

State of the science on test methods, standards and research on flammability of RPD for healthcare workers

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FDA recommended standards for Surgical Masks*

- CPSC CS-191-53 Flammability Test Method(16 CFR 1610) Standard for Flammability of Clothing Textiles
- NFPA Standard 702-1980: Standard for Classification of Flammability of Wearing Apparel
- UL 2154: Test that measures the level of atmospheric oxygen required to propagate flame when ignition is caused by an electrosurgical laser

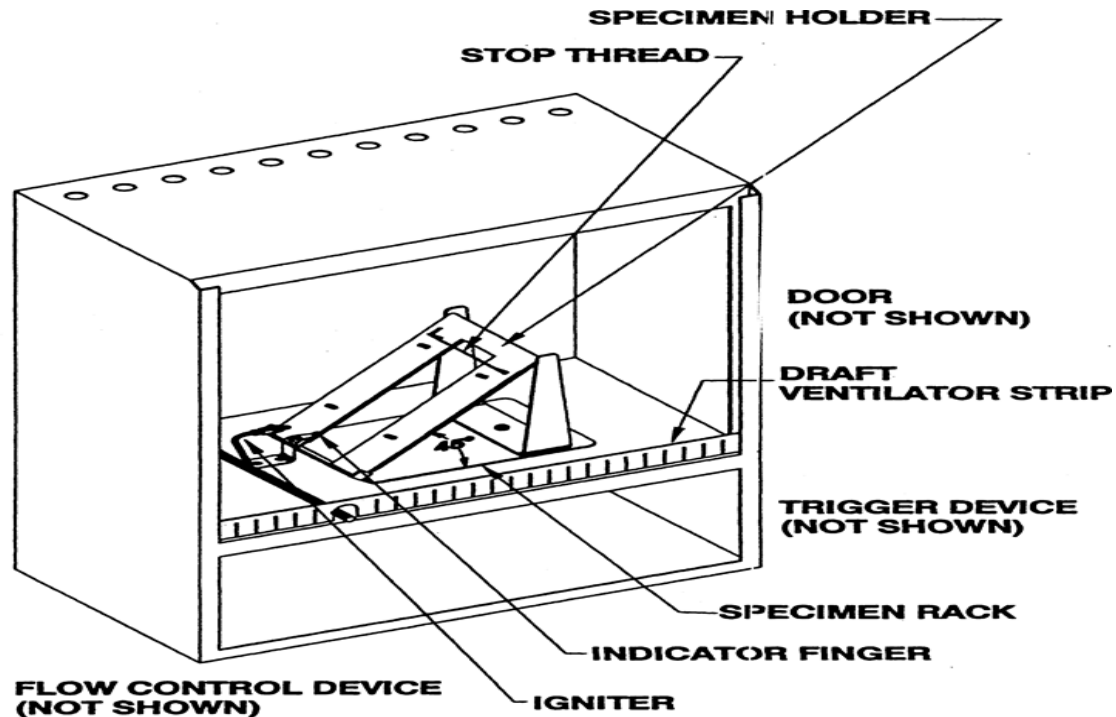
* Guidance for Industry and FDA Staff, Surgical Masks-Premarket Notification[501(k)] Submissions, U.S Department of Health and Human Services, Food and Drug Administration

SDL Atlas 45 deg. Flammability Tester*



* <http://www.sdlatlas.com/product/134/AFC-45-Automatic-Flammability-Tester>

CSC 16 CFR Part 1610*



SKETCH OF FLAMMABILITY APPARATUS
FIGURE 1

* Consumer Product Safety Commission 16 CFR Part 1610, Standard for the Flammability of Clothing Textiles

CSC 16 CFR Part 1610

- Flammability standard for all general wearing apparel
- Establishes 3 classes of flammability based on rate of burn propagation(burn time)
 - Class 1: Normal flammability-acceptable for use in clothing(burn time 3.5 s or more for plain surface fabrics, 7.0 s for raised surface fabrics)
 - Class 2 : Intermediate flammability(for raised surface fabrics: burn time 4.0-7.0 s.)
 - Class 3: Rapid and intense burning(burn time less than 3.5 s). Considered dangerously flammable.

FDA recommendations for surgical masks

- FDA recommends that class 1 and class 2 flammability materials be used in surgical masks intended for use in the operating room. For NFPA, class 1 indicates relatively slow burning. FDA believes that that devices with NFPA class 4 rating are not appropriate for OR use. Class 3 should have a flammability warning. Further state that:
- There are “many sources of ignition in OR, including surgical lasers, electrosurgical units, endoscopic fiber optics, and high energy electro-medical devices.
- All materials will burn if a high intensity heat source is applied to them, especially in presence of elevated oxygen levels”.
- NIOSH has established no flammability requirements for N95 respirators
- ASTM F2100 requires all medical face masks to meet or exceed class 1(as defined by 16 CFR Part 1610)*

*ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks, ASTM International, West Conshohocken, Pa.

General considerations for test method selection/development

Many variables determine flammability

- Ignition source(open flame, laser, etc.)
- Oxygen level
- Flammability metric(ease of ignition, burn rate, heat release, thermal stability, etc.)
- Materials vs. systems test?
- Modern instrumented systems level testing systems are available



O₂

Fuel



What are some important considerations?

- For assessing flammability test method or need for development?
- Understanding flammability hazards in surgical or non-surgical environments in relation to face mask exposures
- Matching flammability requirement with potential hazard
- Need for uniformity in reporting test results
- Importance of risk assessment

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