

# Personal Protective Equipment for Infection Control

Personal protective equipment (PPE) refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.

PPE is commonly used in health care settings such as hospitals, doctor's offices and clinical labs. When used properly, PPE acts as a barrier between infectious materials such as viral and bacterial contaminants and your skin, mouth, nose, or eyes (mucous membranes). The barrier has the potential to block transmission of contaminants from blood, body fluids, or respiratory secretions. PPE may also protect patients who are at high risk for contracting infections through a surgical procedure or who have a medical condition, such as, an immunodeficiency, from being exposed to substances or potentially infectious material brought in by visitors and healthcare workers. When used properly and with other infection control practices such as hand-washing, using alcohol-based hand sanitizers, and covering coughs and sneezes, it minimizes the spread of infection from one person to another. Effective use of PPE includes properly removing and disposing of contaminated PPE to prevent exposing both the wearer and other people to infection.

When an infection outbreak affects a broad population in the United States, the Centers for Disease Control and Prevention (CDC), is responsible for making specific recommendations for infection control measures in different circumstances and settings. For example, the CDC has provided the following recommendations:

- What You Should Know about the Flu (<http://www.cdc.gov/flu/index.htm>)
- What You Should Know about Ebola (<http://www.cdc.gov/vhf/ebola/pdf/what-need-to-know-ebola.pdf>)

## The FDA's role in regulating personal protective equipment

All personal protective equipment (PPE) that is intended for use as a medical device must follow The FDA's regulations and should meet applicable voluntary consensus standards for protection. This includes surgical masks, N95 respirators, medical gloves, and gowns. The consensus standards and the FDA's requirements vary depending on the specific type of PPE. When these standards and regulations are followed, they provide reasonable assurance that the device is safe and effective.

Some PPEs are reviewed by the FDA before they can be legally sold in the United States. In this review, known as Premarket Notification or 510(k) clearance (<http://www.fda.gov>

[/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm](#)), the manufacturers have to show they meet specific criteria for performance, labeling, and intended use to demonstrate substantial equivalence. One way substantial equivalence may be demonstrated, in part, is by conforming to consensus standards for barrier performance and resistance to tears and snags. Voluntary consensus standards may also be used to demonstrate sterility (when applicable), biocompatibility, fluid resistance, and flammability. Manufacturers must validate the methods used to test conformance to standards and support each product with appropriate performance test data.

For additional information on the FDA's role in regulating specific PPE, please go to:

- [Masks and N95 Respirators \(/medical-devices/personal-protective-equipment-infection-control/masks-and-n95-respirators\)](#)
- [Medical Gloves \(/medical-devices/personal-protective-equipment-infection-control/medical-gloves\)](#)
- [Medical Gowns \(/medical-devices/personal-protective-equipment-infection-control/medical-gowns\)](#)