Answers to Frequently Asked Questions (FAQs) on Personal Protective Equipment (PPE) / Covered Materials

November 24, 2020

New or revised questions appear in blue.

Table of Contents

- *Will the special contract requirement be added to awards to Public International Organizations (PIOs)?*
- *How should we handle awards that use funds from the International Disaster Assistance (IDA) account with Supplemental appropriations for COVID-19 that include a more-restrictive clause on Covered Material?*

Local and Regional Procurement

- *What constitutes "local and regional procurement"?*
- *Under Exception 2 in the guidance, is procuring PPE manufactured regionally, but not in the same region where the country is located, allowed? For example, can Senegal purchase PPE manufactured in India or Turkey?*

Procurement of Restricted Items

- *Can implementing partners use funding from USAID to procure test kits for COVID-19?*
- *Are reagents subject to procurement limitations?*
- *Where can I find additional information about COVID-19 diagnostics?*

Program-Funded Local Production of PPE

- *Can implementing partners use funding from USAID to finance the local production of PPE in partner countries?*

Agency Communications about PPE

- *Can USAID's Missions or Washington-based Bureaus or Independent Offices (B/IOs) promote stories about past distributions of PPE?*
- *Can USAID's Missions or Washington-based B/IOs promote stories about the production of PPE for local use by USAID-funded programs?*

Temporary Final Rule on Certain Essential Medical Supplies

- *What is the Temporary Final Rule (TFR) on Certain Essential Medical Supplies and how does it affect USAID?*
- *What actions do I need to take to procure Essential Medical Supplies?*
- *Is the June 20, 2020 PPE/Covered Materials Guidance and the August 26, 2020 Updated Guidance still valid?*

General Questions

Question: How does the updated FEMA rule change USAID's PPE guidance?

Answer (August 26, 2020): As noted in FEMA's updated rule, two items are being eliminated from the covered materials list as there are currently no indications that supply is not meeting domestic demand to require these items to continue to be subject to this order. FEMA is removing other filtering facepiece respirators as this category of respirator has seen a significant drop in the number of orders received from state, local, tribal, and territorial (SLTT) jurisdictions and the current supply is sufficient to fill demand from these jurisdictions. FEMA is also removing elastomeric, air-purifying respirators and appropriate particulate filters/cartridges from the list of covered materials as these items have seen low demand from SLTT jurisdictions and FEMA has been able to fill all orders that have been placed for these items in the past 45 days, as of July 16, 2020.

FEMA has also added updates and clarifications to its previous list of covered materials, including specifying the type of gloves that are restricted and adding surgical gowns to the list.

Please see below for a revised list of covered materials:

1. **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;
2. PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials;
3. 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
4. **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.

Note that ventilators, COVID-19 test kits, elastomeric, air-purifying respirators and appropriate particulate filters/cartridges, and other filtering facepiece respirators have been removed from FEMA's list and therefore USAID's list of covered materials. Items not on this current list are not restricted from procurement or subject to the requirements described in this guidance.

Question: How will awards be modified to reflect the changes in this list of covered materials?

Answer (August 26, 2020):
A) For all new awards, the revised language with the updated list of covered materials will be included in the clause;

B) For existing awards:

- AOs will notify partners in writing that the list of Covered Materials has changed; and
- AOs will include the revised language in awards if/when the existing awards are modified.

Question: *Can guidance be shared with external networks (e.g., not USAID implementing partners (IPs))?*

Answer (June 20, 2020): Yes.

Question: *Can you clarify who is included in each of the exceptions noted in the guidance?*

Answer (June 20, 2020): IPs must seek written approval from AOs or COs to procure any of the items listed here:

1. 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;
2. PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials;
3. 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
4. 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, IPs may use USAID funding to procure these Covered Materials without written approval from AOs/COs in either of these two situations:

- One, for the protection of and use by their own staff or for sub-recipient or sub-contracting staff. In this situation, Covered Materials may be procured from any source, not just local or regional manufacturers.
- Two, for the safe and effective continuity of USAID-funded programs, which include the protection of recipients and/or beneficiaries. In this situation, implementing partners may only procure Covered Materials from local or regional manufacturers, provided the Covered Material is not, and could not reasonably be intended, for the U.S. market.

Question: *Can you explain how "staff" is defined under Exception 1?*

Answer (June 20, 2020): For the purposes of Exception 1 in this guidance, staff are considered to be individuals receiving financial compensation from a USAID implementing partner (prime or sub-level) for the work being performed on the USAID project.

Question: *What information should be included in the partner's determination under Exception 2? To what extent are AOs/COs supposed to fact-check/confirm the partner's determination?*

Answer (June 20, 2020): A brief, contemporaneously dated statement that states that the order of PPE is not meant for, and could not reasonably be meant for, the U.S. market, is sufficient. This documentation can take the form of a simple email verification from a vendor or a brief, contemporaneously dated, written statement from the partner confirming its conversation with the vendor. There is no standard or recommended template or format to capture this information, as long as it is documented in the partner's files and a copy is sent to the AO/CO to upload to ASIST. AOs/COs are not required to fact-check or verify the partner's determination.

Question: *How often should the determination under Exception 2 be done? Is a determination for each new PPE vendor or order required?*

Answer (June 20, 2020): For each purchase of each different type of Covered Material under Exception 2, IPs must confirm that the products are not intended for, or could not reasonably be intended for, the U.S. market. Similarly, this confirmation must also be obtained from each new vendor from which the partner procures Covered Material.

Question: *Regarding Exception 2, does the determination apply to a supplier's whole inventory, or just the specific order being placed?*

Answer (June 20, 2020): The determination applies to the specific type of Covered Material being procured (e.g. masks, gloves). In cases where a supplier's inventory includes multiple product lines, the determination may not necessarily apply to the supplier's whole inventory. Under Exception 2, implementing partners may not procure a specific type of Covered Material from a supplier that is currently fulfilling orders for the U.S. market for that product type. Implementing partners must discuss with the supplier to ensure that the specific type of Covered Material they intend to procure is not, and could not reasonably be, intended for the U.S. market.

Given that suppliers change customers, geographies served, and approaches on a regular basis, this determination must be made for each order of PPE. For instance, if a supplier produces filtration masks and is currently fulfilling orders for filtration masks for the U.S. market, implementing partners may not procure filtration masks from that supplier as long as it is fulfilling orders for the U.S. market. However, if the same supplier also produces surgical gloves and is currently not fulfilling orders for those gloves for the U.S. market, the implementing partner may procure gloves from that supplier. In short, each type of PPE within a specific order must receive confirmation from the supplier that those products are not, and could not reasonably be, intended for the U.S. market.

Question: *What about other types of PPE not explicitly mentioned in this guidance?*

Answer (June 20, 2020): All other PPE, as well as COVID-19 test kits, are not restricted from procurement or subject to limitations pursuant to this guidance.

Question: *Are hand sanitizer and soap considered PPE?*

Answer (June 20, 2020): Hand sanitizer, disinfecting wipes, soap, non-medical rubber gloves, and other cleaning products are not considered PPE and are not subject to any limitations on procurement. Implementing partners should procure them in accordance from the most efficient and available sources.

Question: *Are there restrictions on the procurement of cloth masks?*

Answer (June 20, 2020): 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. It is important to note that cloth masks are not substitutes for medical-grade PPE.

Question: *What about the use of existing stockpiles of PPE?*

Answer (June 20, 2020): The use of existing stockpiles does not involve the procurement of PPE and therefore is not subject to the limitations set forth in this guidance:

A) The USAID-funded stockpile managed by the United Nations Food and Agriculture Organization (FAO) provides PPE for outbreaks of, and investigations into, animal pests and diseases, including zoonotic pathogens:

    a) Missions and B/IOs may continue to request to use the FAO-managed stockpile to provide PPE for investigations of outbreaks of animal pests and diseases, including zoonotic diseases.

    b) Requests for the use of the FAO-managed stockpile should continue to go through the cognizant Agreement Officer's/Contracting Officer's Representative (AOR/COR).

B) The USAID-funded stockpile managed by the World Health Organization (WHO) provides PPE for outbreaks of human diseases and is explicitly meant to serve low- and middle-income countries:

    a) Missions and B/IOs may continue to ask to use this stockpile to fulfill requests from national governments for PPE to respond to outbreaks.

    b) Requests for use of the WHO stockpile should continue to go through the cognizant AOR/COR.

C) The USAID Bureau for Humanitarian Assistance maintains relief supplies, including PPE, in warehouses around the world for quick shipment to disaster-affected countries.

Question: *What if I am an AO/CO and have questions about if / when to approve the procurement of restricted commodities?*

Answer (June 20, 2020): For any other requests to procure Covered Material that does not meet the exceptions described above, AOs/COs can consult with USAID's leadership by sending an email to the following inbox: coveredmaterials@usaid.gov

Question: *For how long is this guidance applicable?*

Answer (June 20, 2020): The rules set forth in this interim guidance will apply as long as the domestic demand in the United States for Covered Material exceeds the

available supply. Once a domestic surplus exists for such items, the Agency will revise this guidance.

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.

Question: *Does the guidance have an effective date or is the guidance retroactive?*

Answer (June 20, 2020): The guidance is effective as of June 9th, 2020. The guidance does not apply retroactively, and is applicable only prospectively moving forward. Restrictions pursuant to this guidance only apply to new awards and existing awards that are modified at the time of funding modifications.

Question: *What if I have further questions about this guidance?*

Answer (June 20, 2020): For any questions not already addressed in the guidance, please send an email to the following inbox: coveredmaterials@usaid.gov.

Current Awards

Question: *Do purchases of PPE require a redirection change notice?*

Answer (June 20, 2020): The updated Covered Material guidance states that if falling into the two exceptions noted, no further approvals are required. Using USAID funding to purchase Covered Material for either of the two exceptions noted in the guidance therefore does not require a redirection notice. If Covered Material procurement falls outside those two exceptions, written AO/CO approval is needed. While not required, AOs/COs can feel free to consult with the Task Force through coveredmaterials@usaid.gov if they have questions about providing approval. **In short, there are no further approvals or redirection notices required for purchases of PPE (other than the required AO/CO approval pursuant to the guidance).**

Please note that hand sanitizer and cleaning products are not considered PPE and are not under any procurement restrictions. Procuring these supplies also does not require a redirection or reprogramming notice, as this can be considered tantamount to the cost of doing business in a world with COVID-19.

Question: *Is the redirection/reprogramming process still required?*

Answer (June 20, 2020): Please refer to the redirection and reprogramming guidance. A new notice was recently released and can be found here. Other updates to that guidance may be released soon. As noted in the question above, redirection notices are not required for the purchase of PPE.

Question: *The determination documentation requirement isn't listed within the award provision language. How will recipients know to submit this required determination documentation and how can AOs enforce submission if it's not an award requirement?*

Answer (June 20, 2020): Please see the revised PPE guidance for updated grant/contract language for inclusion in the award document. Implementing partners must submit a brief, contemporaneously dated statement that documents their determination for Exception 2 to AOs/COs. AOs/COs must upload this documentation into ASIST.

Question: *For existing awards where new language has not been amended for COVID, does procurement of PPE or diagnostics need to be specifically in the award prior to procurement?*

Answer (June 20, 2020): No, an award does not need to specifically mention procurement of PPE, as that stipulation is more granular than the language in many of our awards, and it is often included in a general procurement or supplies line items. For example, for a health implementing partner, the award does not need to specifically mention procurement of PPE -- a general mandate to support infection prevention and control in health facilities is sufficient.

If the costs for PPE were allowable in existing awards before the issuance of the guidance, they continue to be allowable unless and until the awards are modified to include the new special contract requirement, at which point the terms of that special contract requirement will apply. AO/AOR review or coordination is only needed if required under the terms of the existing awards.

Question: *As the Agency will add the agreed-upon special contract requirement to existing awards at the time of any funding modifications, can partners continue to procure PPE and other Covered Material under existing awards until any funding modification?*

Answer (June 20, 2020): Yes. Partners may continue to procure PPE and other Covered Material under existing awards that have PPE components consistent with the terms of those awards until USAID adds the special contract requirement to their awards at the time of a funding modification.

Question: *Will the Agency add the special award requirement to awards with PIOs?*

Answer (June 20, 2020): Yes. USAID will add the special award requirement to cost-type PIO agreements that have PPE components. The special award requirements do not apply to project contribution or general contribution PIO agreements.

Question: *How should awards be handled that use supplemental IDA funds for COVID-19 that include a more-restrictive clause on Covered Material?*

Answer (June 20, 2020): Some current awards funded by resources from the IDA account from COVID-19 supplemental appropriations include a more restrictive special requirement but allow the cognizant AOR/COR to approve other procurements. AORs/CORs of the awards that include such special requirements should approve procurements in a manner consistent with the new interim Agency guidance. The cognizant AO/CO should modify these awards to include the new special contract requirement at the time of any funding modification.

Local and Regional Procurement

Question: *What constitutes "local and regional procurement"?*

Answer (June 20, 2020): When procuring Covered Material for the safe and effective continuity of USAID's programs, including the protection of beneficiaries, implementing partners may procure PPE from in-country manufacturers, or from manufacturers 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). If seeking to procure from a manufacturer that also provides products for the U.S. domestic market, partners should engage in conversation with the supplier and ensure it is not fulfilling orders for the U.S. domestic 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).

Question: *Under Exception 2 in the guidance, is procuring PPE manufactured regionally, but not in the same region where the country is located, allowed? For example, can Senegal purchase face masks manufactured in India or Turkey and sold in local Senegalese pharmacies?*

Answer (August 26, 2020): Written AO/CO approval is required for this type of situation, given that this example falls outside of both exceptions. Partners must still ensure that the products are not, and could not reasonably be, intended for the U.S. market.

In order to implement the approved local or regional procurement, the AO/CO should review the source and nationality clause(s) or provision in the acquisition or assistance instrument. If procuring the following PPE/Covered Materials,

- 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;

procure in accordance with the source and nationality clause in your contract, grant, or cooperative agreement. The clause or provision may have been updated recently, consistent with the clauses in the PPE Guidance. **Please note that if your award instrument has not been modified to include the Covered Materials clause, then the local/regional manufacturing restriction for Covered Materials does not apply.**

If you are procuring items that are not included in the Covered Materials list above, then refer to the source and nationality clause or provision in your contract, grant, or cooperative agreement. It also may have been updated recently to reflect flexibilities in the Outbreaks EPP. There may be a source-nationality waiver under an Expedited Procedures Package (EPP) or another source-nationality waiver that applies.

If AOs/COs have questions about approving this type of request, they are encouraged to contact their GC backstop attorney/RLO.

Procurement of Restricted Items

Question: *Can implementing partners use funds from USAID to procure COVID-19 test kits?*

Answer (August 26, 2020): Yes, procurement of COVID-19 test kits with USAID's funds is permissible pursuant to approved Scopes of Work that include the purchase of diagnostics and is not subject to the procurement limitations set forth in this guidance.

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.

Question: *Are reagents subject to procurement limitations?*

Answer (June 20, 2020)*:* No, reagents are not subject to the procurement limitations set forth in this guidance.

Question: *Where can I find additional information about COVID-19 diagnostics?*

Answer (August 26, 2020): In May, USAID published a COVID-19 Laboratory and Diagnostics: Guide for Missions document. USAID has also published a FAQ document specific to diagnostics that has updates and clarifications from the background document.

Program-Funded Local Production of PPE

Question: *Can implementing partners use funds from USAID for the local production of PPE in partner countries?*

Answer (June 20, 2020): Yes. The prior Task Force notice still applies. Implementing partners may use funds from USAID to finance the local production of medical-grade and non-medical-grade PPE, including (but not limited to) masks, gowns, face shields, protective eyewear, boot covers, linens, and gloves. This guidance pertains to all USAID programs funded from any appropriation account, including supplemental appropriations. Where feasible, USAID's B/IOs may also invest in, advise on, or encourage local regulatory authorities to validate manufacturing practices for, or conduct quality-assurance testing on, PPE. Further guidance from the Bureau for Global Health in this area is forthcoming.

Agency Communications about PPE

Question: *Can USAID's Missions or Washington-based B/IOs promote stories about past distributions of PPE?*

Answer (June 20, 2020): Yes. USAID's Missions and B/IOs may share stories and photos of past PPE deliveries publicly.

Question: *Can USAID's Missions or Washington-based B/IOs promote stories about the production of PPE for local use by USAID-funded programs?*

Answer (June 20, 2020): Yes. USAID's Missions and B/IOs can promote stories and information about the production of PPE for local use by USAID-funded programs.

Temporary Final Rule on Certain Essential Medical Supplies

Question: *What is the Temporary Final Rule (TFR) on Certain Essential Medical Supplies and how does it affect USAID?*

Answer (November 24, 2020): On October 23, 2020, USAID issued a Temporary Final Rule (TFR) in the Federal Register entitled "Procurement of Certain Essential Medical Supplies to Address the COVID-19 Pandemic." The TFR is effective immediately and will expire on April 30, 2021.

The TFR amends the 22 CFR Part 228 (Rules for Procurement of Commodities and Services Financed By USAID) waiver authority relating to the source and nationality rule applicable to USAID activities to accommodate the procurement of Essential Medical Supplies (EMS) needed to address the COVID-19 pandemic. The TFR defines "Essential Medical Supplies" to include personal protective equipment (PPE), medical products and equipment, pharmaceuticals, and other medical countermeasures needed to combat COVID-19.

The TFR allows USAID to prioritize the purchase of EMS to address the COVID-19 pandemic from the United States only, the cooperating/recipient country, or any country that is in the same geographical region as the country receiving assistance, as defined by the Department of State's regional system (i.e., Africa; East Asia and Pacific; Europe and Eurasia; Near East; South and Central Asia; Western Hemisphere). The TFR is not self-executing. A waiver will be required to prioritize or use certain geographic regions. The TFR will have no impact on acquisition or assistance instruments unless a waiver is issued and the implementing partner (IP) receives implementation guidance from its contracting/agreement officer.

Question: *What actions do I need to take to procure Essential Medical Supplies?*

Answer (November 24, 2020): An IP must first check its award to determine whether it contains the clause set forth in the June 30, 2020 Guidance on Procuring Personal Protective Equipment (PPE)/Covered Material or in the August 26, 2020 Updated

Guidance on Procuring Personal Protective Equipment (PPE)/Covered Material. If the clause is included in the instrument, the IP must seek written approval from their cognizant AOs or COs to procure any of the items listed here:

- **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.

However, IPs may use USAID funding to procure these Covered Materials without written approval from AOs/COs in either of these two situations:

- One, for the protection of and use by their own staff or for sub-recipient or sub-contracting staff. In this situation, Covered Materials may be procured from any source, not just local or regional manufacturers.
- Two, for the safe and effective continuity of USAID-funded programs, which include the protection of recipients and/or beneficiaries. In this situation, implementing partners may only procure Covered Materials from local or regional manufacturers, provided the Covered Material is not, and could not reasonably be intended, for the U.S. market.

If you are procuring EMS other than the PPE/Covered Material listed above or if your award does not include the June 30, 2020 or August 26, 2020 clause, then refer to and follow the source and nationality clause or provision in your contract, grant, or cooperative agreement.

If you have any questions, please contact your AO/CO or AOR/COR for guidance. You may also email coveredmaterials@usaid.gov for questions on PPE or GCFEDREGMailbox@usaid.gov for questions on the TFR.

Question: *Is the June 20, 2020 PPE/Covered Materials Guidance and the August 26, 2020 Updated Guidance still valid?*

Answer (November 24, 2020): Yes. The PPE/Covered Materials guidance is still valid.