

Supporting Statement for Paperwork Reduction Act Submissions

OMB Control Number: 1660 – 0148

**Title: Letter of Attestation regarding Export of Certain Scarce or
Threatened Medical Resources**

Form Number(s): None

General Instructions

A Supporting Statement, including the text of the notice to the public required by 5 CFR 1320.5(a)(i)(iv) and its actual or estimated date of publication in the Federal Register, must accompany each request for approval of a collection of information. The Supporting Statement must be prepared in the format described below, and must contain the information specified in Section A below. If an item is not applicable, provide a brief explanation. When Item 17 or the OMB Form 83-I is checked “Yes”, Section B of the Supporting Statement must be completed. OMB reserves the right to require the submission of additional information with respect to any request for approval.

Specific Instructions

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information. Provide a detailed description of the nature and source of the information to be collected.

On April 10, 2020, the FEMA Administrator (Administrator) issued a temporary final rule (the “rule”) to allocate certain scarce or threatened materials for domestic use, so that these materials may not be exported from the United States without explicit approval by FEMA. The rule aids the response of the United States to the spread of COVID-19 by ensuring that certain scarce or threatened health and medical resources are appropriately allocated for domestic use.

The Administrator issued the rule under the authority of the Defense Production Act of 1950, as amended (DPA), and related executive orders and delegations. Most prominently, on April 3, 2020, the President signed a Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (Memorandum). In the Memorandum, the President directed the Secretary of Homeland Security, through the Administrator, and in consultation with the Secretary of Health and Human Services (HHS), to use any and all authority available under section 101 of the DPA to allocate to domestic use, as appropriate, five types of personal protective equipment (PPE) materials (covered materials).

Consistent with the Memorandum, the rule provided that until August 10, 2020, and subject to certain exemptions, no shipments of covered materials may leave the United States without explicit approval by FEMA. The rule required U.S. Customs and Border Protection (CBP), in coordination with such other officials as may be appropriate, to notify FEMA of an intended export of covered materials. CBP must temporarily detain any shipment of such covered materials pending the Administrator's determination whether to return for domestic use, issue a rated order for, or allow the export of part or all of the shipment. In making such determination, the Administrator may consult other agencies and will consider the totality of the circumstances, including: (1) the need to ensure that scarce or threatened items are appropriately allocated for domestic use; (2) minimization of disruption to the supply chain, both domestically and abroad; (3) the circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns; (4) the quantity and quality of the materials; (5) humanitarian considerations; and (6) international relations and diplomatic considerations.

FEMA requires a letter of attestation regarding the Export of Certain Scarce or Threatened Medical Resources be submitted to FEMA via CPB's document imaging system and placed on file with CBP, certifying to FEMA the purpose of the shipment of covered materials.

FEMA published a Temporary Final Rule (TFR) in the Federal Register on August 10, 2020 that allocated certain health and medical resources for domestic use in the response to COVID-19. This TFR is an extension and modification of the rule published in the Federal Register on April 10, 2020 which outlined the implementation of the President's Memorandum, "Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use." This extension allows the previous rule to remain in effect, with certain modifications, through Dec. 31, 2020. Modifications were made to the types of Personal Protective Equipment (PPE) exports FEMA may review and hold for domestic use due to change in the supply and demand, as indicated by the number of open requests for such materials from State, local, Tribal, and territorial (SLTT) jurisdictions. 2.

Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information

received from the current collection. Provide a detailed description of: how the information will be shared, if applicable, and for what programmatic purpose.

The information is used by the Office of Policy and Program Analysis, Marc Geier, Federal Emergency Management Agency, 500 C Street, SW, Washington, DC 20472, (telephone) 202-924-0196, or (email) FEMA-DPA@fema.dhs.gov.

FEMA requires a letter of attestation regarding the Export of Certain Scarce or Threatened Medical Resources be submitted to FEMA via CBP's document imaging system as part of the exporter's typical submission into the Automated Export System, which is part of the International Trade Data System, certifying to FEMA the purpose of the shipment of covered materials.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

The use of the Automated Export System (AES), part of the International Trade Data System, for recordkeeping and data retrieval by many business entities facilitates the generation of necessary information.

FEMA requires a letter of attestation regarding the Export of Certain Scarce or Threatened Medical Resources be submitted to FEMA via CPB's document imaging system, certifying to FEMA the purpose of the shipment of covered materials. The required elements of a letter of attestation is currently available via the Internet from the FEMA DPA website <https://www.fema.gov/defense-production-act-program>.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The exporter is the only known source of this information. There is no similar information available.

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize.

There is no method used to minimize, but the AES system is web accessible and does not require capital investment beyond those needed for general business facilitation to file.

6. Describe the consequence to Federal/FEMA program or policy activities if the collection of information is not conducted or is conducted less frequently as well as any technical or legal obstacles to reducing burden.

Failure to collect this information would severely limit, or altogether prohibit, FEMA's ability to carry out the April 3rd Presidential Memorandum and subsequent allocation order.

In order to implement the order, FEMA and CBP must identify shipments of covered materials that are scheduled for export, and determine whether it is in the national defense interest for the export to proceed as planned, or whether the national defense interest is better served by FEMA purchase of the materials, or by return of the materials for domestic distribution. In order to make this determination, FEMA needs to obtain information about the shipment's purpose which is not otherwise available.

FEMA believes that the least burdensome way to obtain this information is to request a letter of attestation verifying certain details about the shipment – for instance, that the materials are being exported for assembly abroad and return to the U.S. for sale, or that the materials are planned for donation abroad. There is no less burdensome way to collect this information. Without this information, FEMA cannot make the necessary national defense determinations needed to carry out the Presidential Memorandum or subsequent order.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- (a) Requiring respondents to report information to the agency more often than quarterly.**
- (b) Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it.**
- (c) Requiring respondents to submit more than an original and two copies of any document.**
- (d) Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years.**
- (e) In connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study.**
- (f) Requiring the use of a statistical data classification that has not been reviewed and approved by OMB.**
- (g) That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure**

and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use.

(h) Requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

There are no special circumstances that require the information collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.6.

8. Federal Register Notice:

a. Provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

A 60-day Federal Register Notice inviting public comments was published on July 17, 2020, 85 FR 43592. Comments related to Letter of Attestation regarding Export of Certain Scarce or Threatened Medical Resources must be submitted on or by September 15, 2020

A 30-day Federal Register Notice inviting public comments was published on September 21, 2020, 85 FR 59323. No comments were received

b. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

The agency has consulted with the interagency and with relevant stakeholders to minimize the burden of this collection while providing the maximum flexibility to exporters under the export restrictions.

c. Describe consultations with representatives of those from whom information is to be obtained or those who must compile records. Consultation should occur at least once every three years, even if the collection of information activities is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Given the national emergency caused by COVID-19, it would be impracticable and contrary to the public health—and, by extension, the public interest—to delay implementing this information collection until after FEMA has consulted with persons outside of the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. Although FEMA has not completed any formal consultations with industry representatives regarding submission of the Letters of Attestation, informal communications with industry representatives throughout the administration of the rule have not raised concerns with the need to submit a Letter.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

There is no plan to provide any payment or gift to respondents.

10. Describe any assurance of confidentiality provided to respondents. Present the basis for the assurance in statute, regulation, or agency policy.

On April 17, 2020, the Department of Homeland Security Privacy Threshold Adjudication was completed. The System is covered by the following existing Privacy Impact Assessments (PIA): DHS/CBP/PIA-003(b) Automated Commercial Environment (ACE) and DHS/CBP/PIA-020 Export Information System (EIS). The System is also covered by the following System of Records Notice: DHS/CBP-020 Export Information System, September 2, 2015, 80 FR 53181.

CBP is updating the EIS PIA and will include discussion of this FEMA sharing in that update. The CBP Privacy Office reviewed and cleared this PTA on 04/17/20.

11. Provide additional justification for any question of a sensitive nature (such as sexual behavior and attitudes, religious beliefs and other matters that are commonly considered private). This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- a. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated for each collection instrument (separately list each instrument and describe information as requested).**

Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desired. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.

b. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

c. Provide an estimate of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. NOTE: The wage-rate category for each respondent must be multiplied by 1.4 and this total should be entered in the cell for “Avg. Hourly Wage Rate”. The cost to the respondents of contracting out or paying outside parties for information collection activities should not be included here. Instead this cost should be included in Item 13.

Estimated Annualized Burden Hours and Costs								
Type of Respondent	Form Name / Form No.	No. of Respondents	No. of Responses per Respondent	Total No. of Responses	Avg. Burden per Response (in hours)	Total Annual Burden (in Hours)	Avg. Hourly Wage Rate	Total Annual Respondent Cost
For-Profit Business	Letter of Attestation regarding the Export of Certain Scarce or Threatened Medical Resources	168	1	168	0.5	84	\$102.00	\$8,568
Total		168		168		84		\$8,568

Instruction for Wage-rate category multiplier: Take each non-loaded “Avg. Hourly Wage Rate” from the BLS website table and multiply that number by 1.46¹. For

¹ Bureau of Labor Statistics, Employer Costs for Employee Compensation, Table 1. “Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Civilian workers, by major occupational and industry group, March 2019.” Available at http://www.bls.gov/news.release/archives/ecec_06182019.pdf. Accessed April 14, 2020. The wage multiplier is calculated by dividing total compensation for all workers of \$36.77 by wages and salaries for all workers of \$25.22 per hour yielding a benefits multiplier of approximately 1.46.

example, a non-loaded BLS table wage rate of \$42.51 would be multiplied by 1.46, and the entry for the “Avg. Hourly Wage Rate” would be \$62.06.

According to the U.S. Department of Labor, Bureau of Labor Statistics², the May 2019 Occupational Employment and Wage Estimates wage rate for Lawyers (SOC 23-1011) is \$69.86. Including the wage rate multiplier of 1.46, the fully-loaded wage rate is \$102.00 per hour. Therefore, the annual burden hour cost is estimated to be \$8,568 (\$102.00 x 84 hours).

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. (Do not include the cost of any hour burden shown in Items 12 and 14.)

The cost estimates should be split into two components:

a. Operation and Maintenance and purchase of services component. These estimates should take into account cost associated with generating, maintaining, and disclosing or providing information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred.

b. Capital and Start-up-Cost should include, among other items, preparations for collecting information such as purchasing computers and software, monitoring sampling, drilling and testing equipment, and record storage facilities.

Annual Cost Burden to Respondents or Recordkeepers				
Data Collection Activity/Instrument	*Annual Capital Start-Up Cost (investments in overhead, equipment, and other one-time expenditures)	*Annual Operations and Maintenance Costs (such as recordkeeping, technical/professional services, etc.)	Annual Non-Labor Cost (expenditures on training, travel, and other resources)	Total Annual Cost to Respondents
Total	\$0	\$0	\$0	\$0

The AES system is web accessible and does not require capital beyond that necessary for routine business needs. This collection adds a requirement to existing business processes for filing.

² Information on the mean wage rate from the U.S. Department of Labor Bureau of Labor Statistics is available online at: <https://www.bls.gov/oes/tables.htm>.

14. Provide estimates of annualized cost to the federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing and support staff), and any other expense that would have been incurred without this collection of information. You may also aggregate cost estimates for Items 12, 13, and 14 in a single table.

Annual Cost to the Federal Government	
Item	Cost (\$)
Contract Costs [Describe]	\$0
Staff Salaries ¹ : CBP GS-12 Step 5 spending approximately 15 min. per submission. FEMA GS-13 Step 5 spending approximately 30 min. per submission [($\$46.88 \times 1.46^2 \times 0.25 \times 168$) + ($\$57.55 \times 1.46 \times 0.5 \times 168$) = \$9,932.61]	\$9,933
Facilities [cost for renting, overhead, etc. for data collection activity]	\$0
Administrative Costs: [Describe]	
Computer Hardware and Software [cost of equipment annual lifecycle]	\$0
Equipment Maintenance [cost of annual maintenance/service agreements for equipment]	\$0
Travel	\$0
Total	\$9,933
<p>1 Office of Personnel Management 2020 Pay and Leave Tables for the Washington-Baltimore-Arlington, DC-MD-VA-WV-PA locality. Available online at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/20Tables/html/DCB.aspx. Accessed April 14, 2020.</p> <p>2 Wage rate includes a 1.46 multiplier to reflect the fully-loaded wage rate.</p>	

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I in a narrative form. Present the itemized changes in hour burden and cost burden according to program changes or adjustments in Table 5. Denote a program increase as a positive number, and a program decrease as a negative number.

A "**Program increase**" is an additional burden resulting from an federal government regulatory action or directive. (e.g., an increase in sample size or coverage, amount of information, reporting frequency, or expanded use of an existing form). This also includes previously in-use and unapproved information collections discovered during the ICB process, or during the fiscal year, which will be in use during the next fiscal year.

A "**Program decrease**", is a reduction in burden because of: (1) the discontinuation of an information collection; or (2) a change in an existing information collection by a Federal agency (e.g., the use of sampling (or smaller samples), a decrease in the amount of information requested (fewer questions), or a decrease in reporting frequency).

"**Adjustment**" denotes a change in burden hours due to factors over which the government has no control, such as population growth, or in factors which do not affect what information the government collects or changes in the methods used to estimate burden or correction of errors in burden estimates.

Itemized Changes in Annual Burden Hours						
Data Collection Activity/Instrument	Program Change (hours currently on OMB inventory)	Program Change (new)	Difference	Adjustment (hours currently on OMB inventory)	Adjustment (new)	Difference
Total	2,500	84	2,416	0	0	0

Explain: When this collection began, it was unclear how many Letters of Attestation would be submitted, so we provided our best estimate based on the number of shipments that we thought would require a letter of attestation. However, this turned out to be an over-estimate. Over the three-month period from April 13, 2020 through July 15, 2020, 42 letters were submitted. Therefore, we expect to receive approximately 168 letters over the course of a full calendar year.

Itemized Changes in Annual Cost Burden						
Data Collection Activity/Instrument	Program Change (cost currently on OMB inventory)	Program Change (new)	Difference	Adjustment (cost currently on OMB inventory)	Adjustment (new)	Difference
Total	\$127,500	\$8,568	\$-118,932	\$0	\$0	\$0

Explain:

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

There are no outline plans for tabulation and publication of data for this information collection as the information is considered business proprietary and is not to be published.

17. If seeking approval not to display the expiration date for OMB approval of the information collection, explain reasons that display would be inappropriate.

This collection does not seek approval to not display the expiration date for OMB approval.

**18. Explain each exception to the certification statement identified in Item 19
“Certification for Paperwork Reduction Act Submissions,” of OMB Form 83-I.**

This collection does not seek exception to “Certification for Paperwork Reduction Act Submissions”. This collection does not use efficient statistical survey methodology or use of information technology. Statistical Survey methodology "is not applicable"
Question #3 in the supporting statement justifies the non-use of information technology.