

Information for Exporters with a Surplus of Medical Supplies and Equipment

Release Date: Tháng 5 19, 2021

*This document was updated as of May 19, 2021

[FEMA published a Temporary Final Rule \(TFR\)](#) in the *Federal Register* on December 31, 2020. It allocates certain scarce critical medical and healthcare resources for domestic use to ensure domestic needs are met during the COVID-19 pandemic, and to ensure supplies of certain materials are not exported abroad inappropriately. The current TFR is in effect until June 30, 2021.

FEMA strives to keep the TFR up to date while reflecting the most current information about critical medical supplies and healthcare resources. The process requires a balance between potential domestic shortages, protection of the national defense interest, promotion of the domestic economy, and an acknowledgment of international and diplomatic considerations.

To adapt to consistently fluid supply chain considerations, FEMA is announcing some changes under the current TFR.

Effective immediately, the following are no longer restricted from export under the TFR:

- Industrial N95 Respirators, including devices that are currently NIOSH approved for use in healthcare settings under an Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA)
- PPE Surgical Masks, as described by 21 CFR 878.4040, including masks that cover the user's nose and mouth providing a physical barrier to fluids and particular materials, that meet fluid barrier protection standards pursuant to: ASTM F 1862; and Class I or Class II flammability tests under CPSC CS 191-53, NFPA Standard 702-1980, or UL 2154 standards
- Piston syringes that allow for the controlled and precise flow of liquid as described by [21 CFR 880.5860](#), that are compliant with ISO 7886-1:2017 and use only Current Good Manufacturing Practices (CGMP) processes; or



FEMA

Page 1 of 3

- Hypodermic single lumen needles that have engineered sharps injury protections as described in the Needlestick Safety and Prevention Act, [Pub. L. 106-430](#), 114 Stat. 1901 (Nov. 6, 2000).

The review and restriction from export under the TFR remains unchanged for these items:

- Surgical N95 Respirators, that are single-use, disposable respiratory protective devices used in a healthcare setting that are worn by healthcare personnel during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181.
- PPE Nitrile Gloves, specifically those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such nitrile gloves intended for the same purposes.
- Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all of the requirements in ANSI/AAMI PB70 and ASTM F2407-06 and are classified by Surgical Gown Barrier Performance based on AAMI PB70

Additional Information

If you are a manufacturer or distributor of one of the remaining covered items under the TFR, and believe you have a surplus you may request an exemption due to a surplus of materials. This is only required for the three covered items remaining , surgical N95 Respirators, PPE Nitrile Gloves, or Level 3 and Level 4 Surgical Gowns and Surgical Isolation Gowns. You will be asked to demonstrate a good-faith and unsuccessful attempt to sell the material to the domestic market.

To request this TFR export process exemption due to a surplus of materials, please submit a Letter of Attestation with the following information to docs@cbp.dhs.gov:

1. The surplus material you wish to export
2. The commercially reasonable efforts you have made to market and sell the material domestically
3. The difference, to the extent known, between the domestic demand and the domestic production



4. How the proposed export volume will not interfere with continued satisfaction of domestic demand.

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

For more information on submitting Letters of Attestation and allocated exports, visit the [CSMS #42506108- CBP Frequently Asked Questions About PPE Exports](#).

For information on additional exemptions to the allocation order, go to the [Notice of Exemptions](#) published in the Federal Register in April 2020.

[Export Allocation Rule on Medical Supplies and Equipment for COVID-19](#)



FEMA