Guidelines for Personal Protective Equipment (PPE)

PERSONAL PROTECTIVE EQUIPMENT

Ventilators

- The FDA released new guidance that allows more manufacturers to make ventilators at this time.
- The agency is allowing for device modification, and the utilization of ventilators intended for other environments.

Nasal swab for COVID-19 test kits

- Nasal swab guidance for COVID-19 test kits can be found here.
- The Flocked swab tip must be synthetic (dacron or rayon) fiber and appropriately small sized for a nasal cavity (OP is too large)
- Shaft must be narrow and made of flexible plastic
- Shaft must have a break point adequately distal from the swab tip to avoid breaking in the nasal cavity

N95 Respirators (hospitals)

- There are two types of respirators that are appropriate for healthcare workers with close contact with COVID-19 patients: 1) N95 Respirators; and 2) Surgical N95 Respirators.
    - **Surgical N95 Respirators** are the appropriate device in the healthcare setting when both aerosol and barrier protection (i.e., splash or sterile field) are needed and must be approved by both NIOSH as a FFR (42 CFR Part 84) and FDA as Class II Medical Device (21 CFR 878.4040).
        - FDA tests: Fluid resistance (ASTM F1862), flammability, and biocompatibility.
    - **N95 Respirators** (approved by NIOSH under 42 CFR Part 84) are appropriate for healthcare settings where only protection from patient generated aerosols is required.

Medical (surgical) masks

- Surgical masks must be FDA approved under 21 CFR 878.4040 as Class II Medical Devices.
- Tested for fluid resistance (ASTM F1862), flammability, and biocompatibility.

Exam gloves

- Non-sterile, disposable patient examination gloves are appropriate for care of COVID-19 patients.
- The American Society for Testing and Materials (ASTM) has standards for patient examination gloves:
    - ASTM D6319 – Standard specification for nitrile examination gloves for medical applications.

Gowns (medical), disposable with elastic wrists

- Non-sterile, disposable patient isolation gowns are appropriate for care of COVID-19 patients.
- Four defined levels of protection tested to meet ANSI/AAMI PB70:
    - Level 1: *Minimal risk*, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit;
    - Level 2: *Low risk*, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab;
    - Level 3: *Moderate risk*, to be used, for example, during arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases;
    - Level 4: *High risk*, to be used, for example, during long, fluid intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne).
- A **surgical gown** is regulated by the FDA as a Class II medical device that requires a 510(k) premarket notification. Surgical gowns can be used for any risk level (Levels 1-4).

Eye/face shields

- Must meet ANSI Z87.1 for splash protection

Goggles

- Must meet ANSI Z87.1 for splash protection

DRUGS AND CONSUMABLES

Biohazard bag (Regulated Waste)

- Must meet DOH requirements for the collection of Regulated Medical Waste (RMW) under Title 10 part 70-2.2
    - Red plastic bag, of sufficient strength
- Must meet DOT requirements for the transportation of RMW under 49 CFR 173.197 (e)
    - Cannot exceed a volume of 46 gallons, must pass tests prescribed for tear and impact resistance under ASTM D 1922 and ASTM D 1709

respectively. Must meet a tear resistance of 480grams in both parallel and perpendicular planes with respect to length of the bag and an impact resistance of 165 grams.

- Must meet OSHA requirements under 29 CFR 1910.1030(g)(1) (i)
    - Marked with a biohazard symbol

Soap, liquid (1L size)

Safety box needle (Sharps) disposal

- OSHA's minimum requirements for sharps containers include:
    - Closable;
    - Puncture-resistant;
    - Leakproof on side and bottom; and
    - Labeled (Biohazard) or color-coded (red) in accordance with standard.
- Production of a sharps container is regulated by the FDA as a Class II medical device that requires a 510(k) premarket notification.
- Sharps containers must meet DOH requirements for the collection of RMW under Title 10 part 70-2.2
    - Marked with a biohazard symbol, rigid, leakproof, puncture-resistant, and closable (Same as OSHA).
- Must meet DOT requirements for the transportation of sharps under 49 CFR 173.134(c)(2)(x)
    - Securely closed to prevent leaks or punctures, less than 18-gallon capacity if transported in a wheeled rack, and made of puncture resistant plastic that meets ASTM standard F2132-01.