

324.7002 Policy.

It is the policy of HHS to protect personal interests of individuals, corporate interests of non-governmental organizations, and the capacity of the Government to provide public services when information from or about individuals, organizations, or Federal agencies is provided to or obtained by contractors in performance of HHS contracts. This protection depends on the contractor's recognition and proper handling of such information. As a result, the "Confidentiality of Information" contract clause was developed.

324.7003 Applicability.

(a) The "Confidentiality of Information" clause, set forth in 352.24-70, should be used in solicitations and resultant contracts whenever the need exists to keep information confidential. Examples of situations where the clause may be appropriate include:

(1) Studies performed by the contractor which generate information or involve Government-furnished information that is personally identifiable, such as medical records, vital statistics, surveys, and questionnaires;

(2) Contracts which involve the use of salary structures, wage schedules, proprietary plans or processes, or confidential financial information of organizations other than the contractor's; and

(3) Studies or research which may result in preliminary or unvalidated findings which, upon disclosure to the public, might create erroneous conclusions which, if acted upon, could threaten public health or safety.

(b) With regard to protecting individuals, this subpart and contract clause are not meant to regulate or control the method of selecting subjects and performing studies or experiments involving them. These matters are dealt with in the HHS regulation entitled "Protection of Human Subjects," 45 CFR part 46. If a system of records under contract, or portions thereof, is determined to be subject to the requirements of the Privacy Act, in accordance with FAR 24.1 and 324.1 and Title 45 CFR part 5b, the procedures cited in those references are applicable and the Privacy Act contract clause shall be included in the contract. If the

contract also involves confidential information, as described herein, which is not subject to the Privacy Act, the contract shall include the "Confidentiality of Information" clause in addition to the Privacy Act clause.

324.7004 Required clause.

The clause set forth in 352.224-70 shall be included in any RFP and resultant contract(s) where it has been determined that confidentiality of information provisions may apply. Any REP announcing the intent to include this clause in any resultant contract(s) shall indicate, as specifically as possible, the types of data which would be covered and requirements for handling such data.

PART 325—FOREIGN ACQUISITION**Subpart 325.1—Buy American Act—Supplies**

Sec.

325.102 Policy.

325.108 Excepted articles, materials, and supplies.

325.108-70 Formats for nonavailability determinations.

Subpart 325.3—Balance of Payments Program

325.302 Policy.

AUTHORITY: 5 U.S.C. 301; 40 U.S.C. 486(c).

SOURCE: 49 FR 14015, Apr. 9, 1984, unless otherwise noted.

Subpart 325.1—Buy American Act—Supplies**325.102 Policy.**

(b) The head of the contracting activity shall make the determinations required by FAR 25.102(a) (1) through (5) and FAR 25.102(b).

[51 FR 44294, Dec. 9, 1986; 51 FR 47353, Dec. 31, 1986]

325.108 Excepted articles, materials, and supplies.

(b) Articles, materials, and supplies not listed in FAR 25.108(d) may be excepted only after a written determination has been made by the head of the contracting activity. These determinations are required only in instances

where it has been determined that only suppliers of foreign source end items shall be solicited. However, approvals and determinations covering individual acquisitions in the following categories may be made by the contracting officer:

(1) Acquisition of spare and replacement parts for foreign manufactured items, if the acquisition must be restricted to the original manufacturer or its supplier; and

(2) Acquisition of foreign drugs when it has been determined, in writing, by the responsible program official, that only the requested foreign drug will fulfill the requirement.

Formats for the above referenced written determinations are shown in 325.108-70.

325.108-70 Formats for nonavailability determinations.

(a) The following is the format for a nonavailability determination made by a contracting officer:

DETERMINATION OF NONAVAILABILITY

Pursuant to the authority contained in section 2, Title III, of the Act of March 3, 1933, popularly called the Buy American Act (41 U.S.C. 10(a-d)), and authority delegated to me by 325.108(b), I hereby find that:

(a) (Insert a description of the item or items to be acquired, including unit, quantity, and estimated cost inclusive of duty and transportation costs to destination.)

(b) (Enter the name and address of the proposed contractor or supplier, and country of origin of the item or items.)

(c) (Include a statement of the necessity for the acquisition.)

(d) (Include a statement of facts establishing the nonavailability of a similar item or items of domestic origin. If there is no known domestic item or items which can be used as a reasonable substitute, a statement to this effect will be made.)

Based upon these findings, it is determined that the above-described item(s) is (are) not mined, produced, or manufactured, or the articles, materials, or supplies from which it (they) is (are) manufactured, are not mined, produced, or manufactured, as the case may be, in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality.

Accordingly, the requirement of the Buy American Act that acquisition be made from domestic sources and that it be of domestic origin is not applicable to this acquisition, since the referenced acquisition is within the nonavailability exception stated in the Buy

American Act. Authority is granted to acquire the above-described item(s) of foreign origin (country of origin) at an estimated total cost of \$, including duty and transportation cost to destination.

(Date)

(Contracting Officer)

(b) The following is the format for a nonavailability determination made by the head of the contracting activity. Part 1 of the determination shall be signed by the preparing authority (contracting officer of official with contracting authority), and Part 2 shall be signed by the approving authority.

DETERMINATION OF NONAVAILABILITY

Part 1

Date

Pursuant to the authority contained in Section 2, Title III, of the Act of March 3, 1933, popularly called the Buy American Act (41 U.S.C. 10(a-d)), I hereby find:

(a) (Insert a description of the item or items to be acquired, including unit, quantity, and estimated cost inclusive of duty and transportation costs to destination.)

(b) (Insert a brief statement of the necessity for the acquisition.)

(c) (Include a statement of facts establishing the nonavailability of a similar item or items of domestic origin.)

Based upon the above showing of fact, it is determined that the above described item(s) is (are) not mined, produced, or manufactured, or the articles, materials, or supplies from which it (they) is (are) manufactured, are not mined, produced or manufactured, as the case may be, in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality.

(Signature)

Part 2

The requirement of the Buy American Act that acquisition be made from domestic sources and that it be of domestic origin is not applicable to the above described acquisition, since the referenced acquisition is within the nonavailability exception stated in the Act. The feasibility of foregoing the requirement or providing a United States substitute has been considered. Authority is granted to acquire the above described item(s) of foreign origin (country of origin) at an estimated total cost of \$, including duty and transportation costs to destination.

(Signature)

Department of Health and Human Services

325.302

**Subpart 325.3—Balance of
Payments Program**

official responsible for acquisition (not
delegable).

325.302 Policy.

All determinations addressed in FAR
25.302 shall be made by the principal of-