCC 127)
  - Non-stockpiled Gowns—A summary of the hydrostatic resistance testing results for the non-stockpiled Level 3 surgical gowns can be seen in **Table 11**. A total of 128 chest CZ, 64 tie attachments CZ, and 128 sleeve seams non-stockpiled CZ samples were tested. **Testing for one production lot strongly indicated quality issues (9 seam failures), and testing for a second**

production lot indicated quality issues may exist (3 seam failures). Testing for the remaining two production lots did not indicate any quality issues.

- The failure rates for both the Medline Proxima Aurora and Cardinal Health Astound non-stockpiled and stockpiled models when tested against AATCC 42 are shown in **Figures 6** and **7**, respectively. Additionally, **Tables A1** and **A2** in the Appendix provide more detail on the failure rates for these models.

Table 11: Summary of Hydrostatic Resistance (AATCC 127) Test Results for Non-stockpiled (Control) Level 3 Surgical Gowns by Critical Zone (CZ).

Hydrostatic Resistance: Non-Stockpiled Gowns				
Gown Model	**CZ**	**Total Tested**	**# CZ Samples Failing Test Criteria in Table 2**	**CZ Interpretation Based on # of CZ Failures**
Medline Proxima Aurora Lot A (Mfr. 01/2018)	Chest	32	0	Green
	Seam	32	1	Green
Medline Proxima Aurora Lot B (Mfr. 03/2018)	Chest	32	0	Green
	Seam	32	9	Red
Cardinal Health Astound Lot A (Mfr. 04/2018)	Chest	32	1	Green
	Tie	32	1	Green
	Seam	32	0	Green
Cardinal Health Astound Lot B (Mfr. 05/2018)	Chest	32	1	Green
	Tie	32	2	Green
	Seam	32	3	Yellow

- Stockpiled Gowns—A summary of the hydrostatic resistance testing results for the stockpiled Level 3 surgical gowns can be seen in **Table 12**.
  - A total of 542 chest, 222 tie attachments, and 542 sleeve seam critical zones were tested.
  - **Testing for 1 of the 16 stockpiled production lots strongly indicated that quality issues exist (8 chest failures). The remaining production lots tested did not indicate any quality issues.**
  - The percent failure rates for both the Medline Proxima Aurora and Cardinal Health Astound non-stockpiled and stockpiled models when tested against AATCC 127 are shown in **Figures 6** and **7**, respectively. Additionally, **Tables A3** and **A4** in the Appendix provide more detail on the percent failure rates for these models. The percent critical zones not meeting AATCC 127 criteria are shown in comparison to the failure rate of 12.5% as the threshold of strongly indicating a quality issue based on 4+ critical zone failures out of 32 within one critical zone type.

Table 12: Summary of Hydrostatic Resistance (AATCC 127) Test Results for Level 3 Stockpiled Surgical Gowns by Critical Zone (CZ).

Hydrostatic Resistance: Stockpiled Gowns				
Stockpile/Gown Model	**CZ**	**Total Tested**	**# CZ Samples Failing Test Criteria in Table 2**	**Interpretation Based on # of CZ Sample Failures**
Medline Proxima Aurora SP 1 Lot A (Mfr. 11/2008)[19]	Chest	32	2	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 1 Lot B (Mfr. 08/2008)	Chest	32	0	Green
	Seam	32	0	Green
Cardinal Health Astound SP 1 Lot A (Mfr. 2008)	Chest	32	8	Red
	Tie	32	1	Green
	Seam	32	0	Green
Cardinal Health Astound SP 1 Lot B (Mfr. 2008)	Chest	32	0	Green
	Tie	32	1	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 2 Lot A (Mfr. 11/2008)	Chest	32	0	Green
	Seam	32	1	Green
Medline Proxima Aurora SP 2 Lot B (Mfr. 07/2008)	Chest	32	0	Green
	Seam	32	2	Green
Medline Proxima Aurora SP 4 Lot A	Chest	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 4 Lot B	Chest	32	0	Green
	Seam	32	0	Green
Cardinal Health Astound SP 4 Lot A	Chest	32	0	Green
	Tie	32	0	Green
	Seam	32	0	Green
Cardinal Health Astound SP 4 Lot B	Chest	32	1	Green
	Tie	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 6 Lot A (Mfr. 06/2008)	Chest	32	2	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 6 Lot B	Chest	32	0	Green
	Seam	32	0	Green
Cardinal Health Astound SP 6 Lot A[20]	Chest	48	0	Green
	Tie	48	5	Green
	Seam	48	0	Green
Cardinal Health Astound SP 7 Lot A (Mfr. 2008)[14]	Chest	46	2	Green
	Tie	46	2	Green
	Seam	46	0	Green
Medline Proxima Aurora SP 10 Lot A (Mfr. 2008)	Chest	32	0	Green
	Seam	32	0	Green
Medline Proxima Aurora SP 10 Lot B (Mfr. 2008)	Chest	32	0	Green
	Seam	32	0	Green

[19] Medline Proxima Aurora Lot A from SP 1 and SP 2 are the same production lot.

[20] NIOSH's stoplight analogy was adjusted for these lots with an increased sample size. With a sample size of 48 CZ samples within a CZ type, $\leq$5 CZ failures are permitted within an RQL of 20% (β=0.1). With a sample size of 46 CZ samples within a CZ type, up to $\leq$5 CZ failures are permitted within an RQL of 20% (β=0.1).

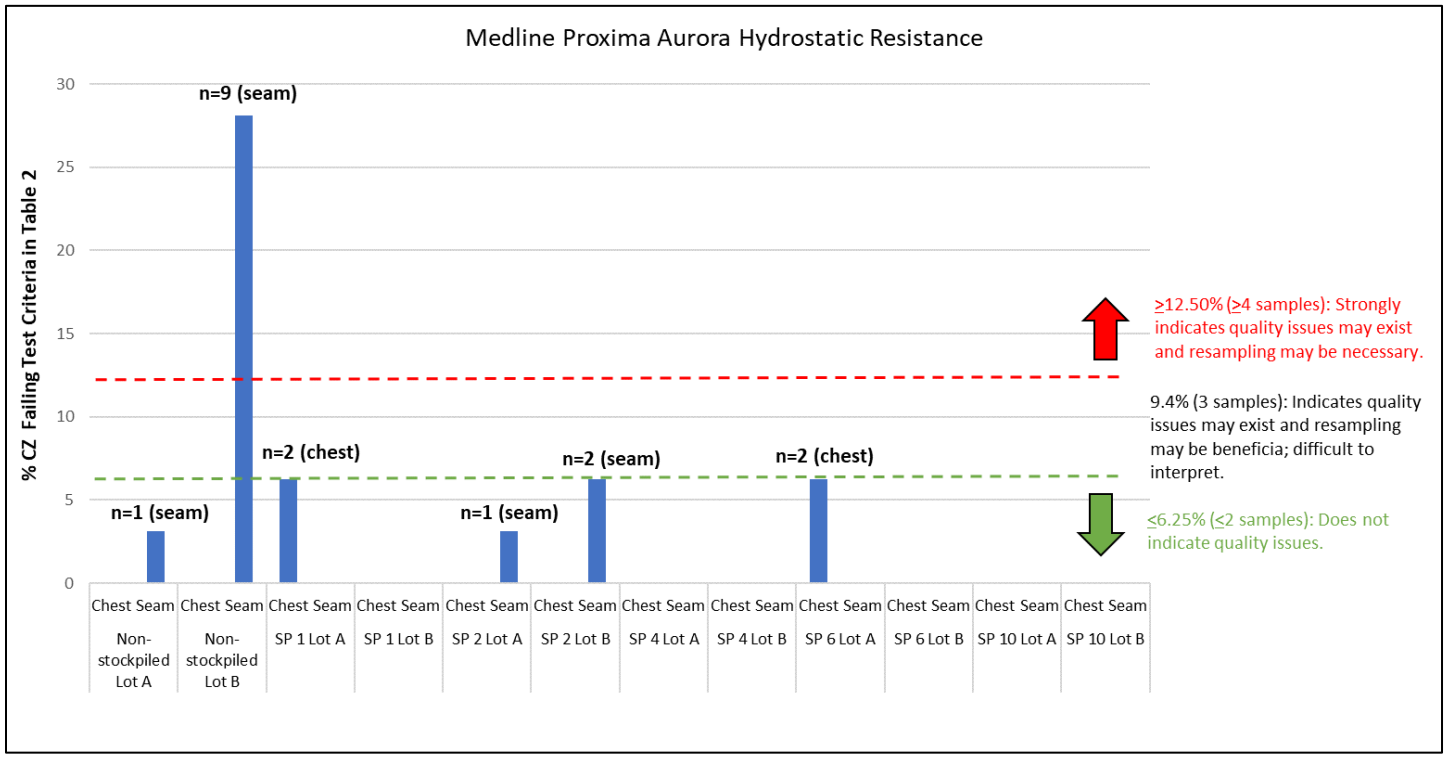

Figure 6: Percent of Medline Proxima Aurora critical zone samples failing hydrostatic resistance test criteria in Table 2.

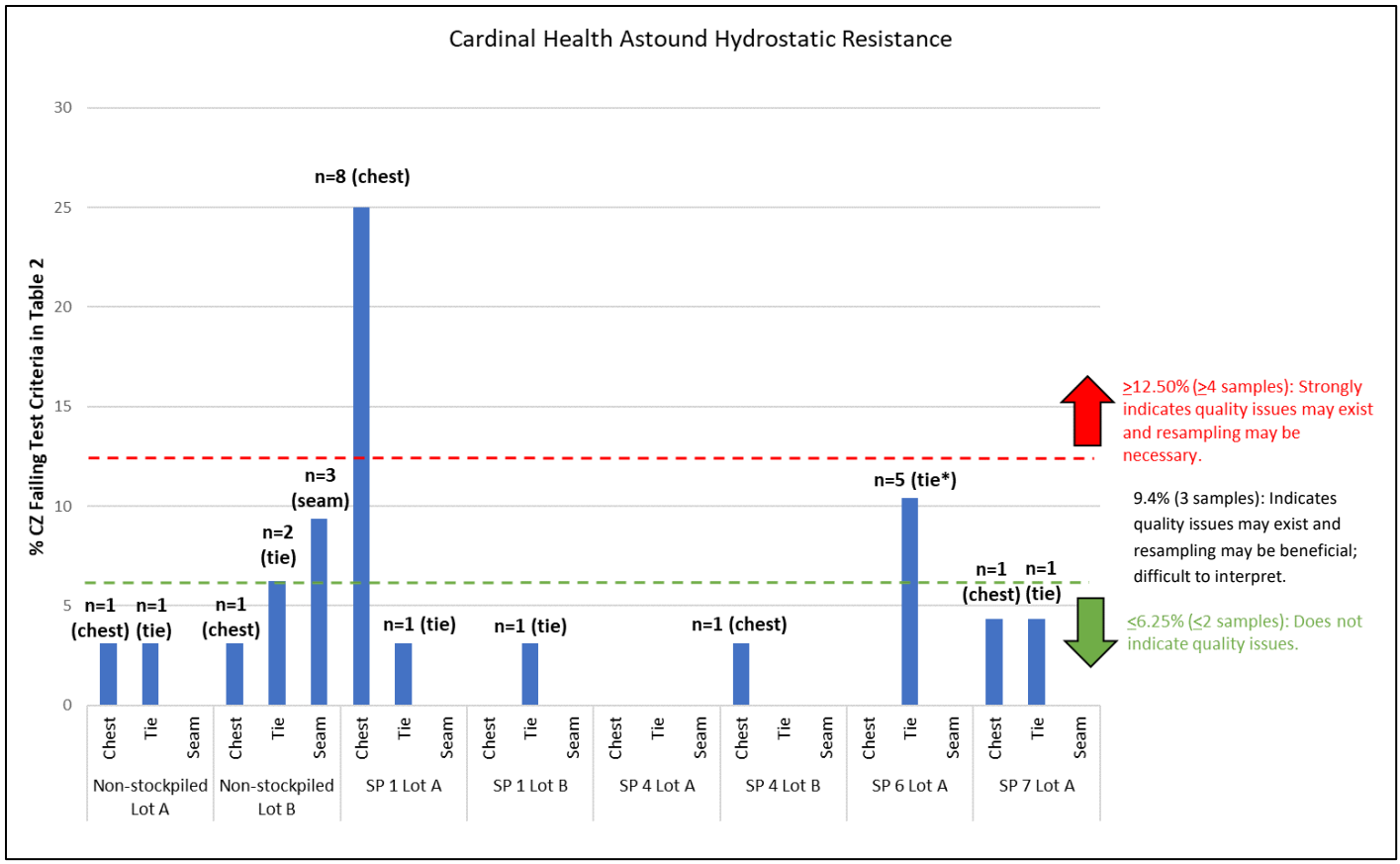

Figure 7: Percent of Cardinal Health Astound critical zone samples failing hydrostatic resistance test criteria in Table 2. *See footnote 21.

Tie Attachment Sample Performance (Medline Proxima Aurora)

- Non-stockpiled gowns—A summary of the spray impact testing results for the non-stockpiled Medline Proxima Aurora surgical gown tie attachment samples can be seen in **Table 13**. A total of 64 non-stockpiled tie attachment samples were tested.
  - **All sample sets from each of the four non-stockpiled gown production lots met the AAMI PB70 performance requirements—i.e., no more than three critical zone samples failed within each critical zone type and within each production lot.**

Table 13: Summary of Spray Impact (AATCC 42) Test Results for Non-stockpiled (reference) Medline Proxima Aurora Surgical Gown Tie Attachment Samples

Spray Impact: Non-stockpiled Gowns (Controls)				
Gown Model	**Sample**	**Total Tested**	**# Tie Attachment Samples Failing Test Criteria in Table 2**	**Interpretation Based on # of Sample Failures**
Medline Proxima Aurora Lot A (Mfr. 01/2018)	Tie	32	0	Green
Medline Proxima Aurora Lot B (Mfr. 03/2018)	Tie	32	1	Green

- Stockpiled Gowns—A summary of the spray impact testing results for the stockpiled Medline Proxima Aurora surgical gown tie attachment samples can be seen in **Table 14**.
  - A total of 320 tie attachments samples[21] were tested.
  - **No quality issues were indicated among the sample sets tested from the 10 stockpiled production lots—i.e., no more than three failures within each critical zone type occurred within each production lot. However, the results for AATCC 127 (hydrostatic resistance, data provided below) must be considered in the final determination for the production lot.**

Table 14: Summary of Spray Impact (AATCC 42) Test Results for Stockpiled Medline Proxima Aurora Surgical Gown Tie Attachment Samples.

Spray Impact: Stockpiled Gowns				
Stockpile/Gown Model	**Sample**	**Total Tested**	**# Tie Attachment Samples Failing Test Criteria in Table 2**	**Interpretation Based on # of Sample Failures**
Medline Proxima Aurora SP 1 Lot A (Mfr. 11/2008)	Tie	32	0	Green
Medline Proxima Aurora SP 1 Lot B (Mfr. 08/2008)	Tie	32	0	Green
Medline Proxima Aurora SP 2 Lot A (Mfr. 11/2008)	Tie	32	0	Green
Medline Proxima Aurora SP 2 Lot B (Mfr. 07/2008)	Tie	32	0	Green
Medline Proxima Aurora SP 4 Lot A (Mfr. 2008)	Tie	32	0	Green
Medline Proxima Aurora SP 4 Lot B (Mfr. 2008)	Tie	32	0	Green
Medline Proxima Aurora SP 6 Lot A (Mfr. 06/2008)	Tie	32	0	Green
Medline Proxima Aurora SP 6 Lot B (Mfr. 2008)	Tie	32	0	Green
Medline Proxima Aurora SP 10 Lot A (Mfr. 2008)	Tie	32	0	Green
Medline Proxima Aurora SP 10 Lot B (Mfr. 2008)	Tie	32	0	Green

- Hydrostatic Resistance (AATCC 127)
  - Non-stockpiled Gowns—A summary of the hydrostatic resistance testing results for the non-stockpiled Medline Proxima Aurora surgical gown tie attachment samples can be seen in **Table 15**. A total of 64 tie attachments samples were tested. **No quality issues were indicated among the sample sets tested from the 10 stockpiled production lots—i.e., no more than three failures within each critical zone type occurred within each production lot.**

[21] Since only one tie attachment is available per gown, conducting hydrostatic resistance testing for tie attachments was prioritized over conducting spray impact testing for tie attachments.

Table 15: Summary of Hydrostatic Resistance (AATCC 127) Test Results for Medline Proxima Aurora Surgical Gowns Tie Attachment Samples.

Hydrostatic Resistance: Non-Stockpiled Gowns				
Gown Model	**Sample**	**Total Tested**	**# Tie Attachment Samples Failing Test Criteria in Table 2**	**Interpretation Based on # of Tie Attachment Sample Failures**
Medline Proxima Aurora Lot A (Mfr. 01/2018)	Tie	32	0	Green
Medline Proxima Aurora Lot B (Mfr. 03/2018)	Tie	32	2	Green

- Stockpiled Gowns—A summary of the hydrostatic resistance testing results for the stockpiled Level 3 surgical gowns can be seen in **Table 16**.
  - A total of 320 tie attachment samples were tested.
  - **Testing for 5 of the 10 (50%) stockpiled production lots strongly indicated that quality issues exist (see all "red" critical zone interpretations). The remaining 50% of the production lots tested did not indicate any quality issues.**
  - The percent failure rates for the Medline Proxima Aurora non-stockpiled and stockpiled tie attachment samples when tested against AATCC 127 are shown in **Figure 8.** Additionally, **Tables A3** and **A4** in the Appendix provide more detail on the percent failure rates for these models. The percent critical zones not meeting AATCC 127 criteria are shown in comparison to the failure rate of 12.5% as the threshold of strongly indicating a quality issue based on 4+ critical zone failures out of 32 within one critical zone type.

Table 16: Summary of Hydrostatic Resistance (AATCC 127) Test Results for Medline Proxima Aurora Surgical Gowns Tie Attachment Samples.

Hydrostatic Resistance: Stockpiled Gowns				
Stockpile/Gown Model	**Sample**	**Total Tested**	**# Tie Attachment Samples Failing Test Criteria in Table 2**	**Interpretation Based on # of Sample Failures**
Medline Proxima Aurora SP 1 Lot A (Mfr. 11/2008)[22]	Tie Attachment	32	10	Red
Medline Proxima Aurora SP 1 Lot B (Mfr. 08/2008)	Tie Attachment	32	4	Red
Medline Proxima Aurora SP 2 Lot A (Mfr. 11/2008)	Tie Attachment	32	16	Red
Medline Proxima Aurora SP 2 Lot B (Mfr. 07/2008)	Tie Attachment	32	9	Red
Medline Proxima Aurora SP 4 Lot A	Tie Attachment	32	12	Red
Medline Proxima Aurora SP 4 Lot B	Tie Attachment	32	0	Green
Medline Proxima Aurora SP 6 Lot A (Mfr. 06/2008)	Tie Attachment	32	1	Green
Medline Proxima Aurora SP 6 Lot B	Tie Attachment	32	0	Green
Medline Proxima Aurora SP 10 Lot A (Mfr. 2008)	Tie Attachment	32	1	Green
Medline Proxima Aurora SP 10 Lot B (Mfr. 2008)	Tie Attachment	32	0	Green

[22] Medline Proxima Aurora Lot A from SP 1 and SP 2 are the same production lot.

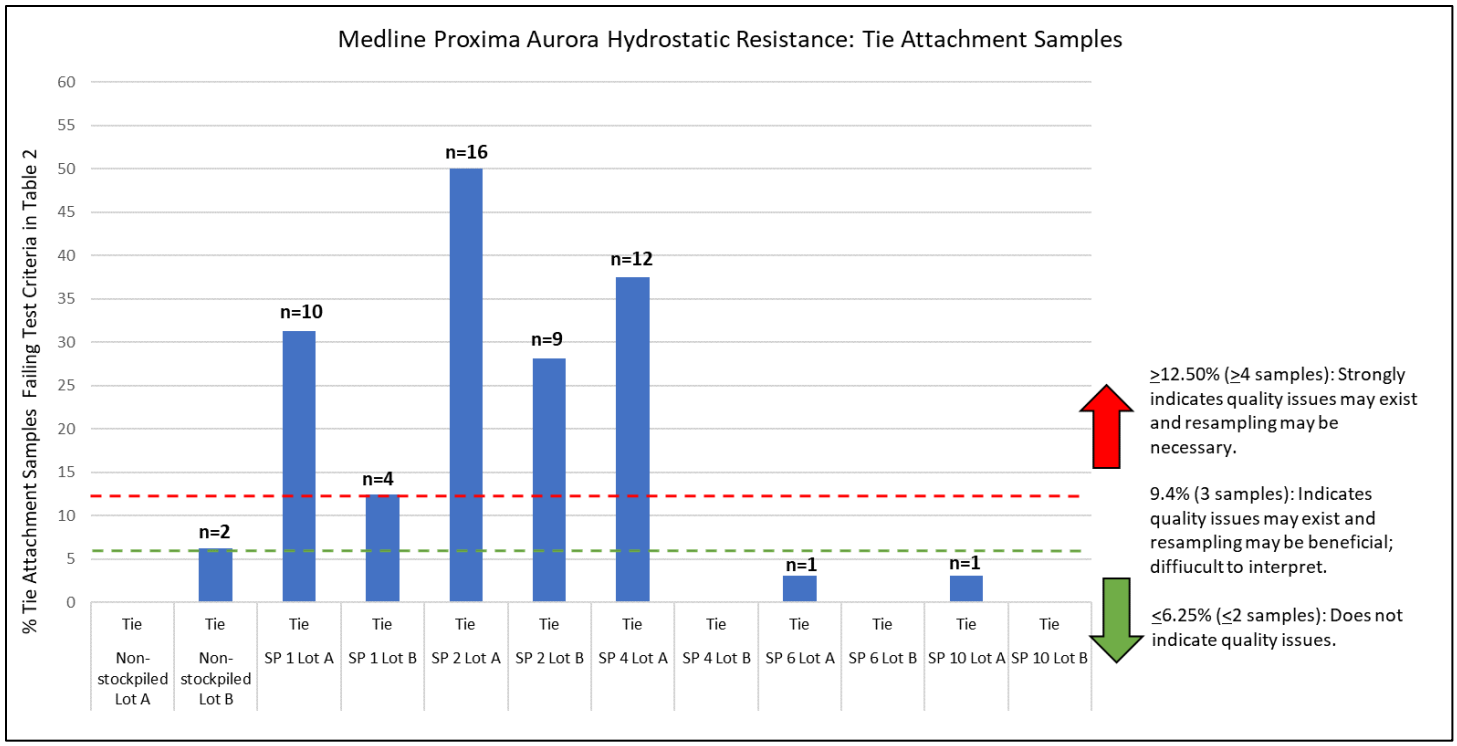

Figure 8: Percent of Medline Proxima Aurora tie attachment samples failing hydrostatic resistance test criteria in Table 2.

CASE Findings

NIOSH evaluated a total of 1,040 Level 3 surgical gowns from six U.S. stockpile facilities. These gowns came from 16 production lots from 2 surgical gown models: Medline Proxima Aurora and Cardinal Health Astound. All gowns were manufactured in 2008; only some lots had a 5-year expiration date information on the packaging at the time of sampling.

Samples were taken from three critical zones on the gowns (i.e., the chest area, the tie attachment, and the sleeve seam) and were tested to two standard test methods per AAMI PB70 requirements: AATCC 42 (Spray Impact) and AATCC 127 (Hydrostatic Resistance). The critical zones defined in AAMI PB70 were considered for testing. For Cardinal Astound surgical gowns, critical zones included three areas (chest, sleeve seams, and tie attachments). For the Medline Aurora gowns, the manufacturer only considered the chest and sleeve seams as CZ. However, the tie attachments were still evaluated as an exploratory effort in the event these attachments moved to the front area of the gown if incorrectly sized or improper size selection occurred. A total of 3,208 stockpiled gown critical zones or tie attachment samples were tested. Additionally, 256 non-stockpiled gowns (768 critical zone or tie attachment samples) were tested.

AAMI PB70 was the only barrier classification standard identified for surgical gowns in the United States [NIOSH 2017b; NIOSH 2018]. Although it is possible for a third-party entity (e.g., federal or state stockpiles, hospitals) to use the barrier performance test methods outlined in AAMI PB70 (i.e., ASTM and AATCC test methods) in a post-market application as was done in this study, it is difficult to draw conclusions related to quality since the current standard is not designed for that application as indicated by specific language that excludes using this standard for quality assurance interpretation (refer to Section 1.3 Exclusions, J of the standard). For this reason, NIOSH (and any other entity that desires post-market quality assurance information) was/is only able to determine if there is indication that a quality issue may exist – while additional sampling may increase confidence in any post-market decisions that are made by a third-party entity (e.g., federal, state, and local hospitals), no increase in sampling can result in that entity making a pass/fail determination for the larger population of product that this third-party received/purchased based on the samples tested.

Findings for Gown and Case Visual Inspections

- Overall, no individual surgical gown bags had visual inspection concerns nor any bag seal leak issues. Visual inspection concerns were noted for 20 of the 48 sampled cases, including crushing, punctures, and tears. No signs of mold or water damage to the gowns or gown cases were observed.

Findings for the Medline Proxima Aurora Model

Chest and Seam Critical Zone Samples: Samples of this model were collected from five stockpiles. In total, 1,536 stockpiled (1,280) and non-stockpiled (256) critical zones samples were tested for spray impact and hydrostatic resistance. **No stockpiled surgical gowns tested for spray impact (AATCC 42) or hydrostatic pressures (AATCC 127) indicated quality issues. However, one non-stockpiled (control) lot indicated quality issues when tested for hydrostatic pressure (AATCC 127).**

Tie Attachment Samples: In total, 1,768 stockpiled and non-stockpiled tie attachment samples were tested for spray impact and hydrostatic resistance. **As part of this exploratory effort, the barrier performance of five of the 10 stockpiled surgical gown lots did not meet the requirements specified in the AAMI PB70 standard for hydrostatic resistance (AATCC 127).** This may pose issues in the event of the tie attachment area moving to the front of the gown during improper size selection.

Findings for the Cardinal Health Astound Model

- Samples of this model were collected from three stockpiles. In total, 1,686 stockpiled (1,302) and non-stockpiled (384) critical zone samples were tested for spray impact and hydrostatic resistance. **Testing for spray impact (AATCC 42) did not indicate quality issues. However, when tested for hydrostatic pressure (AATCC 127), testing for 1 of the 6 (17%) stockpiled Cardinal Health Astound model production lots strongly indicated that quality issues exist, and one non-stockpiled lot strongly indicated quality issues. The barrier performance of the stockpiled surgical gowns did not meet the requirements specified in the AAMI PB70 standard which may be due to quality issues.**

Additional Recommendations and Limitations

AAMI PB70 is designed to allow a manufacturer to evaluate production quality in a continuous manner, and quality assurance is specifically excluded in this standard (Section 1.3 Exclusions, J). Due to this limitation and limited number of production lots available for sampling from the stockpiles, NIOSH does not have enough information to definitively know the level of protection that may be provided by all stockpiled surgical gowns that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the manufacturer's designated shelf life (if applicable). Meaning, the results are not generalizable across all stockpiled gowns from different models.

Despite this limitation, the data shows instances where both the stockpiled (Cardinal Health Astound) and non-stockpiled (Medline Proxima Aurora) Level 3 surgical gowns sampled strongly indicate the potential for quality issues and the gowns may not offer the expected level of protection. A small number of reference gowns were evaluated.

Gowns of the same model sampled within the same stockpile facility showed inter-lot variability which may be related to quality control issues. For example, gowns sampled from select production lots of a particular model demonstrated a higher number of failures compared to units from a different lot of the same model, stored in the same facility. Furthermore, select models demonstrated a statistically significantly higher number of failures when sampled from one facility but not from another with similar conditions and years of storage.

Some of the non-stockpiled and stockpiled gowns evaluated in this study strongly suggested that a production quality issue may exist. Additionally, AAMI PB70 does not provide guidance for determining whether a new gown or a gown that has exceeded its shelf life will perform as expected. Therefore, NIOSH recommends that AAMI PB70 be expanded to include guidance for post-market quality assurance sampling and data interpretation for third party entities (e.g., stockpiles, hospitals, those conducting post-market surveillance activities to inform conformity assessment decision-makers, researchers, and entities attempting to identify potential counterfeit products). This expanded language should be designed to allow third party entities to objectively assess the conformance of the surgical gowns. The sampling plan specified in AAMI PB70 is not a standalone plan and is used in other standards (e.g., ISO 2859, ISO Z1.4); specifically, updates to AAMI PB70 should provide more sampling options and interpretation guidance for entities that may not know the entire production lot size for their surgical gowns. Further, revisions to AAMI PB70 to define minimum critical zone boundaries and include guidance for post-market quality assurance sampling and data interpretation for third party entities will enhance end user protections

Users that are provided any Level 3 surgical gowns that have been stored for prolonged periods (e.g., 5+ years) or are past their shelf life should be forewarned to avoid a false sense of confidence. Furthermore, these products should be considered to not be used for high-risk procedures that involve high amount of body fluids. As observed in this study, quality issues have also been previously reported for other "new/non-stockpiled" Level 3 and Level 4 surgical gowns [NIOSH 2017, NIOSH 2018] and isolation gowns [NIOSH 2015].

NIOSH does not recommend the use of gowns past their shelf life during routine, conventional use (i.e., where there are no supply shortages). We recommend contacting the manufacturers of the gowns in the stockpile with specific questions regarding the shelf life if it is not clearly visible on the product packaging and any potential use of the product past its shelf life during public health emergencies when extreme gown shortages may occur. For contingency capacity strategies during anticipated gown shortages, consideration can be given to using gowns past their manufacturer-designated shelf life for training purposes [CDC 2020]. ASTM F2407-20—a surgical gown standard updated in 2020 which establishes requirements for the performance, documentation, and labeling of surgical gowns in healthcare settings—specifies that surgical gown packages should include the use-by date [ASTM 2020].

What Can Stockpile Personnel and the PPE Community Do?

- Stockpile personnel should work with the manufacturers of the stockpiled products to address specific questions regarding shelf life and the use of product past its shelf life. The risks of using surgical gowns that have reached their shelf lives in an emergency should be evaluated and communicated to end users. If the stockpiled surgical gowns do not meet the relevant performance requirements, consideration can be given to relabeling and using these gowns for lower risk activities. The assessment of risk must be hazard-specific.
- Because no consensus standard currently exists that enables third-party post-market evaluation and quality interpretation of surgical gowns to provide purchasers confidence in their expected performance, members of the PPE community should engage with standards development organizations to elevate the need to resolve this issue within these organizations. These organizations may include ANSI/AAMI, ASTM, and AATCC.
- The PPE community should consider how these findings should be integrated into the portfolio of surgical gown standards.
- Proper size selection is important for surgical gowns to ensure non-critical zone areas of the gown are not moved into the critical zone areas during patient care.
- To share experiences with or provide input to AAMI PB70, email ppeconcerns@cdc.gov as a coauthor is a NIOSH representative on this standard.
- Sign up for NPPTL's Listserv at https://www.cdc.gov/niosh/npptl/sub-NPPTL.html to receive email notifications relevant to PPE, including webinar announcements, updated guidance releases, alerting users to an issue with a NIOSH Approved® respirator, and publication of federal register notices.

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Disclaimer

The recommendations in this report are made based on the findings at the stockpiles evaluated and may not be applicable to other stockpile facilities.

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

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Appendix

Table A1: Percent fail rates by lot for the Medline Proxima Aurora when tested against AATCC 42

Medline Proxima Aurora: Spray Impact (AATCC 42) % Fail Rates within a Lot													
		Non-stockpiled		Stockpile 1		Stockpile 2		Stockpile 4		Stockpile 6		Stockpile 10	
	Lot #	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B
Chest CZ	# of Failures	0	0	0	1	0	0	0	0	0	0	0	0
	# of Tests	32	32	32	32	32	32	32	32	32	32	32	32
	Fail Rate	0.00%	0.00%	0.00%	3.13%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Seam CZ	# of Failures	0	0	0	0	0	0	0	0	0	0	0	0
	# of Tests	32	32	32	32	32	32	32	32	32	32	32	32
	Fail Rate	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Tie Attachment **Samples**	# of Failures	0	1	0	0	0	0	0	0	0	0	0	0
	# of Tests	32	32	32	32	32	32	32	32	32	32	32	32
	Fail Rate	0.00%	3.13%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Table A2: Percent fail rates by lot for the Cardinal Health Astound when tested against AATCC 42

Cardinal Health Astound: Spray Impact (AATCC 42) % Fail Rates within a Lot									
		Non-stockpiled		Stockpile 1		Stockpile 4		Stockpile 6	Stockpile 7
	Lot #	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B	Lot A	Lot A
Chest CZ	# of Failures	0	0	0	0	0	0	0	0
	# of Tests	32	32	32	32	32	32	48	46
	Fail Rate	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Seam CZ	# of Failures	0	0	0	0	0	0	0	0
	# of Tests	32	32	32	32	32	32	48	46
	Fail Rate	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Tie CZ	# of Failures	2	0	0	0	1	0	0	0
	# of Tests	32	32	32	32	32	32	32	32
	Fail Rate	6.25%	0.00%	0.00%	0.00%	3.13%	0.00%	0.00%	0.00%

Table A3: Percent fail rates by lot for the Medline Proxima Aurora when tested against AATCC 127

Medline Proxima Aurora: Hydrostatic Resistance (AATCC 127) % Fail Rates within a Lot[1,2]													
		Non-stockpiled		Stockpile 1		Stockpile 2		Stockpile 4		Stockpile 6		Stockpile 10	
	Lot #	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B
Chest CZ	# of Failures	0	0	2	0	0	0	0	0	0	2	0	0
	# of Tests	32	32	32	32	32	32	32	32	32	32	32	32
	Fail Rate	0.00%	0.00%	6.25%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	6.25%	0.00%	0.00%
Seam CZ	# of Failures	1	9	0	0	2	1	0	0	0	0	0	0
	# of Tests	32	32	32	32	32	32	32	32	32	32	32	32
	Fail Rate	3.13%	28.13%	0.00%	0.00%	6.25%	3.13%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Tie Attachment Samples	# of Failures	0	2	10	4	9	16	12	0	0	1	0	2
	# of Tests	32	32	32	32	32	32	32	32	32	32	32	32
	Fail Rate	0.00%	6.25%	31.25%	12.50%	28.13%	50.00%	37.50%	0.00%	0.00%	3.13%	0.00%	6.25%

Table A4: Percent fail rates by lot for the Cardinal Health Astound when tested against AATCC 127

Cardinal Health Astound: Hydrostatic Resistance (AATCC 127) % Fail Rates within a Lot[1,2]									
		Non-stockpiled		Stockpile 1		Stockpile 4		Stockpile 6	Stockpile 7
	Lot #	Lot A	Lot B	Lot A	Lot B	Lot A	Lot B	Lot A	Lot A
Chest CZ	# of Failures	1	1	8	0	0	1	0	2
	# of Tests	32	32	32	32	32	32	48	46
	Fail Rate	3.13%	3.13%	25.00%	0.00%	0.00%	3.13%	0.00%	4.35%
Seam CZ	# of Failures	0	3	0	0	0	0	0	0
	# of Tests	32	32	32	32	32	32	48	46
	Fail Rate	0.00%	9.38%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Tie CZ	# of Failures	1	2	1	1	0	0	5	2
	# of Tests	32	32	32	32	32	32	48	46
	Fail Rate	3.13%	6.25%	3.13%	3.13%	0.00%	0.00%	10.4%	4.35%