Classifications and Testing Requirements for PPE in Medical Environments and Personal Use

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Masks and Gowns- relevant standards and requirements

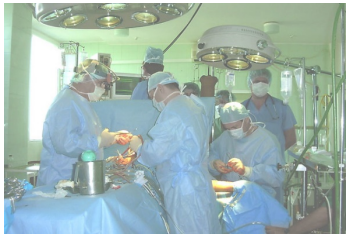
Today's content will be around;

Masks:

- Respirators (N95)
- Surgical masks
- Medical masks
- Non-medical masks

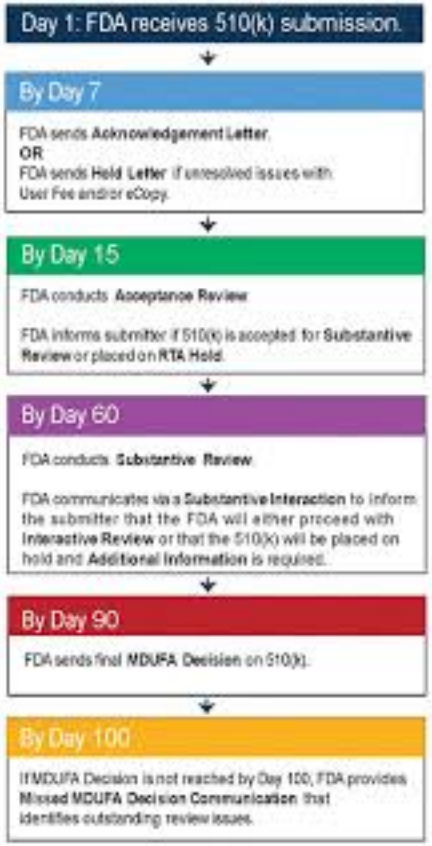
Gowns:

- Surgical gowns
- Medical gowns



Masks and Surgical gowns are FDA Class II products – "510(k) devices"

- Section 510(k) of the *Food, Drug, and Cosmetic Act* requires a manufacturer to submit a Premarket Notification (the so-called 510[k]) to the FDA at least ninety (90) days in advance when the manufacturer wishes to market.
- For all Class II devices in the U.S. the 510(k) must show that the device to be marketed is **substantially equivalent** to a legally marketed similar device by **demonstrating that the new device is as safe and effective** as the legally marketed device.
- Occasionally, the FDA will require a clinical investigation to determine the substantial equivalence.



Masks - relevant standards and requirements

- Respirators (N95): respiratory protection, regulated by NIOSH, certified by NPPTL (NIOSH lab);
- Surgical masks: medical device, regulated by FDA, subject to premarket notification 510(k) – not respiratory protection PPE;
- Medical masks: medical device, regulated by FDA, subject to premarket notification 510(k) that has temporarily be suspended – not respiratory protection PPE;
- Non-medical masks: not regulated;

Masks: N95 versus Surgical mask

- The difference between a respirator and a fluid/splash protection
- Entirely different certification processes

Understanding the Difference

	 Surgical Mask	 N95 Respirator
Testing and Approval	Cleared by the U.S. Food and Drug Administration (FDA)	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84
Intended Use and Purpose	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).
Face Seal Fit	Loose-fitting	Tight-fitting
Fit Testing Requirement	No	Yes
User Seal Check Requirement	No	Yes. Required each time the respirator is donned (put on)
Filtration	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles
Leakage	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales
Use Limitations	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.

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

Masks - relevant standards and requirements

- Respirators (N95):
  - respiratory protection, regulated by NIOSH, certified by NPPTL (NIOSH lab);
  - Federal regulation: 42 CFR Part 84
  - Process: submit product and documentation to NIOSH/NPPTL for testing and certification
  - Extensive requirements and testing

Masks - relevant standards and requirements

- **Respirators (N95) – Requirements, 24 CFR § 84.181**
  - (b) Filters shall be prominently labeled as follows:
    - (1) N/P/R100 filters have 99.97% filter efficiency
    - (2) N/P/R99 filters have 99% filter efficiency level
    - (3) N/P/R95 filters have 95% filter efficiency level
  - Airflow resistance tests.
    - (a) Resistance to airflow will be measured (complete respirator) with air flowing at continuous rate of 85±2 liters per minute, before each test conducted in accordance with § 84.182.
    - (b) The resistances upon initial inhalation shall not exceed 35 mm water column height pressure and upon initial exhalation shall not exceed 25 mm water column height pressure.

Masks - relevant standards and requirements

- **Respirators (N95) – Main Requirements:**
  - Non-powered air-purifying particulate filter efficiency level determination.
  - (a) Twenty filters of each non-powered air-purifying particulate respirator model shall be tested for filter efficiency against:
    - (1) A solid sodium chloride particulate aerosol as per this section, if N-series certification is requested by the applicant.
    - (2) A dioctyl phthalate or equivalent liquid particulate aerosol as per this section, if R-series or P-series certification is requested by the applicant. (i.e. oil repellency)

Masks - relevant standards and requirements

- **Respirators (N95) – Main Requirements:**
  - (e) For non-powered air-purifying particulate respirators with a single filter, filters shall be tested at a continuous airflow rate of 85±4 liters per minute.
  - (f) Filter efficiency test aerosols.
    - (1) Solid particles: sodium chloride or equivalent solid aerosol at 25±5°C and relative humidity of 30±10 percent
    - Each filter shall be challenged with a concentration not exceeding 200 mg/m3
    - (2) When testing R-series and P-series filters, a neat cold-nebulized dioctyl phthalate (DOP) or equivalent aerosol at 25±5 °C that has been neutralized to the Boltzmann equilibrium state shall be used. Each filter shall be challenged with a concentration not exceeding 200 mg/m

Masks - relevant standards and requirements

Respirators (N95) - Requirements:

- (g) The sodium chloride test aerosol has an average shall have a particle size distribution with count median diameter of 0.075±0.020 micrometer and a standard geometric deviation not exceeding 1.86.
  - → i.e. particles size range is about 0.05 to 0.4 micron.
- The DOP aerosol (oil repellency for R/P filters) shall have a particle size distribution with count median diameter of 0.185±0.020 micrometer and a standard geometric deviation not exceeding 1.60.

Masks - relevant standards and requirements

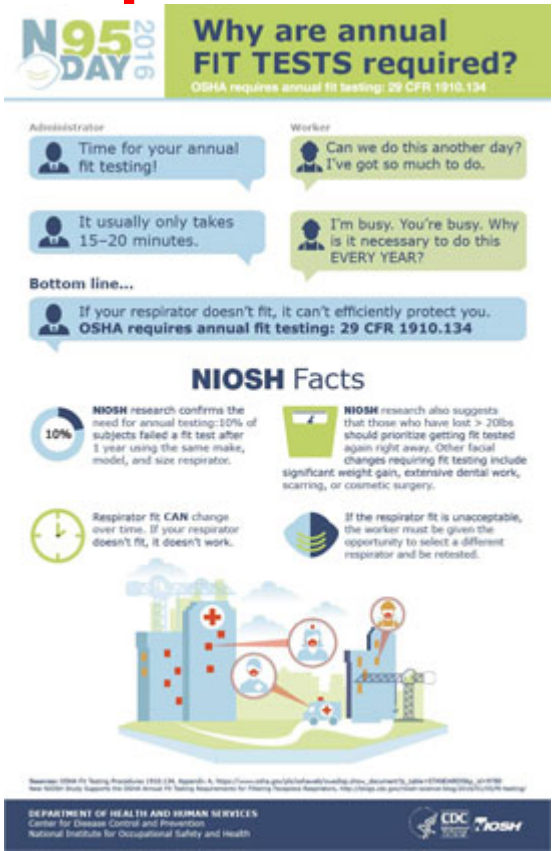
- Respirators (N95) - Requirements:

- Fit testing: N95 masks have to be fit tested prior to use,
  - 1) they are evaluated on a head form, but
  - 2) wearers have to be individually fit-tested to achieve optimal fit to the wearer: Particulate Respirator Qualitative Fit Test Utilizing Saccharin or Bitrex Solutions
- Fit is extremely important to achieve respiratory protection to protect the wearer from the environment
- Leakage has very often shown to be the biggest factor in effective reduction of protection

Masks - relevant standards and requirements

- Respirators (N95) - Requirements:

- Fit testing: novel N95 masks also have to be fit tested prior to certification,
  - 0005* Qualitative Fit Testing Procedure
  - Isoamyl-acetate test with human subjects
  - A panel of 18 subjects across a range of sizes
  - 8 minutes test with various activities
    - 2 minutes Nodding and moving head side-to-side
    - 2 minutes Callisthenic arm movements
    - 2 minutes Running in place
    - 2 minutes Pumping with tire pump
  - If the subject detects any odor (specific) the test fails



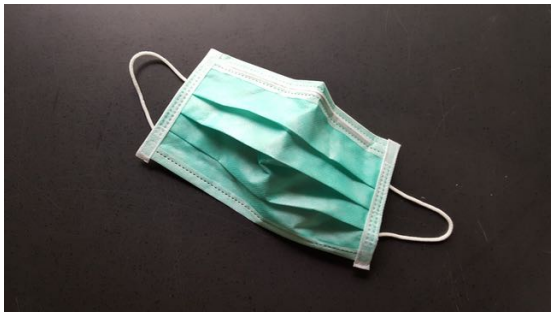
Masks - relevant standards and requirements

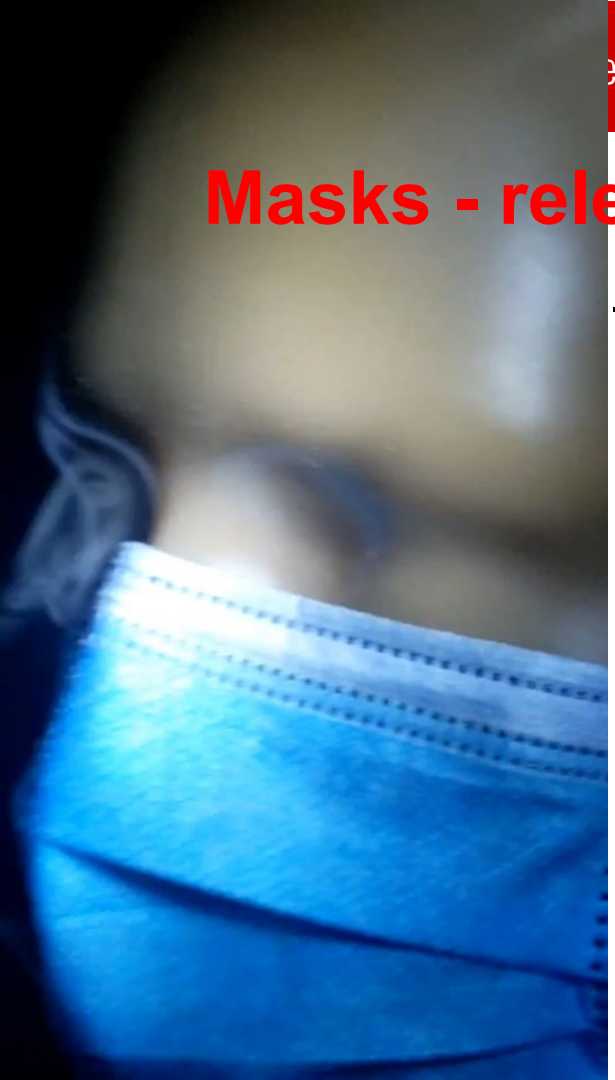
- **Respirators (N95) – General structure**
  - Referring to Steven Sharp's webinar last week and next week webinar
  - N95 are technical highly effective filtration fabrics
  - small fiber content to achieve low weight low pore sizes
  - usually including electrete functionality (charged) to achieve >95% filtration efficiency at relevant flow

Manufacturer information:
https://www.cdc.gov/niosh/npptl/respmanuf.html
Detailed Certification information:
https://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/APR-FFR-03122018-508.pdf

Masks - relevant standards and requirements

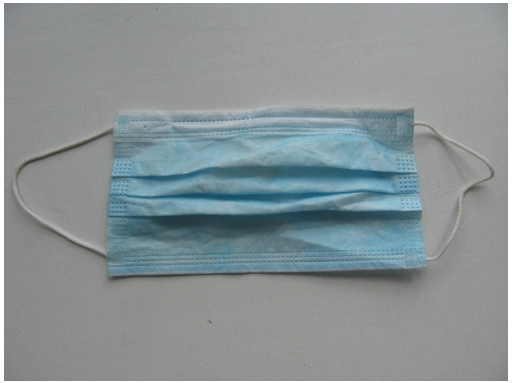
- **Surgical masks:**
  - No respiratory protection, regulated by FDA, intended for “Aerosol generating procedures”
  - Focus on fluid resistance and splash protection
  - Fabric filtration requirements, no mask performance (no fit-test)
  - Subject to pre-market approval
  - Process: submit documentation to FDA to demonstrate “”Substantial Equivalency”
    - If you have never dealt with FDA, try to get some help
  - Guidance: follow ASTM F2100





Masks - relevant standards and requirements

- **Medical masks:**
  - No respiratory protection, regulated by FDA, other procedures in hospitals
  - Subject to pre-market approval
  - Process: submit documentation to FDA to demonstrate “”Substantial Equivalency”
  - Limited requirements available



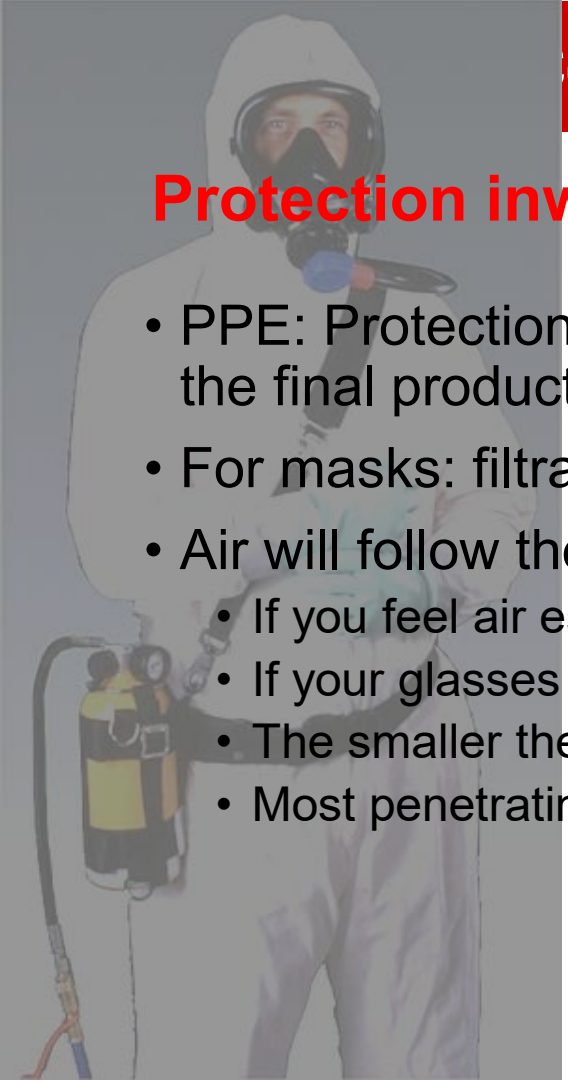
Surgical/Medical Masks - relevant standards and requirements

Guidance: follow ASTM F2100, level 3 should be sufficient for Surgical masks

Characteristic	Level 1 barrier	Level 2 barrier	Level 3 barrier	Associated test method – ASTM
Bacterial filtration efficiency, %	≥95	≥98	≥98	ASTM F2101
Differential Pressure, mm H2O/cm2	<5.0	<6.0	<6.0	EN 14683:2019, Annex C (ASTM D737 might be used but needs significant conversions)
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥95	≥98	≥98	ASTM F2299
Resistance to penetration by synthetic blood, min. pressure to pass in mmHg	80	120	160	ASTM F1862
Flame spread	Class 1	Class 1	Class 1	16 CFR Part 1610

Masks - relevant standards and requirements

- **Non-Medical masks – general purpose/general public:**
  - No guidance or guidelines available
  - Voluntary draft is now available, see temporary link:
    - https://www.aatcc.org/wp-content/uploads/2020/06/Face-Covering-Monograph.pdf
    - Basic design and guidance
    - Limited fabric and mask protection
    - Basic breathability requirement
    - Very basic construction suggestions



Protection inward and outward – general reminders

- PPE: Protection is not only about the fabric used, but all about the final product and how it fits on the person
- For masks: filtration fabric + good fit to the face
- Air will follow the path of least resistance
  - If you feel air escape, that is where most of it is going
  - If your glasses fog up, your protection is low (inward and outward)
  - The smaller the particles (aerosols) the better they follow the air flow
  - Most penetrating particle size (most challenging) around 0.3 micron

Surgical vs. Non-surgical Gowns

- A number of different terms used: surgical gowns, isolation gowns, surgical isolation gowns, non-surgical gowns, cover gowns, comfort gowns, procedural gowns, and operating room gowns.

Cardinal Level 4 Surgical Gown

Halyard Procedure Gown

Medline Isolation Gown

Regulatory Path – 510(k) Submission

- 2015 FDA guidance document specifies that surgical gowns are classified as Class II medical devices which will require 510(k) clearance.
- A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA.
- Guidance document FDA 510(k) Program: https://www.fda.gov/media/82395/download
- First priority is to find predicate devices:

https://www.fda.gov/medical-devices/premarket-notification-510k/how-find-and-effectively-use-predicate-devices

- Available databases: 510k(s), Total Product Life Cycle (TPLC)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

Other Resources

- FDA Guidance On Medical Gowns: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns
- FDA Process Validation: https://www.fda.gov/media/94074/download
- FDA Design Control: https://www.fda.gov/media/116762/download
- PPE Donning (Put on) https://www.youtube.com/watch?v=Ca66dpjPWZc
- PPE Doffing (Take off) https://www.youtube.com/watch?v=bZA424c5sWQ

- IFAI / NC State PPE Webinar: June 16, 2020 1.00 pm EDT
  "Surgical Gowns Manufacturing Basics"

NC State – IFAI Webinars

Today we focused on regulations and standards.

Follow-up and more details on these topics in the following webinars:

- **IFAI / NC State PPE Webinar: June 9, 2020 1.00 pm EDT "Mask protection basics":**
  - Learn about the basic protection factors to donning and wearing a mask and how it can help protect the wearer. Also, learn how fit can impact protection and the key areas for mask protection that make it effective PPE for different users. Newly developed testing methodologies will also be covered in this area to better understand the material and developmental requirements for different mask types.

- **IFAI / NC State PPE Webinar: June 16, 2020 1.00 pm EDT "Surgical Gowns Manufacturing Basics":**
  - You will learn more details about typical materials used in the various types of gowns and how to design and package them to accommodate proper donning and doffing procedures in healthcare settings.

Thanks for your attention

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