PROTECTION OF HUMAN SUBJECTS (JUL 2009)

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

(1) *Assurance of compliance* means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

(2) *Human Research Protection Official (HRPO)* means the individual designated by the head of the applicable DoD component and identified in the component's Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

(3) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (32 CFR 219.102(f)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

(4) *Institution* means any public or private entity or agency (32 CFR 219.102(b)).

(5) *Institutional Review Board (IRB)* means a board established for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

(6) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) *Research* means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).

(b) The Contractor shall oversee the execution of the research to ensure compliance with this clause. The Contractor shall comply fully with 32 CFR Part 219 and DoD Directive 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.

(c) The Contractor shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

(1) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, an assurance of compliance and IRB approval and receives notification from the Contracting Officer that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Contractor may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Contractor shall notify the Contracting Officer immediately of any suspensions or terminations of the assurance.

(2) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the Contracting Officer that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Contractor's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the contract.

(d) DoD staff, consultants, and advisory groups may independently review and inspect the Contractor's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

(e) Failure of the Contractor to comply with the requirements of this clause will result in the issuance of a stop-work order under Federal Acquisition Regulation clause 52.242–15 to immediately suspend, in whole or in part, work and further payment under this contract, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Contracting Officer.

(f) The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Directive 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.

(End of clause)

[FR Doc. E9–17949 Filed 7–28–09; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 217 and 252

RIN 0750–AG29

Defense Federal Acquisition Regulation Supplement; Requirements Applicable to Undefinitized Contract Actions (DFARS Case 2008–D029)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD has issued a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to address requirements for DoD management and oversight of undefinitized contract actions, consistent with the provisions of Section 809 of the National Defense Authorization Act for Fiscal Year 2008.

DATES: *Effective Date:* July 29, 2009.

FOR FURTHER INFORMATION CONTACT: Ms. Cassandra Freeman, Defense Acquisition Regulations System, OUSD (AT&L) DPAP (DARS), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone 703–602–8383; facsimile 703–602–7887. Please cite DFARS Case 2008–D029.

SUPPLEMENTARY INFORMATION:

A. Background

Section 809 of the National Defense Authorization Act for Fiscal Year 2008 (Pub. L. 110–181) required DoD to issue guidance to ensure the implementation and enforcement of requirements applicable to undefinitized contract actions. On August 29, 2008, the Director, Defense Procurement and Acquisition Policy, issued a memorandum to DoD departments and agencies as required by Section 809 of Public Law 110–181. This final rule amends the DFARS to address the requirements of the August 29, 2008 memorandum, specifically, requirements for DoD departments and agencies to submit semi-annual reports regarding undefinitized contract actions exceeding $5 million; for obligation of funds for the undefinitized period consistent with the contractor's proposal for that period; and for compliance with existing DFARS policy relating to profit computation for undefinitized contract actions.

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

This rule will not have a significant cost or administrative impact on contractors or offerors, or a significant effect beyond the internal operating procedures of DoD. Therefore, publication for public comment under 41 U.S.C. 418b is not required. However, DoD will consider comments from small entities concerning the affected DFARS subparts in accordance with 5 U.S.C. 610. Such comments should cite DFARS Case 2008–D029.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply, because the rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 217 and 252

Government procurement.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

■ Therefore, 48 CFR parts 217 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR Parts 217 and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 217—SPECIAL CONTRACTING METHODS

■ 2. Section 217.7404–4 is amended by designating the existing text as paragraph (a) and adding paragraph (b) to read as follows:

217.7404–4 Limitations on obligations.

* * * * *

(b) In determining the appropriate amount to obligate, the contracting officer shall assess the contractor's proposal for the undefinitized period and shall obligate funds only in an amount consistent with the contractor's requirements for the undefinitized period.

■ 3. Section 217.7404–6 is revised to read as follows:

217.7404–6 Allowable profit.

When the final price of a UCA is negotiated after a substantial portion of the required performance has been completed, the head of the contracting activity shall ensure the profit allowed reflects—

(a) Any reduced cost risk to the contractor for costs incurred during contract performance before negotiation of the final price;

(b) The contractor's reduced cost risk for costs incurred during performance of the remainder of the contract; and

(c) The requirements at 215.404–71–3(d)(2). The risk assessment shall be documented in the contract file.

217.7405 [Redesignated as 217.7406]

■ 4. Section 217.7405 is redesignated as section 217.7406.

■ 5. A new section 217.7405 is added to read as follows:

217.7405 Plans and reports.

(a) To provide for enhanced management and oversight of UCAs, departments and agencies shall—

(1) Prepare and maintain a Consolidated UCA Management Plan; and

(2) Prepare semi-annual Consolidated UCA Management Reports addressing each UCA with an estimated value exceeding $5 million.

(b) Consolidated UCA Management Reports and Consolidated UCA Management Plan updates shall be submitted to the Office of the Director, Defense Procurement and Acquisition Policy, by October 31 and April 30 of each year in accordance with the procedures at PGI 217.7405.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.217–7027 [Amended]

■ 6. Section 252.217–7027 is amended in the introductory text by removing ''217.7405'' and adding in its place ''217.7406''.

[FR Doc. E9–17947 Filed 7–28–09; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 225 and 252

RIN 0750–AG31

Defense Federal Acquisition Regulation Supplement; Trade Agreements—Costa Rica and Peru (DFARS Case 2008–D046)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule with request for comments.

SUMMARY: DoD has issued an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement the Dominican Republic-Central America-United States Free Trade Agreement with respect to Costa Rica, and the United States-Peru Trade Promotion Agreement. The trade agreements waive the applicability of the Buy American Act for some foreign supplies and construction materials and specify procurement procedures designed to ensure fairness.

DATES: *Effective date:* July 29, 2009.

Comment date: Comments on the interim rule should be submitted in writing to the address shown below on or before September 28, 2009, to be considered in the formation of the final rule.

ADDRESSES: You may submit comments, identified by DFARS Case 2008–D046, using any of the following methods:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

○ *E-mail: dfars@osd.mil.* Include DFARS Case 2008–D046 in the subject line of the message.

○ *Fax:* 703–602–7887.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Amy Williams, OUSD (AT&L) DPAP (DARS), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062.

○ *Hand Delivery/Courier:* Defense Acquisition Regulations System, Crystal Square 4, Suite 200A, 241 18th Street, Arlington, VA 22202–3402.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, 703–602–0328.

SUPPLEMENTARY INFORMATION

A. Background

This interim rule amends trade agreement provisions and clauses in DFARS Part 252 to implement the Dominican Republic-Central America-United States Free Trade Agreement with respect to Costa Rica, and the United States-Peru Trade Promotion Agreement. Congress approved these trade agreements in the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act (Pub. L. 109–53) and the United States-Peru Trade Promotion Agreement Implementation Act (Pub. L. 110–138) (19 U.S.C. 3805 note). Presidential proclamations were published in the **Federal Register** on December 30, 2008, with regard to Costa Rica (73 FR 79585) and on January 22, 2009, with regard to Peru (74 FR 4105). The corresponding determinations by the Office of the United States Trade Representative were published in the **Federal Register** on January 6, 2009 (74 FR 472), and