Interim Guidance for Processing Single-Use Gowns in Response to Product Shortages during COVID-19

**The Situation**

The COVID-19 pandemic has revealed both strengths and weaknesses in how our healthcare systems respond to a widespread emerging virus. A significant weakness that has captivated the spotlight is the nationwide shortage of personal protective equipment (PPE), specifically protective gowns. Despite efforts to resolve this situation, healthcare facilities continue to face PPE shortages to the point where some healthcare professionals (HCP) report there are no gowns available to them for use.

ALM has been and continues to be a fervent supporter of reusable textiles and their role as safe, comfortable, and sustainable products. The president of the American Reusable Textile Association (ARTA), Gabriel Boardman of MIP, sums up the situation best saying, “The COVID-19 event has shone a spotlight on the acute vulnerability our healthcare system has in its reliance on disposable PPE. Hospitals that have **reusable PPE programs are not having shortages** — soiled PPE is washed overnight and delivered back to the hospital the next morning for use again. Many healthcare organizations are learning from this and signing up to convert to reusable PPE as soon as this resource becomes available.”

While we have learned a great lesson here, it does not resolve the situation that healthcare facilities are now facing. This formidable situation calls for creative minds to develop unique approaches to alleviate the current nationwide shortage of PPE gowns until manufacturing can meet the demand. In an effort to provide utility in this situation, ALM has collaborated with three of our esteemed vendor members to examine and test the feasibility of reprocessing disposable PPE gowns as a possible solution to the nationwide temporary shortage. Use of reprocessed disposable gowns to provide services that do not require PPE gowns will allow HCPs to reserve their existing inventory of PPE gowns for their intended purpose. Any laundry intending to use this interim guidance is strongly encouraged to review the [Considerations for Laundries Implementing](#) document prior to undertaking this guidance.

**Background**

Three types of used disposable protective gowns were procured directly from a regional healthcare system. Proper infection control and engineering practices were followed in the collection and wash process. The gowns were processed in a commercial washer utilizing a specific wash formula and chemical formulation. (Provided below) The gowns were then dried and examined for overall condition, wash formulation effectiveness, and effects of the wash process on the gowns’ associated features.

**The Trial Process**

The gowns utilized in this project were soiled, but not blood soaked or otherwise heavily soiled, as typical with some protective gowns. The soil level was best categorized as medium-light upon inspection when placed into the washer/extractor. The process utilized a gentle wash cycle and high-water levels in all operations to inhibit mechanical action and to maintain the integrity of the gowns. A pH indicator test was performed at the conclusion of the wash process with outcomes slightly above pH 7.

The washer was loaded to half/three-quarters cylinder capacity after initial wet out (see picture). The **gentle cycle** feature on this washer was used. Chemical products were measured and hand poured into the washer at the appropriate time in the cycle.
Gowns were dried for 20 minutes at or below 120°F with a 5-minute cool down, which resulted in the greater majority of the gowns being completely dry. Several cuffs were slightly damp. One manufacturer’s gown tended to stick to the other gowns due to the heat, but were easily separated without tearing. The gowns, wash program, washer type, chemicals used, and source water analysis are listed below.

Equipment and products utilized
A 60-lb commercial washer/extractor (Milnor EP Plus, Model # 30022V6J with 9 cubic foot cylinder) was used in the trial for this project. The fabric content and need to control agitation and extraction for the gowns was best suited for a washer/extractor vs. a tunnel/continuous batch washer equipment.

The disposable gowns and the quantity used included:
- **Polyethylene Thumb Loop Isolation Gowns (blue); material only passes ASTM F1670 synthetic blood penetration tests sold in bags of 15 - 5 gowns included in the trial load referenced.**
- **Non-Reinforced Surgical Gown with critical zones for front chest, sleeve, sleeve seam and front belt attachment point, blue spunbond-meltblow-spunbond (SMS), non-woven, polypropylene fabric with polyester cuffs, AAMI Level 3 - 3 extra-large gowns included in the trial load referenced.**
- **Sterile Polyethylene-reinforced front and breathable film sleeve gowns with hook & loop closures (blue); AAMI Level 4 - 22 large gowns included in the trial load referenced.**

Wash Cycle Specifics

<table>
<thead>
<tr>
<th>Operation</th>
<th>Time</th>
<th>Temperature</th>
<th>Water Level</th>
<th>Alkalinity</th>
<th>pH</th>
<th>Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wash</td>
<td>5 min.</td>
<td>101°F/38°C</td>
<td>High</td>
<td>150 ppm</td>
<td>10</td>
<td>4 oz dry enzyme detergent</td>
</tr>
<tr>
<td>Wash/Carry Over</td>
<td>8 min.</td>
<td>104°F/40°C</td>
<td>High</td>
<td>50 ppm</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Rinse</td>
<td>3 min.</td>
<td>100°F/37°C</td>
<td>High</td>
<td>0 ppm</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Finish / Sanitizer</td>
<td>5 min.</td>
<td>101°F/38°C</td>
<td>High</td>
<td>0 ppm</td>
<td>7</td>
<td>1 oz quaternary bacteriostatic</td>
</tr>
<tr>
<td>Low Extract</td>
<td>1 min.</td>
<td>Used to de-water goods</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumble</td>
<td>1 min.</td>
<td>Tumble to let trapped water drain; aids in reducing fabric stress &amp; plastering of goods, that may reduce tensile strength during final extract</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Extract</td>
<td>3 min.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Intake source water reported at a pH of 7, iron at zero, slight tract of chlorine with 30 ppm bicarbonate alkalinity.

Observations
Overall, the project process was relatively easy to complete. Programming of the washer for the specific project formula took 10 minutes by a technician familiar with the machine. The gowns produced were clean and odor free. Water repellency properties of the gowns was observed via beading after coming out of the washer. The majority of the gowns processed were usable (i.e., structurally intact); the gowns that were deemed unusable were those that sustained some level of destruction prior to washing (e.g., the PPE gown ties broken in the doffing process after use at the source facility).

Some gowns used in the trial process contained polyurethane and did not appear to be affected. However, it is important to closely manage dryer temperatures with these products; a maximum temperature of 120°F is desired to avoid destruction of the gowns.
The PPE gowns manufactured as an AAMI level 3 or 4 barrier gown held up best in the wash process. However, since they are manufactured for a single/one-time use at that level, it is likely there are no feasible mechanisms available to laundries for determining the suitability of these reprocessed PPE for use at that level.

Q & A

Why not use home-style/residential washers and dryers for this process?
The wash process, temperatures, and detergents/chemicals used in commercial operations are designed to produce hygienically clean textiles following the guidance of the CDC and cannot be validated in a home style/residential washer, given the variables in equipment, textiles, and detergents. Plus, these items were used as PPE and should not be taken into home for washing, as per the OSHA standard.

What action is recommended if the gowns are heavily soiled with blood?
ALM stresses that HCPs continue to adhere to OSHA BBP regulations, so the employee is protected as in the trial. You can try the formula we used in the trial and, if the gown does not come visibly clean, it can be discarded. The iron in blood can leave a residual stain and the product still be hygienically clean. This is also true for medicinal staining. Determination of suitability is left to user discretion.

I didn’t see chlorine bleach in the wash formula; how is this safe for use?
For the trial, we chose not to use chlorine bleach due to the nature of the gowns used in real-life applications. Chlorine has been known to be a problem for polyurethane, which is sometimes used in manufacturing select protective gowns and we didn’t want to destroy the product integrity in the process. However, the enzyme product selected in the trial contains sodium perborate that is a source of active oxygen and is a less aggressive bleach than chlorine-based bleaches; therefore, is thought to be a better selection given the textiles being washed. You will notice the sanitizer used in the final rinse to provide additional disinfecting properties.

Did the wash process remove/destroy the fluid repellency features of the gowns?
That subject was discussed in our collaboration meetings, and, while we recognize that is a valuable feature of the gowns, unfortunately commercial laundering facilities who had the equipment necessary to test barrier products for performance to the ANSI/AAMI PB:70 guidelines removed that equipment when healthcare providers made the switch to single-use products, as it was no longer needed. This testing would be necessary if the laundry processor were to make claims that the gowns performed at specific levels. There are products available from laundry chemical companies that can be used to restore the repellency features and their addition, according to the manufacturer’s instructions, would be an advantage to the wearer and are an available option for the laundry to consider.

So what can HCPs use these gowns for and what information should be provided to them?
First and foremost, the HCPs need to understand these gowns, although intended for single-use, have been reprocessed and no claims can be made as to their protection abilities i.e., they should not be used as PPE. They are provided as a resource to be used at the HCP’s discretion in these unusual circumstances. For laundries to service these products and return them to the hospital for consideration, the HCPs need to utilize doffing measures like those used for the reusable products, typically requiring a second individual in appropriate attire/gloves to untie the gown at the back before completing the doffing process.

It seems that drying the gowns may be a challenge, what else was learned from the testing process?
It is important that dryer temperature settings remain low and it would be prudent to closely monitor this step in the process to maintain temperatures at/below 120 °F. At this level, the test load referenced in this document were dry with the cotton cuffs providing the greatest challenge as some were slightly damp after the process referenced above.
How will HCPs know that the single-use gown has been washed?
Communication methods with the HCPs must be clear. Each gown that has been processed should be visibly labeled as such. Further, no claims as to the barrier protection of the gown is made. Laundries should not rely solely on labeling the outside container of the gowns. Suggestions include following the FDA guidance that includes describing the product as a “gown” or “toga,” and including recommendations against use in a surgical setting or where significant exposures to liquid bodily or other hazardous fluids may be expected or create an undue risk in light of this public health emergency.

Was a rejuvenation product or waterproofing applied?
It was not, but that is an option that a laundry can choose to add in the final rinse. However, it is strongly recommended that, in the absence of the ability to test each product as to their performance capabilities to the product standard, no single-use gown be represented as a barrier product.

References used in the development of this guidance include


This project collaboration was accomplished with a team from Medline Industries, Inc., UNX, Inc., Environmental Infection Prevention, LLC and the Association for Linen Management. This guidance is provided for consideration by HCPs as a stop-gap measure to fill a need for gowns during the 2020 public health emergency resulting from SARS-CoV-2 and the disease Coronavirus Disease 2019 (COVID-19). Laundries should check to make sure that this guidance satisfies the requirements of applicable statutes and regulations and not deviate from their regulatory compliance obligations.

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