

Fluid Resistance Properties of non-FDA cleared FFRs FY15 (927PP02-A)

Objectives

- Understand the risks associated with recommending the use of NIOSH certified (but not FDA cleared) filtering facepiece respirators (FFRs) in healthcare (outside the operating room) during public health emergency scenarios
- Develop NIOSH expertise and capabilities to conduct fluid resistance testing of personal protective equipment (PPE)

Applicable standards

- 42 CFR Part 84
- FDA clearance

Key Partners

- CDC, FDA, OSHA

Stakeholders

- Respirator manufacturers
- FDA
- Healthcare Professionals

Project Scope (all years)

- Measure resistance of non-FDA cleared FFRs to penetration by synthetic blood according to the ASTM F1862 method
- Modify/adapt ASTM F1862 to evaluate fluid resistance to sneeze/cough challenges

FY15 Milestones

- Q1. Set up the test equipment for measuring resistance
- Q2. Standardize the test method for measuring resistance to synthetic blood and coughs/sneezes
- Q3. Test the FFRs for fluid resistance
- Q4. Analyze the data and submit a manuscript

Outputs (completed and/or planned)

- A manuscript titled “Resistance to synthetic blood penetration for NIOSH approved filtering facepiece respirators” has been submitted in eclearance. Once approved the manuscript will be submitted for publication to peer-reviewed journal.

Outcomes (completed and/or planned)

- NIOSH will incorporate requirements such as splash resistance in 42 CFR Part 84 approval process to meet FDA clearance process
- CDC will use project outputs to update/validate current FFR recommendations for use during public health emergency situations

Updated: 21 Feb 2015