(Previous Version) Export Allocation Rule on Medical Supplies and Equipment for COVID-19

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*This document was updated as of May 19, 2021

FEMA published a Temporary Final Rule (TFR) in the *Federal Register* on Dec. 31, 2020 which allocates certain scarce critical health and medical resources for domestic use to ensure needs are met for the American public during the COVID-19 pandemic. This is an extension and modification of a previous TFR published on August 10, 2020 and April 10, 2020, which 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 the 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 certain health and medical resources 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 can be assessed by FEMA prior to export.

Updated May 19, 2021, the health and medical resources subject to this allocation order include:

- 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

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
- 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).

FEMA's Export Cargo Review Working Group

The Export Cargo Review Working Group regularly reviews shipments, provides advice to FEMA regarding implementation of the allocation order, and continues to evaluate the categories of health and medical resources included in the TFR periodically to consider the proper scope of covered materials. This group includes representatives from Customs and Border Protection (CBP), the Department of State, the Department of Commerce, the Department of Health and Human Services, and the Food and Drug Administration.

Evaluation of Exports Submitted through the Automated Export System

In most situations, planned 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, CBP notifies FEMA and the ECRWG will review and decide on the shipment.

Under this temporary final rule extension, covered materials may be temporarily detained before leaving the U.S. In making a determination on to allocate the materials for domestic use, FEMA may continue to consult other agencies and will consider the totality of the circumstances, including the following factors:

- The need to ensure that such items are appropriately allocated for domestic use
- Minimization of disruption to the supply chain, both domestically and abroad
- Circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns
- Quantity and quality of the materials
- Humanitarian considerations
- International relations and diplomatic considerations

FEMA will work quickly and make every attempt to review and make determinations to minimize disruptions to the supply chain. 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.

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

- Purchase part or all of the shipment, using a rated order under 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

FEMA has established 11 exemptions that apply to covered items under the TFR. All exemptions listed below apply to the current TFR, issued on December 31, 2020. FEMA will publish any additional exemptions, or modifications, in the

Federal Register.

FEMA has grouped these exemptions into two types:

Exemptions which do not require a Letter of Attestation. FEMA and CBP will evaluate these shipments and apply appropriate exemptions based on the standard information provided with the shipment

- Shipments in the following categories may proceed as usual:
- 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. Shipments in the following categories may be allowed to export, but shippers must provide a Letter of Attestation describing the applicability of an exemption. (See below for information on Letters of Attestation):

- Shipments made by or on behalf of U.S. manufacturers with continuous customer export agreements in other countries since at least January 1, 2020 as long as at least 80 percent of such manufacturer's domestic production of covered materials, on a per item basis, was distributed in the U.S. 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 for internal use. The letter of attestation for this exemption must state the intended use of the

covered materials. **This exemption does not cover intracompany transfers for the purpose of resale.**
- 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, or shipments in transit through the U.S. 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 these exemptions, see the initial April 10 TFR and the April 21 Notification of Exemptions.

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, or for the exemptions listed above.

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.”

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, 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

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 regarding surplus of covered material.

Exporters who take Advantage of Exemptions

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

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

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.

Additional Resource

Information for Exporters with a Surplus of Medical Supplies and Equipment