August 26, 2020

U.S. Agency for International Development (USAID)
Updated Guidance on Procuring Personal Protective Equipment (PPE) / Covered Material

Summary:

As a general rule, USAID's implementing partners must seek the prior written approval of the cognizant USAID Agreement or Contracting Officer(s) (AOs/COs) to procure the following commodities (collectively, "Covered Material") with any USAID program funds:

a) **Surgical** N95 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;
b) PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials;
c) PPE **nitrile** gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such nitrile gloves intended for the same purposes; and
d) **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.

However, implementing partners may use USAID's program funding to procure this Covered Material *without further approvals* in either of the following two situations:

1) For the protection of, and use by, staff under both grants and contracts from USAID:

    a) In this situation, implementing partners may procure Covered Material from any source; or

2) For the safe and effective continuity of USAID-funded programs, including for the protection of beneficiaries (but not for the protection of an implementing partner's staff, which is addressed in #1 above):

    a) In this situation, implementing partners may procure Covered Material manufactured locally in, or in the same geographical region as, the country in which USAID is providing assistance, as defined by the U.S. Department of State's regional system (Africa, East Asia and the Pacific, Europe and Eurasia, the Near East, South and Central Asia, and the Western Hemisphere), provided that the Covered Materials are not, and could not reasonably be, intended for the U.S. market.

All other PPE not mentioned above, as well as COVID-19 test kits[1], are not restricted from procurement or subject to the requirements described in this guidance. Please note that cloth masks and other face coverings that do not protect the wearer are not considered PPE. The procurement of these items is not subject to the limitations set forth in this guidance.

The categories of PPE included above initially drew from a temporary rule[2] issued by the Federal Emergency Management Agency (FEMA) within the U.S. Department of Homeland Security (DHS) and the designation of "scarce or threatened materials" in the "Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures" published in the *Federal Register* by the U.S. Department of Health and Human Services (HHS). Earlier guidance was consistent with DHS/FEMA's temporary rule, which limits exports from the United States of the select types of PPE subject to specific exemptions. On August 10th, 2020, FEMA issued an updated rule which altered the categories of PPE that are included in this restricted list to reflect that current supply of these items is sufficient to meet the domestic demand. USAID therefore has updated this guidance to be in accordance with FEMA's revised list of restricted commodities.

If the Administration issues guidance through a final Presidential Memorandum or other mandate that differs from the approach outlined here, USAID will revise this guidance and require implementing partners to adapt accordingly. USAID has drafted the grant/contract language below to allow the Agency to modify the terms of awards unilaterally in response.

Implementation:

- First, going forward, AOs/COs will include the provision set forth below in all new awards under which implementing partners potentially might procure Covered Material, regardless of the type of funding.

- Second, for awards that have already been modified to incorporate the Covered Materials clause, AOs/COs will notify partners in writing that the list of Covered Materials

[1] Right now, nucleic-acid tests are the standard for testing for COVID-19, and point-of-care immunochromatographic rapid diagnostic tests (RDTs) are not recommended for diagnostic use at the moment. Based on current evidence, the World Health Organization recommends the use of rapid diagnostic tests only in research settings (such as eventual performance evaluations compared to other tests), but not clinical decision-making until there is much more evidence to support their use.

[2] The DHA/FEMA Temporary Rule initially limited the export of five items from the United States: (1) N95 Filtering Facepiece Respirators; (2) Other Filtering Facepiece Respirators; (3) Elastometric, air-purifying respirators and appropriate particulate filters/cartridges; (4) PPE surgical masks; and, (5) PPE gloves or surgical gloves. It did not preclude the use of U.S. Government funding for the procurement of these items. Additionally, DHS/FEMA subsequently issued exemptions to its export restrictions for the following: (1) Shipments by, or on behalf of, the U.S. Government, including the U.S. military; and, (2) Exports of covered materials by non-profits or non-governmental organizations that are solely for donations to foreign charities or governments for free distribution (not sale) at their destination.

has changed. AOs/COs will continue to work with implementing partners to modify existing awards that include funding from the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (COVID-19 Supplemental), to incorporate the provision.

- Third, AOs/COs will work with partners to incorporate the provision in any existing awards under which implementing partners potentially procure Covered Material at the time of any funding modification, including an incremental funding modification, regardless of the type of funding:

    - Implementing partners can continue to purchase Covered Material under existing awards until such time as USAID incorporates the below provision into their awards.

When implementing partners rely on the second exception above regarding the procurement of Covered Material manufactured locally or regionally, they should engage in conversations with vendors and manufacturers to ensure the Covered Material being procured is not, and could not reasonably be, intended for the U.S. market. Implementing partners must document this determination in their files or records, and provide a copy of such documentation to their cognizant AO/CO, who must upload it into the file for the award(s) in USAID's Agency Secure Image and Storage Tracking System (ASIST).

For any other requests to procure Covered Material that does not meet the exceptions described above, AOs/COs must consult with USAID's leadership through the following email inbox: **CoveredMaterials@usaid.gov**

The rules set forth in this guidance will apply as long as the domestic U.S. demand for Covered Material exceeds the available supply. Once a domestic surplus exists for such items in the United States, the Agency may revise this guidance.

Grant/Contract Language Consistent with the Above Guidance:

Procurement of "Covered Material"

1. Except as provided in paragraph 2 below, and notwithstanding anything in this [award or contract] to the contrary, no funds under this [award or contract] may be used for the procurement of "Covered Material" as listed below without the prior written consent of the [Contracting/Agreement] Officer. For purposes of this [provision or special contract requirement], "Covered Material" shall consist of the following:

    - Surgical N95 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, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such nitrile gloves intended for the same purposes; and
- 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.

For clarity, non-medical grade masks, including cloth masks, are not included in the list of Covered Material above. Further, USAID may modify the list of Covered Material from time-to-time, in writing; any such changes to the list shall apply prospectively.

2. The restrictions set forth in paragraph 1 above shall not apply to the procurement of Covered Material:

(a) for the protection of and use by the [recipient's or contractor's] or sub-[recipient's or contractor's] staff; or

(b) for the safe and effective continuity of USAID-funded programs, including for the protection of beneficiaries, provided that such items are manufactured locally or in the same geographical region as the country in which USAID is providing assistance, as defined by the U.S. Department of State's regional system (Africa, East Asia and the Pacific, Europe and Eurasia, Near East, South and Central Asia, and Western Hemisphere), and provided that such items are not, and could not reasonably be expected to be, meant for the United States market.

The [AO or CO] may change the exemptions set forth in this paragraph in writing; any such changes shall apply prospectively.

3. "Staff" for the purposes of the Exception in 2(a) is defined as any individuals receiving financial compensation from the recipient or contractor or sub-recipient or subcontractor.

4. For each purchase of Covered Material under Exception 2(b), the recipient or contractor must provide the AO/CO with contemporaneously dated documentation that the order of Covered Material is not meant for, and could not reasonably be meant for, the U.S. market. The AO/CO will then upload the statement into ASIST. This documentation can take the form of a simple email verification from a vendor or a brief, contemporaneously dated, written statement or e-mail from the recipient or contractor confirming its conversation with the vendor.