

Important Information Regarding FEMA Temporary Final Rule on Prioritization and Allocation of Certain Scarce or Critical Health and Medical Resources for Domestic Consumption

FEMA published a [Temporary Final Rule](#) (TFR) in the *Federal Register* on Aug. 10, 2020 that allocated certain health and medical resources for domestic use to ensure needs are met for frontline healthcare workers and the American public during the COVID-19 pandemic. This TFR is an extension and modification a TFR published on April 10, 2020 which outlined the implementation of the President’s Memorandum, “[Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use](#)”.

This extension allows the TFR to remain in effect, with certain modifications, through Dec. 31, 2020. Modifications were made to the types of exports of PPE that FEMA will review and may hold for domestic use to reflect changing circumstances. For example, shipments of certain classes of surgical gowns are now covered under the TFR, and may not leave the United States without explicit approval by FEMA.

FEMA’s Export Cargo Review Working Group, which includes representatives from Customs and Border Protection (CBP), the Department of State, the Department of Commerce, and the Food and Drug Administration, will continue to evaluate the PPE items included in the TFR every two weeks to review updated information about the supply and demand of covered PPE. As needed, the Export Cargo Review Working Group will submit requests to the Unified Coordination Group and White House Task Force to make modifications to the TFR.

Covered PPE Under the Allocation Order



FEMA

FEMA is working in close coordination with CBP and the members of the Export Cargo Review Working Group to review shipments of the following PPE materials:

- Surgical N-95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates;
- PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials;
- PPE nitrile gloves, specifically those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and other such nitrile gloves intended for the same purposes;
- Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all the requirements in ANSI/AAMI PB70 and ASTM F2407 – 06 and are classified by Surgical Gown Barrier Performance based on AAMI PB70.

When an Exporter Has a Surplus of a Covered Material and Can Demonstrate a Good-faith Attempt to Sell the Material Domestically

In the months since the first TFR was published in April, the domestic supply of certain covered materials may now exceed the demand within the United States. FEMA recognizes that there may no longer be a need to disrupt the supply chain of certain materials and require that the entire domestic production of these items be allocated for domestic.

If you believe you have a surplus of a covered material and can demonstrate a good-faith and unsuccessful attempt to sell the material domestically, you may submit a request to FEMA to allow the material to be exported. Please submit a Letter of Attestation to NBEOC@max.gov, describing:

1. The material you wish to export;
2. The commercially reasonable efforts you have made to market and sell the material domestically;
3. The delta, with specificity, between the domestic demand and the domestic production; and
4. How the proposed export volume will not interfere with continued satisfaction of domestic demand.



FEMA will review submitted Letters of Attestation and make every effort to provide parties with a Letter of Decision within three business days of receipt of a Letter of Attestation.



FEMA