(2) A warning not to add Lactated Ringer's Injection U.S.P. solution to Red Blood Cell products.

(l) For Platelets, the instruction circular shall contain:

(1) The approximate volume of plasma from which a sample unit of Platelets is prepared.

(2) Instructions to begin administration as soon as possible, but not more than 4 hours after entering the container.

(m) For Plasma, the instruction circular shall contain:

(1) A warning against further processing of the frozen product if there is evidence of breakage or thawing.

(2) Instructions to thaw the frozen product at a temperature between 30 and 37 °C.

(3) When applicable, instructions to begin administration of the product within 6 hours after thawing.

(4) Instructions to administer to ABO-group-compatible recipients.

(5) A statement that this product has the same hepatitis risk as Whole Blood; other plasma volume expanders without this risk are available for treating hypovolemia.

(n) For Cryoprecipitated AHF, the instruction circular shall contain:

(1) A statement that the average potency is 80 or more International Units of antihemophilic factor.

(2) The statement: "Usually contains at least 150 milligrams of fibrinogen"; or, alternatively, the average fibrinogen level determined by assay of representative units.

(3) A warning against further processing of the product if there is evidence of breakage or thawing.

(4) Instructions to thaw the product for no more than 15 minutes at a temperature of 37 °C.

(5) Instructions to store at room temperature after thawing and to begin administration as soon as possible but no more than 4 hours after entering the container or after pooling and within 6 hours after thawing.

(6) A statement that 0.9 percent Sodium Chloride Injection U.S.P. is the preferred diluent.

(7) Adequate instructions for pooling to ensure complete removal of all concentrated material from each container.

(8) The statement: "Good patient management requires monitoring treatment responses to Cryoprecipitated AHF transfusions with periodic plasma factor VIII or fibrinogen assays in hemophilia A and hypofibrinogenemic recipients, respectively."

4. By adding a new clause regarding the OMB control number at the end of § 606.170 to read as follows:

§ 606.170 Adverse reaction file.

* * * * *

(Information collection requirements approved by the Office of Management and Budget under OMB control number 0910-0116)

PART 640—ADDITIONAL STANDARDS FOR BLOOD AND BLOOD PRODUCTS

5. The authority citation for 21 CFR Part 640 continues to read as follows:

Authority: Secs. 215, 351, 58 Stat. 690 as amended; 702 as amended (42 U.S.C. 216, 262); 21 CFR 5.10.

6. In § 640.2 by revising paragraph (f) to read as follows:

§ 640.2 General requirements.

* * * * *

(f) *Issue prior to determination of test results.* Notwithstanding the provisions of § 610.1 of this chapter, blood may be issued by the manufacturer on the request of a physician, hospital, or other medical facility before results of all tests prescribed in § 640.5 and the test for hepatitis B surface antigen prescribed in § 610.40(a) of this chapter have been completed, where such issue is essential to allow time for transportation to ensure arrival of the blood by the time it is needed for transfusion: *Provided,* That (1) the blood is shipped directly to such physician or medical facility, (2) the records of the manufacturer contain a full explanation of the need for such issue, and (3) the label on each container of such blood bears the information required by § 606.121(h) of this chapter.

§§ 640.7, 640.18, 640.26, 640.35, and 640.57 [Removed]

7. By removing § 640.7 *Labeling,* § 640.18 *Labeling,* § 640.26 *Labeling,* § 640.35 *Labeling,* and § 640.57 *Labeling.*

8. In § 640.70 by revising the introductory text of paragraph (a) to read as follows:

§ 640.70 Labeling.

(a) In addition to the labeling requirements of § 610.62 of this chapter, and in lieu of the requirements in §§ 606.121, 610.60, and 610.61 of this chapter, the following information shall appear on the label affixed to each container of Source Plasma:

* * * * *

Dated: August 1, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 85-20739 Filed 8-29-85; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration

[Docket No. 80N-0120]

Guideline for the Uniform Labeling of Blood and Blood Components; Availability of Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guideline for the uniform labeling of blood and blood components. The guideline describes in detail the specifications for a uniform container label for blood-banking use which conform with a final rule published elsewhere in this issue of the Federal Register.

ADDRESS: Written comments and requests for a copy of the guideline (identified with the docket number found in brackets in the heading of this document) to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary Ann Tourault, Center for Drugs and Biologics (HFN-830), Food and Drug Administration, 8800 Rockville Pike, Bethesda, Md 20205, 301-496-4396.

SUPPLEMENTARY INFORMATION: FDA is making available a final guideline prepared by the Office of Biologics Research and Review in the Center for Drugs and Biologics to describe the uniform container label for blood and blood components. In the Federal Register of October 31, 1980 (45 FR 72416), FDA published a proposed rule to revise the labeling requirements for blood and blood components. In the same document, FDA announced the availability of a proposed guideline entitled "Guidelines for the Uniform Labeling of Blood and Blood Components." Preparation of the guideline is part of a program supported by FDA, the American Blood Commission (ABC), and other organizations representing the blood banking industry, to encourage the use of blood container labels of a standard content and format, with certain label elements present in both eye-readable and machine-readable form. Since the time of the announcement of the proposed guideline's availability, FDA has permitted the voluntary use of uniform labeling consistent with the proposed rule and guideline.

Elsewhere in this issue of the Federal Register, FDA is publishing a final rule revising the labeling requirements for blood and blood components. In the Federal Register of January 29, 1985 (50 FR 4128), FDA published a final rule revising the proper names for certain biological products, including blood and blood component products. FDA is announcing the availability of a revised guideline which reflects the labeling requirements and new proper names established in the respective final rules. In cooperation with ABC, FDA has revised the final guideline to correct several errors found in the guideline made available in October 1980. The final guideline provides labeling information for several additional products, including additional blood components, anticoagulants, preservatives, and blood container systems. Although many of these products are not currently licensed or approved by FDA for general use in the United States, FDA expects that these additional products will gain wide acceptance and use in the next few years.

Included with the guideline as Appendix A is "Suggested Evaluation Protocol for Bar-Coded Pressure Sensitive labels" intended for use by printers of labels to determine the acceptability of their products for use in blood banks.

ABC also has made the proposed guideline of October 1980 available to its constituents, along with other instructions for the uniform labeling of blood and blood components. Base upon the practical experience gained through the use of the proposed guideline, ABC has recommended revisions to clarfiy the guideline, to provide additional information concerning the printing and use of the uniform label, and to delete certain unnecessary information. The revised final guideline incorporates ABC's recommendations.

This notice is issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidelines to outline procedures or standards of general applicability that are acceptable to FDA for a subject matter than falls within the laws administered by FDA. Although these guidelines are not a legal requirement, a person may be assured that in following an agency guideline the procedures followed and standards used will be acceptable to FDA. A person may also choose to use alternative procedures or standards for which there is scientific rationale even though they are not provided for in a guideline. A person who chooses to use procedures or standards not in a guideline may discuss the matter further with the agency to prevent an expenditure of resources for work that FDA may later determine to be unacceptable.

FDA is permitting the immediate voluntary use of container labels printed in accordance with the revised final guideline that are consistent with the final regulations published elsewhere in this issue of the Federal Register. Licensed establishments may begin using the new container label and instruction circular without their prior review and approval by FDA, provided that the label is printed in accordance with the specifications described in the guideline. As an amendment to the product license(s), a licensed establishment is required to submit the revised label and instruction circular to the Director, Office of Biologics Research and Review (HFN-800), Center for Drugs and Biologics, 8800 Rockville Pike, Bethesda, MD 20205.

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 35), the reporting and recordkeeping requirements in §§ 606.121 and 606.122 of the final rule on uniform blood labeling (Docket No. 80N-0120) have been submitted for approval to the Office of Management and Budget (OMB). The guideline being made available by the agency has been developed in accordance with the provisions of these sections. The requirements under §§ 606.121 and 606.122 for uniform blood labeling, as described in the final rule published elsewhere in this issue of the Federal Register, will not be effective until FDA obtains OMB approval of the recordkeeping and reporting requirements in §§ 606.121 and 606.122. Prior to November 29, 1985, FDA will publish a notice concerning OMB review of these requirements.

Single copies of the final guideline are available from the Dockets Management Branch (address above). Copies of the final guideline are available also from the American Blood Commission, 1901 N. Ft. Meyer Drive, Suite 300, Arlington, VA 22209 for $5.00 per copy. (The price of the guideline is subject to change.)

Interested persons may submit written comments on the guideline to the Dockets Management Branch. These comments will be considered in determining whether further amendments to, or revisions of, this guideline are warranted. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 1, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 85-20734 Filed 8-29-85; 8:45 am]

BILLING CODE 4160-01-M

federal register

Friday
August 30, 1985

Part VII

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Parts 3, 7, 9, 14, 15, and 52
Federal Acquisition Regulation; Interim Rule With Request for Comments

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 3, 7, 9, 14, 15 and 52

[Federal Acquisition Circular 84-11]

Federal Acquisition Regulation

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

ACTION: Interim rule with request for comments.

SUMMARY: Federal Acquisition Circular (FAC) 84-11 amends the Federal Acquisition Regulation (FAR) with respect to the following: Unreasonable Restriction on Subcontractor Sales, Planning for Purchase of Supplies in Economic Quantities, and Qualification Requirements.

DATES:

Effective Date: August 30, 1985.

Comment Date: Comments must be received on or before September 30, 1985. Please cite FAC 84-11 in all correspondence on this subject.

ADDRESS: Interested parties should submit written comments to: General Services Administration, ATTN: FAR Secretariat (VRS), Room 4041, GS Building, 18th & F Streets, NW., Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Ms. Margaret A. Willis, FAR Secretariat, Telephone (202) 523-4755.

SUPPLEMENTARY INFORMATION:

A. Background

The FAR revisions in FAC 84-11 are required by the Defense Procurement Reform Act of 1984 (Title XII of the Department of Defense Authorization Act, 1985, Pub. L. 98-525), and the Small Business and Federal Procurement Competition Enhancement Act of 1984 (Pub. L. 98-577).

B. Determination to Issue an Interim Regulation

A determination has been made under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator of the National Aeronautics and Space Administration that the regulations in FAC 84-11 must be issued as an interim regulation in compliance with section 22 of the Office of Federal Procurement Policy Act, as amended.

C. Regulatory Flexibility Act

(1) The Regulatory Flexibility Act of 1980, Pub. L. 96-354, specifies circumstances under which a regulatory flexibility analysis is required in connection with the issuance of a general notice of proposed rulemaking or the promulgation of a final rule, and provides that such requirements do not apply to any proposed or final rule if the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Therefore, it is hereby certified that Items I and II of FAC 84-11 will not have a significant economic impact on a substantial number of small entities as follows:

FAC 84-11, Item I, Unreasonable Restriction on Subcontractor Sales, amends the FAR to implement section 1234 of Pub. L. 98-525 and section 206 of Pub. L. 98-577. Under the new coverage contractors are prohibited from restricting the sales of any item or process, of any actual or prospective subcontractor, directly to the Government under the instant contract or any follow-on production contract. This new coverage will not have significant economic impact on a substantial number of small entities because the interim coverage does not impose additional reporting requirements or add new contractual requirements to small businesses.

FAC 84-11, Item II, Planning for the Purchase of Supplies in Economic Quantities, amends the FAR to implement section 1233 of Pub. L. 98-525 and section 205 of Pub. L. 98-577. Under the new coverage, offerors are invited to state an opinion on whether the quantity of supplies to be acquired is economically advantageous to the Government, and if applicable to recommend a more advantageous quantity, including a quoted unit and total price. Since response to the invitation is entirely voluntary, and the type of information requested is of a nature that should normally be readily available in small businesses, there will be no significant economic impact on small entities as a result of the interim regulation.

(2) An initial regulatory flexibility analysis has been prepared for Item III as follows:

FAC 84-11, Item III, Qualification Requirements, may have a significant beneficial economic impact on a substantial number of small entities. Current guidance requires that an initial regulatory flexibility analysis be prepared if the interim rule will have a significant economic impact on a substantial number of small entities even if the economic impact will benefit small entities. Accordingly, an initial regulatory flexibility analysis has been prepared for Item III of this interim rule in accordance with the Regulatory Flexibility Act, Pub. L. 96-354. This initial regulatory flexibility analysis has been prepared in accordance with section 603, Title 5 of the United States Code.

Reasons for Agency Action

Congress amended Title 10 and Title 41 of the United States Code to require agencies to prescribe policies and procedures regarding qualification requirements for acquisitions that are subject to such requirements.

Objectives and Legal Basis

The interim rule implements Pub. L. 98-525 (10 U.S.C. 2319) and Pub. L. 98-577 (41 U.S.C. 253(e)) with the objective of encouraging new competitors for Government contracts. The interim rule seeks to accomplish this by requiring agencies to justify the necessity for establishing qualification requirements, assuring that the requirements are available to all offerors, and permitting offerors to demonstrate their ability to meet these requirements up to the time of award.

Description of and Estimate of Number of Small Entities to which Interim Rule Applies

The interim rule applies to all small businesses that want to contract with the Government and which will either offer a product which is listed on a qualified products list, or which will participate in an acquisition which is limited to certain manufacturers or qualified bidders that can meet established requirements prior to award. It is not feasible to estimate the number of small entities to which the interim rule applies because the number of small businesses who would participate in these types of acquisitions is unknown. Also, the number of qualification requirements which will be modified or eliminated as the result of this interim rule is unknown.

Projected Reporting, Recordkeeping, and Other Compliance Requirements

There are no additional projected reporting, recordkeeping or other compliance requirements likely to result from the interim rule. Small businesses who qualify for reimbursement of testing and evaluation costs by the United States are required by the law to certify to their status as a small business under section 3 of the Small Business Act. This

should not impose an additional burden on small businesses because they are already required to determine their status under Government contracts.

Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Interim Rule

There do not appear to be any relevant Federal rules which duplicate, overlap, or conflict with the interim rule.

Significant Alternatives

The Regulatory Flexibility Act requires consideration of significant alternatives to the interim rule that would accomplish the objectives of the statute and minimize any significant economic impact on small entities. These alternatives include:

(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(2) The clarification, consolidation, or simplification of compliance and reporting requirements under the interim rule for such small entities;

(3) The use of performance rather than design standards; and

(4) An exemption from coverage of the interim rule, or any part thereof, for such small entities.

The interim rule does not establish reporting or recordkeeping requirements. The use of performance rather than design standards if feasible is already mandated by Part 10 of the Federal Acquisition Regulation (FAR). Qualification requirements, which must be met by manufacturers or bidders (or their products) before being awarded a contract, are necessary to assure that the Government obtains a product which meets its minimum needs. Although these requirements cannot be waived or relaxed for small entities, the interim rule extends the period offerors have to demonstrate their ability to meet the Government's requirements compared to the prior rule. This should benefit small entities. Also small entities may be reimbursed for costs of testing and evaluation in some cases which should help them to become more competitive on these types of acquisitions.

List of Subjects in 48 CFR Parts 3, 7, 9, 14, 15, and 52

Government procurement.

Dated: August 27, 1985

Lawrence J. Rizzi,

Director, Office of Federal Acquisition and Regulatory Policy.

Federal Acquisition Circular

[Number 84-11]

The material contained in FAC 84-11 is effective immediately (August 30, 1985).

Eleanor R. Spector,

Deputy Assistant Secretary of Defense for Procurement.

Paul K. Trause,

Acting Administrator.

August 26, 1985.

S.J. Evans,

Assistant Administrator for Procurement, NASA.

Federal Acquisition Circular (FAC) 84-11 amends the Federal Acquisition Regulation (FAR) as specified below.

Item I—Unreasonable Restrictions on Subcontractor Sales

FAR Part 3 is amended to add a new section 3.503 and a new clause at 52.203-6. Under the new coverage contractors and subcontractors are prohibited from asserting or agreeing to unreasonable restrictions on direct sales by subcontractors to the Government.

Item II—Planning for the Purchase of Supplies in Economic Quantities

FAR Subpart 7.2 and Sec. 14.212, 15.415, and 52.207-4 are added to prescribe policies, procedures, and a contract provision for gathering and using information from offerors to assist the Government in planning the most advantageous quantities in which supplies should be purchased. Under the new coverage, offerors are invited to state an opinion on whether the quantity of supplies proposed to be acquired is economically advantageous to the Government and, if applicable, to recommend a more advantageous quantity, including a quoted unit and total price.

Item III—Qualification Requirements

FAR Subpart 9.2 is amended to prescribe policies and procedures regarding qualification requirements. The solicitation provision at 52.209-1 and the contract clause at 52.209-2 are similarly revised for these purposes. The new coverage addresses how agencies will establish and enforce qualification requirements, encourage the qualification of additional sources and products, bear the costs under certain circumstances for products of small businesses to become qualified, and periodically examine the need to continue the use of each qualification requirement.

Therefore, 48 CFR Parts 3, 7, 9, 14, 15, and 52 are amended as set forth below.

1. The authority citation for 48 CFR Parts 3, 7, 9, 14, 15, and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137, and 42 U.S.C. 2453(c).

PART 3—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

2. Sections 3.503, 3.503-1, and 3.503-2 are added to read as follows:

3.503 Unreasonable restrictions on subcontractor sales.

3.503-1 Policy.

10 U.S.C. 2402 and 41 U.S.C. 253(g) require that subcontractors not be unreasonably precluded from making direct sales to the Government of any supplies or services made or furnished under a contract. However, this does not preclude contractors from asserting rights that are otherwise authorized by law or regulation.

3.503-2 Contract clause.

The clause at 52.203-6, Restrictions on Subcontractor Sales to the Government, shall be inserted in solicitations and contracts for supplies or services.

PART 7—ACQUISITION PLANNING

3. Subpart 7.2 is added to read as follows:

Subpart 7.2—Planning for the Purchase of Supplies in Economic Quantities

Sec.

Subpart 7.2—Planning for the Purchase of Supplies in Economical Quantities

7.200 Scope of subpart.

This subpart prescribes policies and procedures for gathering information from offerors to assist the Government in planning the most advantageous quantities in which supplies should be purchased.

7.201 [Reserved]

7.202 Policy.

(a) Agencies are required by 10 U.S.C. 2384(a) and 41 U.S.C. 253(f) to procure supplies in such quantity as (1) will

result in the total cost and unit cost most advantageous to the Government, where practicable, and (2) does not exceed the quantity reasonably expected to be required by the agency.

(b) Each solicitation for a contract for supplies is required, if practicable, to include a provision inviting each offeror responding to the solicitation (1) to state an opinion on whether the quantity of the supplies proposed to be acquired is economically advantageous to the Government, and (2) if applicable, to recommend a quantity or quantities which would be more economically advantageous to the Government. Each such recommendation is required to include a quotation of the total price and the unit price for supplies procured in each recommended quantity.

7.203 Solicitation provision.

Contracting officers shall insert the solicitation provision at 52.207–4, Economic Purchase Quantity—Supplies, in solicitation for supplies; except that, for civilian agencies other than NASA, this solicitation provision is optional in connection with the acquisition of supplies unless the items of supply being acquired are individual parts, components, subassemblies, assemblies or subsystems integral to a major system, and other property which may be replaced during the service life of the system, including spare parts and replenishment spare parts, but not including packaging or labeling associated with shipment or identification of an item.

7.204 Responsibilities of contracting officers.

(a) Contracting officers are responsible for transmitting offeror responses to the solicitation provision at 52.207–4 to appropriate inventory management/requirements development activities in accordance with agency procedures. The economic purchase quantity data so obtained are intended to assist inventory managers in establishing and evaluating economic order quantities for supplies under their cognizance.

(b) In recognition of the fact that economic purchase quantity data furnished by offerors are only one of many data inputs required for determining the most economical order quantities, contracting officers should generally take no action to revise quantities to be acquired in connection with the instant procurement. However, if a significant price variation is evident from offeror responses, and the potential for significant savings is apparent, the contracting officer shall consult with the cognizant inventory manager or requirements development activity before proceeding with an award or negotiations. If this consultation discloses that the Government should be ordering an item of supply in different quantities and the inventory manager/requirements development activity concurs, the solicitation for the item should be amended or canceled and a new requisition should be obtained.

PART 9—CONTRACTOR QUALIFICATIONS

4. Subpart 9.2 is revised to read as follows:

Subpart 9.2—Qualification Requirements

Sec.

Subpart 9.2—Qualifications Requirements

9.200 Scope of subpart.

This subpart implements 10 U.S.C. 2319 and 41 U.S.C. 253(e) and prescribes policies and procedures regarding qualification requirements and the acquisitions that are subject to such requirements.

9.201 Definitions.

"Procuring activity," as used in this part or subpart, means a component of an executive agency having a significant acquisition function and designated as such by the head of the agency. Unless agency regulations specify otherwise, the term "procuring activity" shall be synonymous with "contracting activity" as defined in Subpart 2.1.

"Qualification requirement" means a requirement for testing or other quality assurance demonstration that must be completed by an offeror before the offeror is awarded a contract.

"Qualified bidders list (QBL)" means a list of bidders who have had their products examined and tested and who have satisfied all applicable qualification requirements for that product or have otherwise satisfied all applicable qualification requirements.

"Qualified manufacturers list (QML)" means a list of manufacturers who have had their products examined and tested and who have satisfied all applicable qualification requirements for that product.

"Qualified products list (QPL)" means a list of products which have been examined, tested, and have satisfied all applicable qualification requirements.

9.202 Policy.

(a)(1) The head of the agency or designee shall, before establishing a qualification requirement, prepare a written justification—

(i) Stating the necessity for establishing the qualification requirement and specifying why the qualification requirement must be demonstrated before contract award;

(ii) Estimating the likely costs for a potential offeror of testing and evaluation which a potential offeror will incur to become qualified.

(iii) Specifying all requirements that a potential offeror (or its product) must satisfy in order to become qualified. Only those requirements which are the least restrictive to meet the purposes necessitating the establishment of the qualification requirements shall be specified.

(2) Upon request to the contracting activity, potential offerors shall be provided—

(i) All requirements that they or their products must satisfy to become qualified;

(ii) At their expense (but see 9.204(a)(2) with regard to small businesses), a prompt opportunity to demonstrate their abilities to meet the standards specified for qualification using qualified personnel and facilities of the agency concerned, or of another agency obtained through interagency agreements, or under contract, or other methods approved by the agency (including use of approved testing and evaluation services not provided under contract to the agency).

(3) If the services in (a)(2)(ii) above are provided by contract, the contractors selected to provide testing and evaluation services shall be—

(i) Those that are not expected to benefit from an absence of additional qualified sources; and

(ii) Required by their contracts to adhere to any restriction on technical data asserted by the potential offeror seeking qualification.

(4) A potential offeror seeking qualification shall be promptly informed as to whether qualification is attained and, in the event it is not, promptly furnished specific reasons why qualification was not attained.

(b) When justified under the circumstances, the agency activity

responsible for establishing a qualification requirement shall submit to the competition advocate for the procuring activity responsible for purchasing the item subject to the qualification requirement, a determination that it is unreasonable to specify the standards for qualification which a prospective offeror (or its product) must satisfy. After considering any comments of the competition advocate reviewing the determination, the head of the procuring activity may waive the requirements of 9.202(a)(1)(ii) through (4) above for up to 2 years with respect to the item subject to the qualification requirement. A copy of the waiver shall be furnished to the head of the agency or other official responsible for actions under 9.202(a)(1). The waiver authority provided in this paragraph does not apply with respect to qualification requirements contained in a QPL, QML, or QBL.

(c) If a potential offeror can demonstrate to the satisfaction of the contracting officer that the potential offeror (or its product) meets the standards established for qualification or can meet them before the date specified for award of the contract, a potential offeror may not be denied the opportunity to submit and have considered an offer for a contract solely because the potential offeror—

(1) Is not on a QPL, QML, or QBL maintained by the Department of Defense (DOD) or the National Aeronautics and Space Administration (NASA); or

(2) Has not been identified as meeting a qualification requirement established after October 19, 1984, by DOD or NASA; or

(3) Has not been identified as meeting a qualification requirement established by a civilian agency (not including NASA).

(d) The procedures in Subpart 19.6 for referring matters to the Small Business Administration are not mandatory on the contracting officer when the basis for a referral would involve a challenge by the offeror to either the validity of the qualification requirement or the offeror's compliance with such requirement.

(e) The contracting officer need not delay a proposed award in order to provide a potential offeror with an opportunity to demonstrate its ability to meet the standards specified for qualification. In addition, when approved by the head of an agency or designee, a procurement need not be delayed in order to comply with 9.202(a).

(f) Within 7 years following enforcement of a QPL, QML, or QBL by DOD or NASA, or within 7 years after any qualification requirement was originally established by a civilian agency other than NASA, the qualification requirement shall be examined and revalidated in accordance with the requirements of 9.202(a). For DOD and NASA, qualification requirements, other than QPL's, QML's, and QBL's, shall be examined and revalidated within 7 years after establishment of the requirement under 9.202(a). Any periods for which a waiver under 9.202(b) is in effect shall be excluded in computing the 7 years within which review and revalidation must occur.

9.203 QPL's, QML's and QBL's.

(a) Qualification and listing in a QPL, QML, or QBL is the process by which products are obtained from manufacturers or distributors, examined and tested for compliance with specification requirements, or manufacturers or potential offerors, are provided an opportunity to demonstrate their abilities to meet the standards specified for qualification. The names of successful products, manufacturers, or potential offerors are included on lists evidencing their status. Generally, qualification is performed in advance and independently of any specific acquisition action. After qualification, the products, manufacturers, or potential offerors are included in a Federal or Military QPL, QML, or QBL. (See 9.202(a)(2) with regard to any product, manufacturer, or potential offeror not yet included on an applicable list.)

(b) Specifications requiring a qualified product are included in the following publications:

(1) Index of Federal Specifications and Standards, FPMR 101–29.1.

(2) Department of Defense Index of Specifications and Standards.

(c) Instructions concerning qualification procedures are included in the following publications:

(1) Federal Standardization Handbook, FPMR 101–29, Chapter IV.

(2) Defense Standardization Manual 4120.3–M, Chapter IV, as amended by Military Standards 961 and 962.

(d) The publications listed in paragraphs (b) and (c) above are sold to the public by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Civil agencies may obtain the publications from the General Services Administration, Specifications Section (WFSIS), Washington, DC 20407. Defense agencies may obtain the publications from the Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA 19120.

9.204 Responsibilities for establishment of a qualification requirement.

The responsibilities of agency activities that establish qualification requirements include the following:

(a) Arranging publicity for the qualification requirements. If active competition on anticipated future qualification requirements is likely to be fewer than two manufacturers or the products of two manufacturers, the activity responsible for establishment of the qualification requirements shall—

(1) Periodically publish notice in the Commerce Business Daily soliciting additional sources or products to seek qualification unless the contracting officer determines that such publication would compromise the national security.

(2) Bear the cost of conducting the specified testing and evaluation (excluding the costs associated with producing the item or establishing the production, quality control, or other system to be tested and evaluated) for a small business concern or a product manufactured by a small business concern which has met the standards specified for qualification and which could reasonably be expected to compete for a contract for that requirement. However, such costs may be borne only if it is determined in accordance with agency procedures that such additional qualified sources or products are likely to result in cost savings from increased competition for future requirements sufficient to amortize the costs incurred by the agency within a reasonable period of time, considering the duration and dollar value of anticipated future requirements. A prospective contractor requesting the United States to bear testing and evaluation costs must certify as to its status as a small business concern under section 3 of the Small Business Act in order to receive further consideration.

(b) Qualifying products that meet specification requirements.

(c) Listing manufacturers and suppliers whose products are qualified in accordance with agency procedures.

(d) Furnishing QPL's, QML's, or QBL's or the qualification requirements themselves to prospective offerors and the public upon request (see 9.202(a)(2)(i) above).

(e) Clarifying, as necessary, qualification requirements.

(f) In appropriate cases, when requested by the contracting officer, providing concurrence in a decision not to enforce a qualification requirement for a solicitation.

(g) Withdrawing or omitting qualification of a listed product, manufacturer or offeror, as necessary.

(h) Advising persons furnished any list of products, manufacturers or offerors meeting a qualification requirement and suppliers whose products are on any such list that—

(1) The list does not constitute endorsement of the product, manufacturer, or other source by the Government;

(2) The products or sources listed have been qualified under the latest applicable specification;

(3) The list may be amended without notice;

(4) The listing of a product or source does not release the supplier from compliance with the specification; and

(5) Use of the list for advertising or publicity is permitted. However, it must not be stated or implied that a particular product or source is the only product or source of that type qualified, or that the Government in any way recommends or endorses the products or the source listed.

(i) Reexamining a qualified product or manufacturer when—

(1) The manufacturer has modified its product, or changed the material or the processing sufficiently so that the validity of previous qualifications is questionable;

(2) The requirements in the specification have been amended or revised sufficiently to affect the character of the product; or

(3) It is otherwise necessary to determine that the quality of the product is maintained in conformance with the specification.

9.205 Opportunity for qualification before award.

(a) If an agency determines that a qualification requirement is necessary, the agency activity responsible for establishing the requirement shall urge manufacturers and other potential sources to demonstrate their ability to meet the standards specified for qualification and, when possible, give sufficient time to arrange for qualification before award. The responsible agency activity shall, before establishing any qualification requirement, furnish notice to the U.S. Department of Commerce, Office of Field Operations, P.O. Box 5999, Chicago, Illinois 60680, for synopsis in the Commerce Business Daily. The notice shall include—

(1) Intent to establish a qualification requirement;

(2) The specification number and name of the product;

(3) The name and address of the activity to which a request for the information and opportunity described in 9.202(a)(2) should be submitted;

(4) The anticipated date that the agency will begin awarding contracts subject to the qualification requirement;

(5) A precautionary notice that when a product is submitted for qualification testing, the applicant must furnish any specific information that may be requested of the manufacturer before testing will begin; and

(6) The approximate time period following submission of a product for qualification testing within which the applicant will be notified whether the product passed or failed the qualification testing (see 9.202(a)(4)).

(b) The activity responsible for establishing a qualification requirement shall keep any list maintained of those already qualified open for inclusion of additional products, manufacturers, or other potential sources, including eligible products from designated countries under terms of the International Agreement on Government Procurement (see Subpart 25.4).

9.206 Acquisitions subject to qualification requirements.

9.206-1 General.

(a) Agencies may not enforce any QPL, QML, or QBL without first complying with the requirements of 9.202(a). However, qualification requirements themselves, whether or not previously embodied in a QPL, QML, or QBL, may be enforced without regard to 9.202(a) if they are in either of the following categories:

(1) Any qualification requirement established by statute prior to October 30, 1984, for civilian agencies (not including NASA); or

(2) Any qualification requirement established by statute or administrative action prior to October 19, 1984, for DOD or NASA. Qualification requirements established after the above dates must comply with 9.202(a) to be enforceable.

(b) Except when the agency head or designee determines that an emergency exists, whenever an agency elects not to enforce a qualification requirement which it established, the requirement may not thereafter be enforced unless the agency complies with 9.202(a).

(c) If a qualification requirement applies, the contracting officer need consider only those offers identified as meeting the requirement or included on the applicable QPL, QML, or QBL, unless an offeror can satisfactorily demonstrate to the contracting officer that it or its product can meet the standards established for qualification before the date specified for award.

(d) If a product subject to a qualification requirement is to be acquired by the prime contractor as a component of an end item, the contracting officer shall require the prime contractor to furnish a component that has met the qualification requirement before award of a subcontract for the component. Any delay resulting from the prime contractor's awaiting qualification approval of a component by the Government shall not constitute excusable delay if a previously qualified component could have been acquired by the prime contractor in time to meet the end item delivery schedule (see the clause at 52.209-2, Qualification Requirements—Components of End Items).

(e) In acquisitions subject to qualification requirements, the contracting officer shall take the following steps:

(1) Use presolicitation notices in appropriate cases to advise potential suppliers before issuing solicitations involving qualification requirements. The notices shall identify the specification containing the qualification requirement and establish an allowable time period, consistent with delivery requirements, for prospective offerors to demonstrate their abilities to meet the standards specified for qualification. The notice shall be publicized in accordance with 5.204. Whether or not a presolicitation notice is used, the general synopsizing requirements of Subpart 5.2 apply.

(2) Distribute solicitations to prospective contractors whether or not they have been identified as meeting applicable qualification requirements.

(3) When appropriate, request in accordance with agency procedures that a qualification requirement not be enforced in a particular acquisition and, it granted, so specify in the solicitation (see 9.206-1(b)).

(4) Forward requests from potential suppliers for information on a qualification requirement to the agency activity responsible for establishing the requirement.

(5) Allow the maximum time, consistent with delivery requirements, between issuing the solicitation and the contract award. As a minimum, contracting officers shall comply with the time frames specified in 5.203 when applicable.

9.206-2 Solicitation provision and contract clause.

(a) The contracting officer shall insert the provision at 52.209-1, Qualification Requirements, in solicitations when the acquisition is subject to a qualification requirement.

(b) The contracting officer shall insert the clause at 52.209-2, Qualification Requirements—Components of End Items, in solicitations and contracts, when components of end items are subject to a qualification requirement.

9.206-3 Competition.

(a) *Presolicitation.* If a qualification requirement applies to an acquisition, the contracting officer shall review the applicable QPL, QML, or QBL or other identification of those sources which have met the requirement before issuing a solicitation to ascertain whether the number of sources is adequate for competition. (See 9.204(a) for duties of the agency activity responsible for establishment of the qualification requirement.) If the number of sources is inadequate, the contracting officer shall request the agency activity which established the requirement to—

(1) Indicate the anticipated date on which any sources presently undergoing evaluation will have demonstrated their abilities to meet the qualification requirement so that the solicitation could be rescheduled to allow as many additional sources as possible to qualify; or

(2) Indicate whether a means other than the qualification requirement is feasible for testing or demonstrating quality assurance.

(b) *Postsolicitation.* The contracting officer shall submit to the agency activity which established the qualification requirement the names and addresses of concerns which requested copies of the solicitation but are not included on the applicable QPL, QML, or QBL or identified as meeting the qualification requirement. The activity will then assist interested concerns in meeting the standards specified for qualification (see 9.202(a) (2) and (4)).

9.207 Changes in status regarding qualification requirements.

(a) The contracting officer shall promptly report to the agency activity which established the qualification requirement any conditions which may merit removal or omission from a QPL, QML, or QBL or affect whether a source should continue to be otherwise identified as meeting the requirement. These conditions exist when—

(1) Products or services are submitted for inspection or acceptance that do not meet the qualification requirement;

(2) Products or services were previously rejected and the defects were not corrected when resubmitted for inspection or acceptance;

(3) A supplier fails to request reevaluation following change of location or ownership of the plant where the product which met the qualification requirement was manufactured (see the provision at 52.209-1, Qualification Requirements, and the clause at 52.209-2, Qualification Requirements—Components of End Items);

(4) A manufacturer of a product which met the qualification requirement has discontinued manufacture of the product;

(5) A source requests removal from a QPL, QML, or QBL;

(6) A condition of meeting the qualification requirement was violated; e.g., advertising or publicity contrary to 9.204(h)(5);

(7) A revised specification imposes a new qualification requirement;

(8) Manufacturing or design changes have been incorporated in the qualification requirement;

(9) The source is on the Consolidated List of Debarred, Suspended, and Ineligible Contractors (see Subpart 9.4); or

(10) Performance of a contract subject to a qualification requirement is otherwise unsatisfactory.

(b) After considering any of the above or other conditions reasonably related to whether a product or source continues to meet the standards specified for qualification, an agency may take appropriate action without advance notification. The agency shall, however, promptly notify the affected parties if a product or source is removed from a QPL, QML, or QBL, or will no longer be identified as meeting the standards specified for qualification. This notice shall contain specific information why the product or source no longer meets the qualification requirement.

PART 14—SEALED BIDDING

5. Section 14.212 is added to read as follows:

14.212 Economic purchase quantities (supplies).

Contracting officers shall comply with the economic purchase quantity planning requirements for supplies in Subpart 7.2. See 7.203 for instructions regarding use of the provision at 52.207-4, Economic Purchase Quantity—Supplies, and 7.204 for guidance on handling responses to that provision.

PART 15—CONTRACTING BY NEGOTIATION

6. Section 15.415 is added to read as follows:

15.415 Economic purchase quantities (supplies).

Contracting officers shall comply with the economic purchase quantity planning requirements for supplies in Subpart 7.2. See 7.203 for instructions regarding use of the provision at 52.207-4, Economic Purchase Quantity—Supplies, and 7.204 for guidance on handling responses to that provision.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

7. Section 52.203-6 is added to read as follows:

52.203-6 Restrictions on Subcontractor Sales to the Government.

As prescribed in 3.503-2, insert the following clause:

Restrictions on Contractor Sales to the Government (Jul 1985)

(a) Except as provided in (b) below, the Contractor shall not enter into any agreement with an actual or prospective subcontractor, nor otherwise act in any manner, which has or may have the effect of restricting sales by such subcontractors directly to the Government of any item or process (including computer software) made or furnished by the subcontractor under this contract or under any follow-on production contract.

(b) The prohibition in (a) above does not preclude the Contractor from asserting rights that are otherwise authorized by law or regulation.

(c) The Contractor agrees to incorporate the substance of this clause, including this paragraph (c), in all subcontracts under this contract.

(End of clause)

8. Section 52.207-4 is added to read as follows:

52.207-4 Economic Purchase Quantity—Supplies.

As prescribed in 7.203, insert the following provision:

Economic Purchase Quantity—Supplies (Jul 1985)

(a) Offerors are invited to state an opinion on whether the quantity(ies) of supplies on which bids, proposals or quotes are requested in this solicitation is (are) economically advantageous to the Government.

_____

_____

_____

(b) Each offeror who believes that acquisitions in different quantities would be more advantageous is invited to recommend an economic purchase quantity. If different quantities are recommended, a total and a

unit price must be quoted for applicable items. An economic purchase quantity is that quantity at which a significant price break occurs and beyond which no substantial decrease would result. If there are significant price breaks at different quantity points, this information is desired as well.

OFFEROR RECOMMENDATIONS

Item	Quantity	Price quotation	Total

(c) The information requested in this provision is being solicited to avoid acquisitions in disadvantageous quantities and to assist the Government in developing a data base for future acquisitions of these items. However, the Government reserves the right to amend or cancel the solicitation and resolicit with respect to any individual item in the event quotations received and the Government's requirements indicate that different quantities should be acquired.

(End of provision)

9. Section 52.209–1 is revised to read as follows:

52.209–1 Qualification Requirements.

As prescribed in 9.206–2(a), insert the following provision:

Qualification Requirements (Jul 1985)

(a) Definition: "Qualification requirement," as used in this provision, means a requirement for testing or other quality assurance demonstration that must be completed by an offeror before award of a contract.

(b) This solicitation identifies those supplies or services to which a qualification requirement applies. The Contracting Officer will make awards for those supplies or services requiring qualification only if the offered product, manufacturer, or offeror has demonstrated that it meets the standards prescribed for qualification. The product, manufacturer, or offeror must be qualified by the time of award whether or not the name of the product, manufacturer, or offeror is actually included on a qualified products list, qualified manufacturers list, or qualified bidders list. Offerors should contact the agency activity designated below to obtain all requirements that they or their products must satisfy to become qualified and to arrange for an opportunity to demonstrate their abilities to meet the standards specified for qualification.

(Name) _____

(Address) _____

(c) If an offeror or its product has already met the qualification requirement, the applicable information noted below should be provided.

Offeror's Name _____

Manufacturer's Name _____

Item Name _____

Test Number _____

(to the extent known)

(d) If an offeror or its product has met the qualification requirement but is not yet on a qualified products list, qualified manufacturers list, or qualified bidders list, the offeror shall submit evidence of qualification with its offer in order to receive consideration. If this is a sealed bid acquisition and the product, manufacturer or offeror that is already qualified or is to be qualified before award is not identified, either above or elsewhere in the bid, the Contracting Officer will reject the bid. Unless determined to be in the Government's interests, this acquisition will not be delayed in order to provide an offeror with an opportunity to meet the standards specified for qualification.

(e) Any change in location or ownership of the plant where a previously qualified product was manufactured requires reevaluation of the qualification. Similarly, any change in location or ownership of a previously qualified manufacturer or offeror requires reevaluation of the qualification. The reevaluation must be accomplished before the date of award.

(End of provision)

10. Section 52.209–2 is revised to read as follows:

52.209–2 Qualification Requirements—Components of End Items.

As prescribed in 9.206–2(b), insert the following clause:

Qualification Requirements—Components of End Items (Jul 1985)

(a) Definition: "Qualification requirement," as used in this clause, means a requirement for testing or other quality assurance demonstration that must be completed before award of subcontracts or before beginning manufacture of certain components of end items covered by this contract.

(b) If any of the end items to be acquired by the Government will contain one or more components that are subject to a qualification requirement, the components or their manufacturers must demonstrate their abilities to meet the standards specified for qualification before the Contractor awards any subcontract for the components. If the Contractor plans to manufacture components, the Contractor shall have demonstrated its ability to meet the standards specified for qualification before beginning to manufacture the components. The components need not be qualified before the manufacture of the prototype, preproduction model, or first article, for qualification testing.

(c) Unless required for interchangeability or compatibility, the Contractor shall not cite brand names from any qualified products list or qualified manufacturers list in any subcontractor solicitation, but shall refer to the pertinent specification in order to obtain optimum competition.

(d) Delay resulting from the Contractor's awaiting qualification approval by the Government of a component or its manufacturer shall not constitute excuseable delay when a previously qualified component could have been acquired in time to meet the end item delivery schedule.

(e) Any change in location or ownership of the plant where a previously qualified product was manufactured requires reevaluation of whether the standards specified for qualification are still met. The reevaluation must be completed before the award of any subcontract for the components or before beginning the manufacture of the components.

(End of clause)

[FR Doc. 85–20781 Filed 8–29–85; 8:45 am]

BILLING CODE 6820–61–M