

information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through May 31, 2025. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

**DATES:** DoD, GSA, and NASA will consider all comments received by January 21, 2025.

**ADDRESSES:** DoD, GSA, and NASA invite interested persons to submit comments on this collection through <https://www.regulations.gov> and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202-501-4755 or [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov).

**Instructions:** All items submitted must cite OMB Control No. 9000-0059, North Carolina Sales Tax Certification. Comments received generally will be posted without change to <https://www.regulations.gov>, including any personal and/or business confidential 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.

**FOR FURTHER INFORMATION CONTACT:** Zenaida Delgado, Procurement Analyst, at telephone 202-969-7207, or [zenaida.delgado@gsa.gov](mailto:zenaida.delgado@gsa.gov).

**SUPPLEMENTARY INFORMATION:**

**A. OMB Control Number, Title, and Any Associated Form(s)**

9000-0059, North Carolina Sales Tax Certification.

**B. Need and Uses**

This clearance covers the information that contractors must submit to comply with the requirements of the Federal Acquisition Regulation clause at 52.229-2, North Carolina State and Local Sales and Use Tax. This clause requires contractors for construction or vessel repair to be performed in North Carolina to provide certified statements of the cost of the property purchased from each vendor and the amount of sales or use taxes paid. The North Carolina Sales and Use Tax Act

authorizes counties and incorporated cities and towns, to obtain each year from the Commissioner of Revenue of the State of North Carolina, a refund of sales and use taxes indirectly paid on building materials, supplies, fixtures, and equipment that become a part of or are annexed to any building or structure in North Carolina. However, to substantiate a refund claim for sales or use taxes paid on purchases of building materials, supplies, fixtures, or equipment by a contractor, the Government must secure from the contractor certified statements setting forth the cost of the property purchased from each vendor and the amount of sales or use taxes paid. Similar certified statements by subcontractors must be obtained by the general contractor and furnished to the Government.

The Government will use the information as evidence to establish exemption from State and local taxes.

**C. Annual Burden**

*Respondents:* 182.

*Total Annual Responses:* 182.

*Total Burden Hours:* 227.5.

**Obtaining Copies:** Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202-501-4755 or emailing [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov). Please cite OMB Control No. 9000-0059, North Carolina Sales Tax Certification.

**Janet Fry,**

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**DEPARTMENT OF DEFENSE**

**GENERAL SERVICES  
ADMINISTRATION**

**NATIONAL AERONAUTICS AND  
SPACE ADMINISTRATION**

[OMB Control No. 9000-0048; Docket No. 2024-0053; Sequence No. 15]

**Information Collection; Certain Federal  
Acquisition Regulation Part 15  
Requirements**

**AGENCY:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, and

the Office of Management and Budget (OMB) regulations, DoD, GSA, and NASA invite the public to comment on an extension concerning certain Federal Acquisition Regulation (FAR) part 15 requirements. DoD, GSA, and NASA invite comments on: whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through March 31, 2025. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

**DATES:** DoD, GSA, and NASA will consider all comments received by January 21, 2025.

**ADDRESSES:** DoD, GSA, and NASA invite interested persons to submit comments on this collection through <https://www.regulations.gov> and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202-501-4755 or [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov).

**Instructions:** All items submitted must cite OMB Control No. 9000-0048, Certain Federal Acquisition Regulation Part 15 Requirements. Comments received generally will be posted without change to <https://www.regulations.gov>, including any personal and/or business confidential 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.

**FOR FURTHER INFORMATION CONTACT:** Zenaida Delgado, Procurement Analyst, at telephone 202-969-7207, or [zenaida.delgado@gsa.gov](mailto:zenaida.delgado@gsa.gov).

**SUPPLEMENTARY INFORMATION:**

**A. OMB Control Number, Title, and Any Associated Form(s)**

9000-0048, Certain Federal Acquisition Regulation Part 15 Requirements.

## B. Need and Uses

This clearance covers the information that offerors and contractors must submit to comply with the following FAR requirements:

1. FAR 15.407–2(e), Make-or-buy programs. When prospective contractors are required to submit proposed make-or-buy program plans for negotiated acquisitions, paragraph (e) requires the following information in their proposal:

(a) A description of each major item or work effort;

(b) Categorization of each major item or work effort as “must make,” “must buy,” or “can either make or buy”;

(c) For each item or work effort categorized as “can either make or buy,” a proposal either to “make” or to “buy”;

(d) Reasons for categorizing items and work efforts as “must make” or “must buy,” and proposing to “make” or to “buy” those categorized as “can either make or buy”;

(e) Designation of the plant or division proposed to make each item or perform each work effort, and a statement as to whether the existing or proposed new facility is in or near a labor surplus area;

(f) Identification of proposed subcontractors, if known, and their location and size status;

(g) Any recommendations to defer make-or-buy decisions when categorization of some items or work efforts is impracticable at the time of submission; and

(h) Any other information the contracting officer requires in order to evaluate the program.

2. FAR 52.215–1(c)(2)(iv)—Authorized Negotiators. This provision requires firms offering supplies or services to the Government under negotiated solicitations to provide the names, titles, and telephone and facsimile numbers (and electronic addresses if available) of authorized negotiators to assure that discussions are held with authorized individuals.

Contracting officers use this information during contract negotiations and it becomes part of the official contract file.

3. FAR 52.215–9, Changes or Additions to Make-or-Buy Program. This clause requires the contractor to submit, in writing, for the contracting officer’s advance approval a notification and justification of any proposed change in the make-or-buy program incorporated in the contract.

Contracting officers use the information collected regarding make-or-buy programs at FAR 15.407–2(e) and 52.215–9 to ensure negotiation of reasonable contract prices, satisfactory

performance, or implementation of socioeconomic policies.

4. FAR 52.215–14—Integrity of Unit Prices. This clause requires offerors and contractors under negotiated solicitations and contracts to identify those supplies which they will not manufacture or to which they will not contribute significant value, if requested by the contracting officer or when contracting without adequate price competition.

When a contract action is priced on the basis of a cost estimate, contracting officers use this information to determine whether the intrinsic value of an item has been distorted through allocation of overhead costs and whether such items should be considered for breakout.

5. FAR 52.215–19—Notification of Ownership Changes. This clause requires contractors to notify the administrative contracting officer when the contractor becomes aware that a change in its ownership has occurred, or is certain to occur, that could result in changes in the valuation of its capitalized assets in the accounting records.

The notification of ownership change enables the Government to adequately administer the cost principle at FAR 31.205–52, Asset valuations resulting from business combinations, which addresses the allowability of certain costs resulting from asset valuations following business combinations.

6. FAR 52.215–22, Limitations on Pass-Through Charges—Identification of Subcontract Effort. This provision requires offerors submitting a proposal for a contract, task order, or delivery order to provide the following information with their proposal:

(a) The total cost of the work to be performed by the offeror, and the total cost of the work to be performed by each subcontractor;

(b) If the offeror intends to subcontract more than 70 percent of the total cost of work to be performed, the amount of the offeror’s indirect costs and profit/fee applicable to the work to be performed by the subcontractor(s), and a description of the value added by the offeror as related to the work to be performed by the subcontractor(s); and

(c) If any subcontractor proposed intends to subcontract to a lower-tier subcontractor more than 70 percent of the total cost of work to be performed, the amount of the subcontractor’s indirect costs and profit/fee applicable to the work to be performed by the lower-tier subcontractor(s) and a description of the added value provided by the subcontractor as related to the

work to be performed by the lower-tier subcontractor(s).

7. FAR 52.215–23, Limitations on Pass-Through Charges. This clause requires contractors to provide a description of the value added by the contractor or subcontractor, as applicable, as related to the subcontract effort if the effort changes from the amount identified in the proposal such that it exceeds 70 percent of the total cost of work to be performed.

Contracting officers use the information collected at FAR 52.215–22 and 52.215–23 to assess the value added by a contractor or subcontractor in relation to proposed, billed, or claimed indirect costs or profit/fee on work performed by a subcontractor. This information is required to ensure that pass-through charges under contracts and subcontracts are not excessive.

## C. Annual Burden

*Respondents:* 122,097.

*Total Annual Responses:* 139,074.

*Total Burden Hours:* 43,027 (43,022 reporting hours + 5 recordkeeping hours).

*Obtaining Copies:* Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov). Please cite OMB Control No. 9000–0048, Certain Federal Acquisition Regulation Part 15 Requirements.

**Janet Fry,**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2016–D–2565]

### 510(k) Third Party Review Program and Third Party Emergency Use Authorization Review; Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “510(k) Third Party