

Allocation Rule on Exports of Personal Protective Equipment

Release Date: Dec 31, 2020

FEMA published a [Temporary Final Rule](#) (TFR) in the *Federal Register* on Dec. 31, 2020 that allocated certain scarce and critical health and medical resources for domestic use to ensure needs are met for the American public during the COVID-19 pandemic. This TFR is an extension and modification of a [TFR](#) published on August 10, 2020, that extended and modified the initial allocation order issued on April 10, 2020. The TFR outlined the implementation of the President’s Memorandum, [“Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use”](#) issued on April 3, 2020.

This extension allows this rule to remain in effect, with certain modifications, through June 30, 2021. To reflect changing circumstances, modifications were made to the types of exports of Personal Protective Equipment (PPE) that FEMA will review and may hold for domestic use. Specifically, FEMA narrowed the scope of the surgical masks subject to the order (see below). Additionally, the agency added certain types of syringes and hypodermic needles to the order, so that these items may not leave the United States without explicit approval by FEMA.

The health and medical resources subject to this allocation order include:

- Surgical N95 Respirators;
- Surgical masks, specifically PPE surgical masks that meet fluid barrier protection standards pursuant to specific industry standards;
- Nitrile gloves and exam gloves,
- Surgical Gowns and Surgical Isolation Gowns; and
- Syringes and hypodermic needles (whether distributed separately or attached together) that are either:
 - Piston syringes; or
 - Hypodermic single lumen needles with a safety feature.

FEMA’s Export Cargo Review Working Group

This group includes representatives from Customs and Border Protection (CBP), the Department of State, the Department of Commerce, the Department of Health and



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Human Services, and the Food and Drug Administration, reviews shipments regularly, and will continue to evaluate the categories health and medical resources included in the TFR every two weeks to consider updated information about the supply and demand of covered materials. 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.

Automated Export System

In most situations, planned international exports must be declared in advance by exporters, with details about the shipment submitted into CBP's Automated Export System (AES). CBP will review information submitted into AES to determine if products bound for export are covered under the TFR or if an exemption applies. If the shipment is covered under the TFR and an exemption does not apply, CBP will notify FEMA for a determination on the shipment.

If FEMA determines that it is in the national defense interest for a shipment to remain in the United States to support the COVID-19 pandemic response, the agency may take one of the following two options:

- Purchase part, or all, of the shipment, using a rated order Title 1 of the Defense Production Act.
- Return part or all of the shipment for domestic distribution.
- Allow part, or all, of the shipment to be exported.

Exemptions

- Sealed, sterile medical kits and diagnostic testing kits where only a portion of the kit is made up of one or more covered materials that cannot be easily removed without damaging the kits.
- Declared Diplomatic shipments from foreign embassies and consulates to their home countries. These may be shipped via intermediaries (logistics providers) but are shipped from and consigned to foreign governments.
- Shipments to Overseas U.S. Military Addresses, Foreign Service Posts (e.g., diplomatic post offices), and Embassies.
- Shipments by or on behalf of the U.S. Federal Government, including its military.
- Shipments to U.S. commonwealths and territories, including Guam, American Samoa, Puerto Rico, U.S. Virgin Islands, and the Commonwealth of the Northern Mariana Islands (Including minor outlying islands).



Exemptions which require a Letter of Attestation. (See below for information on Letters of Attestation.)

- Shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, so long as at least 80 percent of such manufacturer's domestic production of covered materials, on a per item basis, was distributed in the United States in the preceding 12 months.
- Exports of covered materials by non-profit or non-governmental organizations that are solely for donation to foreign charities or governments for free distribution (not sale) at their destination(s).
- Intracompany transfers of covered materials by U.S. companies from domestic facilities to company-owned or affiliated foreign facilities.
- Shipments of covered materials that are exported solely for assembly in medical kits and diagnostic testing kits destined for U.S. sale and delivery.
- In-Transit Merchandise: shipments in transit through the United States with a foreign shipper and consignee, including shipments temporarily entered into a warehouse or temporarily admitted to a foreign trade zone.
- Shipments for which the final destination is Canada or Mexico.

For more information on exemptions, see the [Notification of Exemptions](#) which was published in April to supplement the April 10th TFR and now applies to the TFR published on Dec. 31, 2020 as well.

If a shipment is detained for review under the TFR, FEMA and CBP will work to provide a response to the owner of the shipment within 72 hours.

Letters of Attestation

Letters of Attestation are only needed if the shipper plans to export one or more of the covered materials listed in the allocation order, and if this shipment falls under one of the exemptions for which a letter of attestation is required.

FEMA recommends including the following information in a Letter of Attestation:

- Must be on company letterhead.
- Description of the type and quantity of covered materials that are included in the shipment. If the shipment does not contain any of the covered materials, then there is



- no need to file the attestation letter, as the shipment falls outside the allocation order.
- A description of which exemption(s) the owner or exporter believes the shipment falls into.
 - A brief statement describing why the claimed exemption applies.
 - A brief statement describing the expected end use of the exported materials.
 - A statement confirming that the provided information is true and accurate to the best of the exporter's knowledge, and that the exporter is aware that false information is subject to prosecution under the Defense Production Act, as described in the allocation order.

Letters of Attestation **must be submitted** in conjunction with export paperwork through the Automated Export System (AES) to Customs and Border Protection. The AES allows for the attachment of documents, such as Letters of Attestation, under the tab "Document Imaging System."

Exporters with a Surplus of Covered Material

If a shipper believes they have a surplus of a covered material and can demonstrate a good-faith and unsuccessful attempt to sell the material domestically, they may be exempt. For more information on this exemption, [review the fact sheet](#) surplus of covered material.

Exporters who take Advantage of Exemptions

If CBP believes that an exporter is intentionally modifying its shipments to take advantage of one or more exemptions, CBP may detain a shipment and forward information about that shipment (including the basis for CBP's belief of the intentional modification) to FEMA for determination.

In addition, CBP may, in its discretion, forward on additional shipments to FEMA for consideration if the agency does not believe a shipment falls clearly into one or more exemptions.

Contact Info: Questions about a specific shipment should be directed to [Customs and Border Protection](#). Questions about the allocation order and Notification of Exemptions in the Federal Register may be directed to [FEMA National Business Emergency Operations Center](#) at NBEOC@max.gov.

