

**List of Subjects in 40 CFR Parts 281 and 282**

Environmental protection, Administrative practice and procedure, Hazardous substances, Incorporation by reference, Indian country, Petroleum, Reporting and recordkeeping requirements, State program approval, Underground storage tanks.

**Authority:** This document is issued under the authority of sections 2002(a), 9004, and 7004(b) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

Dated: September 25, 2024.

**Jeanne M. Gettle,**

*Acting Regional Administrator, Region 4.*

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**DEPARTMENT OF HOMELAND SECURITY****48 CFR Parts 3025 and 3052**

[Docket No. DHS–2024–0020]

RIN 1601–AB15

**Homeland Security Acquisition Regulation, Make Personal Protective Equipment in America Act Restrictions on Foreign Acquisition (HSAR Case 2024–003)**

**AGENCY:** Office of the Chief Procurement Officer (OCPO), Department of Homeland Security (DHS).

**ACTION:** Proposed rule.

**SUMMARY:** DHS is proposing to amend the Homeland Security Acquisition Regulation (HSAR) to add a new subpart, clause, and provision that would codify how DHS complies with the requirements of the Make Personal Protective Equipment (PPE) in America Act. DHS believes these proposed changes would help to ensure the sustainment and expansion of domestic manufacturing for certain types of PPE critical to the United States' national response to a public health crisis, such as the COVID–19 pandemic.

**DATES:** Comments on the proposed rule should be submitted in writing to one of the addresses shown below on or before December 2, 2024, to be considered in the formation of the final rule.

**ADDRESSES:** Submit comments identified by HSAR Case 2024–003, Make PPE in America Act Restrictions on Foreign Acquisition, using any of the following methods:

• *Regulations.gov:* <https://www.regulations.gov>.

Submit comments via the Federal eRulemaking portal by entering “HSAR

Case 2024–003” under the heading “Enter Keyword or ID” and select “Search.” Select the link “Submit a Comment” that corresponds with “HSAR Case 2024–003.” Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “HSAR Case 2024–003” on your attached document.

• *Fax:* (202) 447–0520.

• *Mail:* Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, ATTN: Ms. Shaundra Ford, 245 Murray Drive, Bldg. 410 (RDS), Washington, DC 20528.

Comments received generally will be posted without change to <https://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check [www.regulations.gov](https://www.regulations.gov), approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

**FOR FURTHER INFORMATION CONTACT:**

Shaundra Ford, Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, at (202) 282–8000 or email at [HSAR@hq.dhs.gov](mailto:HSAR@hq.dhs.gov). Include HSAR Case 2024–003 in the subject line.

**SUPPLEMENTARY INFORMATION:****I. Background**

The Buy American Act of 1933, as amended (BAA), addresses preferences in Federal procurement.<sup>1</sup> The BAA provides a preference for the purchase of domestic supplies.<sup>2</sup>

On November 15, 2021, the Infrastructure Investment and Jobs Act was signed into law.<sup>3</sup> Subtitle C of title IX of Division G of the Infrastructure Investment and Jobs Act is the Make PPE in America Act (“the Act”).<sup>4</sup> The Act requires the Department of Homeland Security (DHS), Department of Veterans Affairs (VA), and the U.S. Department of Health and Human Services (HHS) to take certain actions to ensure the sustainment and expansion of domestic manufacturing for certain types of PPE critical to the United States' national response to a public health crisis, such as the COVID–19 pandemic.<sup>5</sup>

<sup>1</sup> See 41 U.S.C. 8301–8305.

<sup>2</sup> See *e.g.*, 41 U.S.C. 8302.

<sup>3</sup> Infrastructure Investment and Jobs Act, Public Law 117–58, 135 Stat. 429 (2021).

<sup>4</sup> Make PPE in America Act, Public Law 117–58, div. G, title IX, subtitle C, sections 70951–70953, 135 Stat. 1312–1316. The Make PPE in America Act is codified in 41 U.S.C. 8301 note.

<sup>5</sup> Public Law 117–58, 135 Stat. 1312.

The Act defines PPE as surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease.<sup>6</sup> The Act requires that any contracts for the procurement of PPE entered into by DHS, VA, and HHS be for PPE, including the materials and components thereof, that is domestically grown, reprocessed, reused, or produced.<sup>7</sup> The Act also requires that these contracts with DHS, HHS, or VA for PPE last at least two years in duration plus all option periods necessary, to incentivize investment in the domestic production of PPE and the materials and components thereof.<sup>8</sup> The Act allows for alternatives to domestic production under certain conditions (*i.e.*, where PPE assembled outside of the United States contains only materials and components grown, reprocessed, reused or produced in the United States).<sup>9</sup> When using alternatives to domestic production, DHS, HHS, or VA, as applicable, must certify every 120 days that alternatives to domestic production are necessary to procure PPE due to the immediate needs of a public health emergency.<sup>10</sup> The Act further recognizes certain exceptions to the domestic production of PPE, such as due to nonavailability, or where the PPE cannot be procured at U.S. market prices.<sup>11</sup> Where DHS, HHS, or VA respectively grants an exception, that Secretary would also need to certify that implementing these exceptions are necessary to meet the immediate needs of a public health emergency.<sup>12</sup>

The DHS Chief Procurement Officer can issue HSAR deviations when necessary to allow Components to deviate from the HSAR.<sup>13</sup> On October 17, 2022, DHS issued a deviation regarding how DHS would comply with the Make PPE in America Act requirements (Deviation 23–01).<sup>14</sup>

DHS proposes to amend the HSAR at 48 CFR part 3025, Foreign Acquisition, and at 48 CFR part 3052, Solicitation

<sup>6</sup> Public Law 117–58, 135 Stat. 1313.

<sup>7</sup> Public Law. 117–58, 135 Stat. 1313–14.

<sup>8</sup> Public Law 117–58, 135 Stat. 1314.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> See HSAR Deviations, available at: <https://www.dhs.gov/publication/current-hsar-deviations>.

<sup>14</sup> See HSAR Class Deviation 23–01 *Implementation of the Make PPE in America Act* at <https://www.dhs.gov/sites/default/files/2022-10/HSARClassDeviation23-01ImplementationofMakePPEinAmericaAct-508Final.pdf>.

Provisions and Contract Clauses, to reflect the requirements of the Act.

## II. Discussion

DHS is proposing to add a new HSAR subpart, add an HSAR clause, and add an HSAR provision to codify how DHS complies with the Act. These proposed changes would also be consistent with Deviation 23–01. Each of these proposed changes is described in detail in the following paragraphs.

DHS is proposing to add new subpart 3025.71, Make PPE in America Act Restrictions on Foreign Acquisition, to the HSAR. This would codify the restrictions in Deviation 23–01 applicable to the acquisition of certain PPE consistent with the Act. These restrictions include minimum time periods for contract duration, content requirements for certain PPE, alternatives to domestic production when conforming PPE is not available, and exceptions when conforming PPE is either nonavailable or cannot be procured at U.S. market prices (or in other words, only available at an unreasonable cost). This rule also proposes to codify the definitions of terms used in Deviation 23–01.<sup>15</sup> These terms are “component,” “domestic personal protective equipment,” “foreign-assembled domestic personal protective equipment,” “foreign personal protective equipment,” “personal protective equipment,” and “United States.”

HSAR 3025.7102–1 would apply to all types of actions, orders, option exercises, and contracts awarded and administered by DHS. It would require contracting officers to purchase domestic PPE except for certain exceptions specified in HSAR 3025.7102–2 and would require that any contract for PPE have a base period of performance of at least two years, plus option periods.

HSAR 3025.7102–2 proposes to codify the conditions under which acquisitions of PPE, or component thereof, would be excepted from the requirements of HSAR 3025.7102–1 (*i.e.*, alternatives to domestic production, nonavailability, and unreasonable cost) consistent with Deviation 23–01.

Deviation 23–01 lists the clauses and provisions that apply when an exception due to nonavailability or unreasonable cost is used, clarifying that contracting officers still need to comply with applicable laws and regulations.<sup>16</sup> This rule proposes to codify these clauses and provisions.<sup>17</sup>

DHS believes this approach maximizes the use of Made in America laws<sup>18</sup> by defaulting to a Buy American-compliant or Trade Agreements Act-compliant item, depending on the dollar value of the procurement, when both domestic PPE and foreign-assembled domestic PPE cannot be acquired.

HSAR 3025.7103 proposes one provision and one contract clause. DHS is proposing to add HSAR clause 3052.225–7X, Make PPE in America, and HSAR provision HSAR 3052.225–7Y, Make PPE in America Certificate. The clause codifies Deviation 23–01 which requires contractors to deliver only domestic PPE, identify in the provision if foreign-assembled domestic PPE is being provided, and identifies the order of precedence for the Buy American statute and the Trade Agreements Act when neither domestic PPE nor foreign-assembled domestic PPE are available due to nonavailability or unreasonable cost. Regarding the provision, Deviation 23–01 also requires contractors to identify any foreign-assembled domestic PPE being offered to the Department and the country where it was assembled. This proposed rule would codify this clause and provision.<sup>19</sup>

## III. Regulatory Analyses

### A. Executive Orders 12866, 13563, and 14094

Executive Order 12866 (Regulatory Planning and Review), as amended by Executive Order 14094 (Modernizing Regulatory Review) and Executive Order 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

<sup>18</sup> Made in America Laws means all statutes, regulations, rules, and Executive orders relating to Federal financial assistance awards or Federal procurement, including those that refer to “Buy America” or “Buy American,” that require, or provide a preference for, the purchase or acquisition of goods, products, or materials produced in the United States, including iron, steel, and manufactured goods offered in the United States. Made in America Laws include laws requiring domestic preference for maritime transport, including the Merchant Marine Act of 1920 (Pub. L. 66–261), also known as the Jones Act. (See sec. 2, paragraph (b) of Executive Order 14005, *Ensuring the Future Is Made in All of America by All of America’s Workers*.

<sup>19</sup> See proposed 48 CFR 3025.7103.

The Office of Management and Budget (OMB) has not designated this proposed rule a significant regulatory action under section 3(f) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, OMB has not reviewed this regulatory action.

### Background

During the COVID–19 pandemic, the United States encountered challenges obtaining PPE in adequate amounts to address the urgent public health and safety need. This was in part due to an unprecedented increase in demand for PPE and challenges in the supply chain. Before the COVID–19 pandemic, domestic production of PPE was limited and most PPE used in the United States was predominantly imported.<sup>20</sup> The COVID–19 pandemic exposed the vulnerability of the United States PPE supply chains and lack of domestic PPE production.<sup>21</sup> To help address the need for domestically produced PPE, between March 2020 to September 2021, the U.S. Government invested approximately \$957.5 million into expansion of domestic PPE production.<sup>22</sup> These federally-funded projects expanded an existing domestic industrial base to meet surging demand during the pandemic.

On November 15, 2021, the Infrastructure Investment and Jobs Act (Pub. L. 117–58), was signed into law and included the Act. Congress enacted this legislation to sustain domestic demand in PPE manufacturing, support the continuity of domestic PPE material sourcing and manufacturing, and reduce the U.S.’s dependence on foreign-produced PPE. Congress took this action to reduce the vulnerabilities from future pandemic supply chain challenges and to address national security concerns on foreign dependence of critical supplies.

On October 17, 2022, DHS issued Deviation 23–01 to comply with the Act’s requirements. Under Deviation 23–01, solicitations for PPE released on or after February 14, 2022, or contracts awarded on or after February 14, 2022, were subject to the Act’s requirements. Since issuance of Deviation 23–01, DHS Components have incorporated the domestic sourcing and production requirements for PPE in solicitations and contracts, as required by the Act.

<sup>20</sup> Congressional Research Service (CRS), *COVID–19 and Domestic PPE Production and Distribution: Issues and Policy Options*. 5–6. (Dec. 7, 2020) (accessible at <https://crsreports.congress.gov/product/pdf/R/R46628>).

<sup>21</sup> Public Law 117–58, 135 Stat. 1312.

<sup>22</sup> Government Accountability Office (GAO), *Agencies Are Taking Steps to Improve Future Use of Defense Production Act Authorities* (GAO–22–105380), 1, 10 (Dec. 16, 2021) (accessible at <https://www.gao.gov/products/gao-22-105380>).

<sup>15</sup> See proposed 48 CFR 3025.7101.

<sup>16</sup> See proposed 48 CFR 3025.7102–3.

<sup>17</sup> See proposed 48 CFR 3025.7102–3.

DHS has largely transitioned to wholly domestically sourced and manufactured PPE items except for nitrile gloves. The challenges with acquiring nitrile gloves that comply with the Act are two-fold: (1) the domestic nonavailability of nitrile butadiene rubber (NBR) at the required quality and quantity to meet demand and (2) specific to DHS, insufficient domestic manufacturing capacity of

nitrile gloves that can successfully pass Departmental testing requirements for interference with explosives detection equipment.<sup>23</sup> Therefore, prior to publication of this proposed rule, DHS procurements and subsequent contracts for PPE already complied with the Act's requirement through the issuance of Deviation 23–01. In the following table, DHS estimated the total awarded amount for PPE procurement in Fiscal

Years (FY) 2017 through 2023. DHS used data from Federal Procurement Data System<sup>24</sup> and filtered for specific product codes that were most likely to include covered PPE.<sup>25</sup> Table 1 displays the total award amount DHS spent, adjusted to 2023 dollars, on PPE and distribution of awards spent on domestic versus foreign manufacturers.

TABLE 1—DHS PROCUREMENT OF PPE AWARD AMOUNTS  
[2023]<sup>1</sup>

Fiscal year (FY)	Total annual DHS PPE award amount	Total annual DHS PPE award amount domestic	Total annual DHS PPE award amount foreign	Total annual DHS PPE award percentage domestic	Total annual DHS PPE award percentage foreign
2017	\$11,586,965	\$11,542,312	\$44,654	99.61	0.39
2018	7,130,580	7,071,960	58,620	99.18	0.82
2019	6,247,764	6,247,764	0	100.00	0.00
2020	1,534,234,102	506,314,364	1,027,919,738	33.00	67.00
2021	128,945,552	25,025,686	103,919,866	19.41	80.59
2022	132,875	132,875	0	100.00	0.00
2023	6,549,382	6,549,382	0	100.00	0.00

<sup>1</sup> Bureau of Economic Analysis, Table 1.1.9. Implicit Price Deflators for Nondurable Goods, [Index numbers, 2017 = 100], Annual data from 1929 to 2023; data published March 28, 2024.

Need for the Proposed Rule

This proposed rule would codify the requirements as set forth in the Act and Deviation 23–01. DHS proposes this update to the Homeland Security Acquisition Regulation (HSAR) to align with current DHS practice in Deviation 23–01. This proposed rule would provide for consistency between the Act and the HSAR.

Benefits and Costs of the Proposed Rule

The benefits and costs of a regulation are generally measured against a no-action baseline, which is a reasonable forecast of the way the world would look absent the regulatory action being assessed.<sup>26</sup> As the proposed rule would align the regulations with DHS current practice, it would not result in additional costs for the Federal Government. The proposed rule would codify the requirement for contractors to submit a Make PPE in America Certificate, only in the situation when the contractor is proposing foreign-

assembled domestic PPE. DHS already included this contractor requirement to certify compliance in Deviation 23–01. Because DHS contractors already comply with Deviation 23–01, they would not incur new costs due to this proposed rule.

However, Deviation 23–01, which is how DHS complies with the requirements of the Act, may cause DHS to incur additional costs in the form of higher prices for domestically produced PPE compared to foreign-produced PPE. Future DHS procurement price differences between domestic and foreign-sourced PPE are difficult to accurately estimate. External factors (outside of the Act's requirement) may influence prices. For example, U.S. Government investments in domestic PPE production could factor into domestic production costs and prices. There is uncertainty on foreign governments investment in foreign PPE production which would impact foreign prices. An analysis of PPE would have

to be conducted by type of PPE, such as the domestic and foreign prices of masks, protective eyewear, or gloves. Further, DHS has specific requirements in certain procurements such as gloves (*i.e.*, testing for interference with explosive equipment and protection against Fentanyl exposure) that would need to be considered in any price comparisons.<sup>27</sup> Another factor that would be difficult to address in direct price comparisons is product differences. There are no internationally agreed upon guidelines or standards of what specific products make up PPE categories, complicating product comparisons.<sup>28</sup>

Consequently, due to the lack of specific data, complexity of various factors, and uncertainty of external price influences, DHS is not able to estimate the long-run additional DHS cost of an increased shift to domestic PPE procurements due to the requirements of the Act. Importantly, DHS has already complied with the requirements of the

<sup>23</sup> DHS, *Special Notice to Industry on Developments per the Make PPE in America Act*, 1, 1 (Dec. 16, 2023) (accessible at <https://sam.gov/opp/45a5c9581d864342a983dc9184c2c77d/view>).

<sup>24</sup> The Federal Procurement Data System (FPDS) is a centralized site for U.S. Government-wide procurement data. FPDS is managed by the U.S. General Services Administration, and it contains detailed information on Federal procurements over the micro-purchase threshold of \$10,000 (this threshold has increased over time). DHS retrieved FPDS Report via the SAM.gov Data Bank. SAM.gov reports support analysis of the Federal award lifecycle.

<sup>25</sup> DHS filtered for product codes 6516 (Medical and Surgical Instruments, Equipment, and Supplies), 6532 (Hospital and Surgical Clothing and Related Special Purpose Items), 6545 (Replenishable Field Medical Sets, Kits, and Outfits), and 8415 (Clothing, Special Purpose).

<sup>26</sup> See OMB Circular A–4, p. 11 (Nov. 9, 2023) (accessible at <https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf>).

<sup>27</sup> DHS, *White Paper: Current State of Personal Protective Equipment Procurement by Make PPE in America Act Covered Agencies*, 3–4 (March 13, 2024).

<sup>28</sup> “For example, KN95 respirator masks- China made analogues to domestically regulated N–95 respirators- are generally not authorized as medical PPE in the United States. KN95 are authorized in many countries abroad, and received temporary (and limited) Emergency Use Authorization from the [U.S. Food and Drug Administration] FDA.” FDA, *Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection—Letter to Health Care Providers*, October 15, 2020, at <https://www.fda.gov/medical-devices/letters-health-care-providers/certain-filtering-facepiece-respirators-china-may-not-provide-adequate-respiratory-protection-letter>.

Act through Deviation 23–01 and subsequent contract changes.

Congress recognized the need for the United States to have a robust, secure, and wholly domestic PPE supply chain to safeguard public health and national security.<sup>29</sup> This proposed rule codifies the statutory requirements that support the sustainment of the U.S. PPE supply chain. This proposed rule would provide the clarification benefit of consistency and transparency for contractors and DHS contracting officers.

### B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121 (Mar. 29, 1996), hereafter jointly referred to as the “RFA,” requires Federal agencies engaged in rulemaking to consider the economic impacts of their rules on small entities. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people). This proposed rule would codify direct requirements for DHS, which DHS has already implemented through Deviation 23–01. Federal agencies are not included in the definition of small entity set forth in 5 U.S.C. 601. The proposed rule only codifies an existing requirement for contractors to submit the Make PPE in America Certificate with the PPE. Contractors currently provide the Make PPE in America Certificate in compliance with Deviation 23–01. The Make PPE in America Certificate is required only if the offeror is proposing foreign-assembled domestic PPE. DHS estimates the contractor burden based on experience from subject matter experts familiar with Deviation 23–01. DHS estimates it will take a contractor 15 minutes to identify any foreign-assembled domestic PPE items it is offering and complete the Make PPE in America Certificate. DHS assumes an estimated hourly compensation rate of \$57.95 for the time burden.<sup>30</sup> The time burden cost per

certificate would be \$14.49 (15 minutes × \$57.95).

Based on the estimated cost of \$14.49 per certificate, DHS assumes this cost would not be a significant economic impact on a small entity affected by the proposed rule. DHS also believes that contractors generally pass along the cost of complying with DHS contracting requirements to DHS. Therefore, DHS certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

### C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DHS consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of 44 U.S.C. 3507(d), obtain approval from the OMB for each collection of information it conducts, sponsors, or requires through regulations. This proposed rule contains information collection requirements. Accordingly, DHS is updating OMB No. 1600–0005, Solicitation of Proposal Information for Award of Public Contracts.

The collection requirements for this proposed rule are nominal and based on the new provision, 3052.225–7Y, Make PPE in America Certificate.

#### Overview of Information Collection:

(1) *Type of Information Collection:* Modification to Existing Collection.

(2) *Title of the Form/Collection:* Solicitation of Proposal Information for Award of Public Contracts.

(3) *Agency form number, if any, and the applicable component of DHS sponsoring the collection:* No form; OCPO.

(4) *Affected public who will be asked or required to respond; as well as a brief abstract:* The affected public is business or other for-profit institutions. DHS needs the information required by provision 3052.225–7Y to assess contractor compliance with the Make PPE in America Act. Responses are required for respondents to obtain or retain benefits.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated number of respondents for reporting is 0.08. This number is nominal because a response to this provision is required only if the offeror is proposing foreign-assembled domestic PPE. Such response should be rare, because the offeror of such products is unlikely to receive an award, unless no offers for domestic PPE are received. In Fiscal Year (FY) 2022, DHS awarded 8 contracts for

domestic PPE. DHS estimates it will receive ten offers per solicitation. Using the number of contracts awarded in FY 2022, DHS estimates it received 80 offers. DHS estimates 0.2 percent of offers, or 0.16 responses, will include foreign-assembled domestic protective equipment. The average number of responses per respondent is two or 0.08 respondents. DHS estimates it will take each respondent 15 minutes to complete the certificate. These numbers are not unusual given that DHS awarded a mandatory for use, Departmentwide contract for domestic PPE in March of 2022 and the requirements of provision 3052.225–7Y Make PPE in America Certificate were satisfied at the contract level. Standalone contracts are awarded only when the domestic PPE needed is not available under the Departmentwide contract.

(6) *An estimate of the total public burden (in hours) associated with the information collection:* The total estimated annual hour burden associated with this collection is 0.033 hours or 2 minutes.

(7) *An estimate of the total public burden (in cost) associated with the information collection:* The estimated total annual cost burden associated with this collection of information is \$2.32.

### D. National Environmental Policy Act

Section 102 of the National Environmental Policy Act of 1969 (NEPA), Public Law 91–190, 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*), as amended, requires Federal agencies to evaluate the impacts of a proposed major Federal action that may significantly affect the human environment, consider alternatives to the proposed action, provide public notice and opportunity to comment, and properly document its analysis. DHS and its agency components analyze proposed actions to determine whether NEPA applies to them and, if so, what level of documentation and analysis is required.

DHS Directive 023–01, Rev. 01 and DHS Instruction Manual 023–01–001–01, Rev. 01 (Instruction Manual) establish the policies and procedures DHS and its component agencies use to comply with NEPA and the Council on Environmental Quality (CEQ) regulations for implementing NEPA codified in 40 CFR parts 1500 through 1508. The CEQ regulations allow Federal agencies to establish, in their implementing procedures, with CEQ review and concurrence, categories of actions (“categorical exclusions”) that experience has shown do not, individually or in the aggregate, have a significant effect on the human

<sup>29</sup> Public Law 117–58, 135 Stat. 1313.

<sup>30</sup> The average hourly earnings are based upon the U.S. Department of Labor, Bureau of Labor Statistics’ website ([www.bls.gov](http://www.bls.gov)). The wage rate category selected is for Business and Financial Operations Occupations, May 2022. The rate is estimated to be \$57.95 (\$41.39 × 1.4), which includes the wage rate multiplier.

environment and, therefore, do not require preparation of an environmental assessment or environmental impact statement. 40 CFR 1501.4, 1507.3(c)(8). Appendix A of the Instruction Manual lists the DHS categorical exclusions.

Under DHS NEPA implementing procedures, for an action to be categorically excluded, it must satisfy each of the following three conditions: (1) the entire action clearly fits within one or more categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect.

The proposed rule, if finalized, would amend the HSAR to better clarify how DHS complies with the Make PPE in America Act. This would include codifying Deviation 23–01 that is currently in effect. DHS is not aware of any significant impact on the environment, or any change in environmental effect that will result from this proposed rule. DHS finds promulgation of the rule clearly fits within categorical exclusion A3, established in the Department's NEPA implementing procedures.

This proposed rule is a standalone rule and is not part of any larger action. This proposed rule would not result in any major Federal action that would significantly affect the quality of the human environment. Furthermore, DHS has determined that no extraordinary circumstances exist that would create the potential for significant environmental effects. Therefore, this proposed rule is categorically excluded from further NEPA review and documentation.

#### List of Subjects in 48 CFR Parts 3025 and 3052

Government procurement.

Accordingly, for the reasons set forth in the preamble, DHS proposes to amend 48 CFR parts 3025 and 3052 as follows:

#### PART 3025—FOREIGN ACQUISITION

■ 1. The authority citation for part 3025 is revised to read as follows:

**Authority:** 5 U.S.C. 301–302, 41 U.S.C. 1303, 41 U.S.C. 1707, 41 U.S.C. 1702, 41 U.S.C. 8301 note, 48 CFR part 1, subpart 1.3, DHS Delegation No. 00701, Revision No. 03.2, paragraphs (III)(H), and DHS Delegation No. 00702, Revision No. 01.2, paragraphs (III)(M).

■ 2. Add subpart 3025.71 to read as follows:

#### Subpart 3025.71—Make PPE in America Act Restrictions on Foreign Acquisition

Sec.

3025.7100 Scope of subpart.

3025.7101 Definitions.

3025.7102 Restrictions on certain personal protective equipment.

3025.7102–1 Restrictions.

3025.7102–2 Exceptions.

3025.7102–3 Specific application of the Buy American Act and Trade Agreements Act.

3025.7103 Solicitation provisions and contract clauses.

#### 3025.7100 Scope of subpart.

This subpart contains restrictions on the acquisition of certain personal protective equipment (PPE) imposed by the Make PPE in America Act (Pub. L. 117–58) and they apply to all types of actions, orders, option exercises, and contracts entered into on or after February 14, 2022.

#### 3025.7101 Definitions.

As used in this subpart—

(a) *Component*, as applied to an item described in 3025.7102–1, means an article, material, or supply incorporated directly into an item of personal protective equipment.

(b) *Domestic personal protective equipment*, as applied to an item described in 3025.7102–1, means personal protective equipment, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the United States.

(c) *Foreign-assembled domestic personal protective equipment*, as applied to an item described in 3025.7102–2, means personal protective equipment that is assembled outside the United States containing only materials and components that are grown, reprocessed, reused, or produced in the United States.

(d) *Foreign personal protective equipment* means personal protective equipment other than domestic personal protective equipment or foreign-assembled domestic personal protective equipment.

(e) *Personal protective equipment*, as applied to an item described in 3025.7102–1, means surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease.

(f) *United States*, as applied to an item described in 3025.7102–1, means the 50

States, the District of Columbia, and the possessions of the United States.

#### 3025.7102 Restrictions on certain personal protective equipment.

##### 3025.7102–1 Restrictions.

The following restrictions implement section 70953 of the Make PPE in America Act, and they apply to all types of actions, orders, option exercises, and contracts.

(a) Except as provided in 3025.7102–2, contracting officers shall purchase domestic personal protective equipment.

(b) Any contract for personal protective equipment shall have a base period of performance of at least 2 years, plus all option periods.

##### 3025.7102–2 Exceptions.

Acquisitions in the following categories are not subject to the restrictions in 3025.7102–1:

(a) Acquisitions of an item of personal protective equipment, or component thereof, otherwise covered by 3025.7102–1 when the DHS Chief Procurement Officer:

(1) Maximizes sources for foreign-assembled domestic personal protective equipment; and

(2) Certifies every 120 days that it is necessary to procure personal protective equipment under alternative procedures to respond to the immediate needs of a public health emergency.

(b) Acquisitions of an item of personal protective equipment, or component thereof, including those described in paragraph (a) of this section—

(1) That is, or that includes, a material listed in FAR 25.104 as one for which a nonavailability determination has been made; or

(2) As to which the Chief Procurement Officer determines that a sufficient quantity of a satisfactory quality that is grown, reprocessed, reused, or produced in the United States cannot be procured as, and when, needed at United States market prices; and

(3) The Chief Procurement Officer certifies every 120 days that it is necessary to procure personal protective equipment to respond to the immediate needs of a public health emergency.

(c) When either of the exceptions in paragraph (a) or (b) of this section are used:

(1) Only the DHS Chief Procurement Officer is authorized to make the certification in paragraphs (a)(2) and (b)(3) of this section or the nonavailability or unreasonable cost determination in paragraph (b) of this section.

(2) The supporting documentation for the DHS Chief Procurement Officer shall

be prepared by the DHS Component(s) and:

(i) For the certification in paragraphs (a)(2) and (b)(3) of this section:

(A) Include a written justification documenting the immediate public health emergency requiring use of alternative procedures; and

(B) Be concurred on by the Head of the Contracting Activity before submission to the Chief Procurement Officer.

(ii) For the nonavailability or unreasonable cost determination in paragraph (b) of this section:

(A) Include a written justification documenting why a nonavailability or unreasonable cost exception is required; and

(B) Be concurred on by the Head of the Contracting Activity before submission to the Chief Procurement Officer.

**3025.7102-3 Specific application of the Buy American Act and Trade Agreements Act.**

In the event the DHS Chief Procurement Officer determines neither domestic personal protective equipment nor foreign-assembled domestic personal protective equipment is available due to nonavailability or unreasonable cost, contracting officers shall apply one of the following:

(a) The clause at FAR 52.225-1, Buy American—Supplies, and the provision at FAR 52.225-2, Buy American Certificate;

(b) The clause at FAR 52.225-3, Buy American—Free Trade Agreements—Israeli Trade Act, and the provision at FAR 52.225-4, Buy American—Free Trade Agreements—Israeli Trade Act Certificate; or

(c) The clause at FAR 52.225-5, Trade Agreements, and the provision at FAR 52.225-6, Trade Agreements Certificate, as applicable.

**3025.7103 Solicitation provisions and contract clauses.**

(a) Insert the clause at 3052.225-7X, Make PPE in America, in solicitations and contracts, regardless of dollar value, when procuring any item covered under 3025.7102-1(a).

(b) Insert the provision at 3052.225-7Y, Make PPE in America Certificate, in solicitations containing the clause at 3052.225-7X.

**PART 3052—SOLICITATION PROVISIONS AND CONTRACT CLAUSES**

■ 3. The authority citation for part 3052 is revised to read as follows:

**Authority:** 5 U.S.C. 301–302, 41 U.S.C. 1303, 41 U.S.C. 1707, 41 U.S.C. 1702, 41 U.S.C. 8301 note, 48 CFR part 1, subpart 1.3, DHS Delegation No. 00701, Revision No. 03.2, paragraphs (III)(H), and DHS Delegation No. 00702, Revision No. 01.2, paragraphs (III)(M).

■ 4. Add section 3052.225-7X to read as follows:

**3052.225-7X Make PPE in America.**

As prescribed in 3025.7103(a), insert the following clause:

**Make PPE in America (DATE)**

(a) *Definitions.* As used in this clause—

Component, as applied to an item described in paragraph (b) of this clause, means an article, material, or supply incorporated directly into personal protective equipment.

Domestic personal protective equipment, as applied to an item described in paragraph (b) of this clause, means personal protective equipment, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the United States.

Foreign-assembled domestic personal protective equipment, as applied to an item described in paragraph (b) of this clause, means personal protective equipment that is assembled outside the United States containing only materials and components that are grown, reprocessed, reused, or produced in the United States.

Foreign personal protective equipment means personal protective equipment other than domestic personal protective equipment or foreign-assembled domestic personal protective equipment.

Personal protective equipment, as applied to an item described in paragraph (b) of this clause, means surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease.

United States, as applied to an item described in paragraph (b) of this clause, means the 50 States, the District of Columbia, and the possessions of the United States.

(b) The Contractor shall deliver only domestic personal protective equipment except to the extent that it specified delivery of foreign-assembled domestic personal protective equipment in the provision of the solicitation entitled “Make PPE in America Certificate.”

(c) *Order of Precedence.* In the event the Department of Homeland Security determines neither domestic personal protective equipment nor foreign-assembled domestic personal protective equipment are available due to nonavailability or unreasonable cost, the Contractor shall comply with the clauses at Federal Acquisition Regulation (FAR) 52.225-1 Buy American—Supplies or 52.225-3 Buy American—Free Trade Agreements—Israeli Trade Act and the provisions at FAR 52.225-

2 Buy American Certificate or 52.225-4 Buy American—Free Trade Agreements—Israeli Trade Act Certificate or the clause at FAR 52.225-5 Trade Agreements and the provision at FAR 52.225-6 Trade Agreements Certificate, as applicable.

(End of clause)

■ 5. Add section 3052.225-7Y to read as follows:

**3052.225-7Y Make PPE in America Certificate.**

As prescribed in 3025.7103(b), insert the following provision:

**Make PPE in America Certificate (DATE)**

(a)(1) The Offeror certifies that each item of personal protective equipment, except those listed in paragraph (b) of this provision, is domestic personal protective equipment.

(2) The Offeror shall list foreign-assembled domestic personal protective equipment items.

(3) The terms “domestic personal protective equipment,” “foreign-assembled domestic personal protective equipment,” “foreign personal protective equipment,” and “personal protective equipment,” are defined in the clause of this solicitation entitled “Make PPE in America.”

(b) Foreign-assembled Domestic Personal Protective Equipment:

Line item No.	Country of assembly
_____	_____
_____	_____
_____	_____

[List as necessary]

(c) In the event the Department of Homeland Security determines both domestic personal protective equipment and foreign-assembled domestic personal protective equipment are not available due to nonavailability or unreasonable cost, the Contractor shall comply with the clauses at Federal Acquisition Regulation (FAR) 52.225-1 Buy American—Supplies or 52.225-3 Buy American—Free Trade Agreements—Israeli Trade Act and the provisions at FAR 52.225-2 Buy American Certificate or 52.225-4 Buy American—Free Trade Agreements—Israeli Trade Act Certificate or the clause at FAR 52.225-5 Trade Agreements and the provision at FAR 52.225-6 Trade Agreements Certificate, as applicable. The contracting officer will notify offerors if a nonavailability or unreasonable cost determination is made.

(End of provision)

**Paul Courtney,**

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