

# Development of Performance and Design Criteria for Isolation Gowns FY17 (939ZNRT)

## Objective

To provide the basis for and recommend appropriate design and performance criteria for isolation gowns



## Applicable Standards

- OSHA 1991
- ASTM F23
- AAMI PB 70
- AATCC Standards

## Key Partners

- ASTM F23 Committee
- Vestagen Technical Textiles
- Kimberly Clark/Halyard
- United Hospital Services

## Stakeholders

- Healthcare workers
- Infection control professionals
- Manufacturers
- SDO's and others (AORN, APIC, Joint C.)



- Medline
- Nelson Labs
- PGI
- FDA, AORN, ARTA

## Project Scope

- Identify the specific hazards and use conditions
- Determine the performance, design and integration properties needed to demonstrate effectiveness
- Select and develop appropriate test methods to measure performance properties
- Establish design and performance criteria for isolation gowns including integration and interoperability that ensure an appropriate level of protection based on the results and user expectations
- Communicate recommended test methods and criteria to the ASTM F23 Committee on isolation gowns and other industry stakeholders for use in standards

## Milestones FY17

- Q1:** Completed reusable garment physical performance testing (after one & multiple launderings), validated Morgantown Labs AATCC 42 and 127 test results, drafted & submitted a paper on physical performance of disposable gowns for review
- Q2:** Submitted a paper on barrier performance of disposable gowns to a journal, presented findings to ASTM Committee, drafted the new ASTM standard and started balloting, completed barrier resistance testing of reusable gowns (after one & multiple launderings), conducted AATCC 42 and 127 testing on Level 4 gowns
- Q3:** Complete benchtop comfort testing of disposable gowns, start benchtop comfort testing of reusable gowns, draft & submit a paper on physical performance of reusable gowns for review
- Q4:** Complete benchtop comfort testing of reusable gowns, draft & submit a paper on barrier performance of reusable gowns for review, begin Phase II with thermal manikin testing of disposable gowns

## Outputs

- Final report with technical data used by ASTM F23 Committee for the development of a new ASTM standard on isolation gowns
- Manuscripts published in peer-reviewed journals (2 published, 1 submitted, 1 in internal review, 2 in preparation, expected min # of publications: 6)
- Presentations at conferences and SDO's committee meetings (6 so far)
  - Building the Chain of Safety, Jefferson School of Public Health (2011)
  - 39th Annual APIC Educational Conference & International Meeting (2012)
  - ASTM F23 Meetings (2014 and 2017)
  - 42th Annual APIC Educational Conference & International Meeting (2015)
  - TAPPI Innovative Nonwovens Conference (2015)
- Published 2 NIOSH Science Blogs
- Two webinars (Rutgers University, University of Iowa)
- One M.S. Thesis (S. Kamarec)

## Outcomes

- Consensus standards development organizations (ASTM, ISO, ANSI, AAMI), government agencies (FDA, etc.) and professional organizations (AORN, APIC, The Joint Commission) use recommended performance requirements to develop standards and / or guidance documents (**3 outcomes so far: FDA, CDC, and ASTM used findings for the development of new regulations, guidelines, and standards**)
- Healthcare workers use project outputs to select and use ensembles
- Manufacturers use the outputs to develop and /or improve current isolation gowns and use test results to improve manufacturing processes
- Other researchers utilize the findings to initiate research on more effective healthcare worker personal protective ensembles