

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 48 CFR Chapter 3

#### Health and Human Services Acquisition Regulation

**AGENCY:** Department of Health and Human Services.

**ACTION:** Issuance of direct final rule and opportunity for comment.

**SUMMARY:** The Department of Health and Human Services (HHS) is revising its Federal Acquisition Regulation (FAR) Supplement—the HHS Acquisition Regulation (HHSAR) in its entirety to reflect statutory, FAR, and government-wide and HHS policy changes since the last revision to the HHSAR in December 2006.

**DATES:** Comments are due on or before December 28, 2009. If HHS does not receive adverse comments, this direct final rule will be effective on January 26, 2010.

**ADDRESSES:** You may submit comments, identified by docket number or RIN number and title, by any of the following four methods:

- *Access the Federal eRulemaking Portal:* [<http://www.regulations.gov>], and follow the instructions;
- *Mail them to:* Cheryl Howe, Procurement Analyst, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition, Room 336–E, Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201;
- *E-mail them to* [cheryl.howe@hhs.gov](mailto:cheryl.howe@hhs.gov); or
- *Via facsimile to* 202–690–8772.

Due to potential delays in receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments electronically to ensure timely receipt. HHS cannot guarantee that comments mailed will be received before the comment closing date.

If providing comments via e-mail, please include “HHS Acquisition Regulation” in the subject line of your e-mail message. Also, please include the full body of your comments in the text of the electronic message, as well as in an attachment, and include your name, title, organization, postal address, telephone number, and e-mail address in the text of the message.

**Instructions:** All comments or submissions must include the agency name and docket number or Regulatory Information Number (RIN) for this

Federal Register document. The policy is to make comments and other submissions available for public viewing on the Internet at <http://regulations.gov>. These submissions are published just as they are received without changes or deletions of information, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:** Cheryl Howe, Procurement Analyst, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition, telephone (202) 690–5552.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Department of Health and Human Services (HHS) is revising the entire HHSAR (48 CFR chapter 3, parts 301 through 370) to reflect changes since the last revision was published in the **Federal Register** in December 2006. The decision to revise the document in its entirety is based on the number of changes rather than their collective substance.

The amendments generally fall into several categories: (1) Changes to make the document easier to read; (2) changes to reflect internal procedural matters which are administrative in nature and which will not have a major effect on the general public or on contractors or offerors supporting HHS acquisition programs; (3) changes which HHS previously issued on an interim basis (and posted on its publicly available Web site), following coordination with the HHS Operating Divisions’ (OPDIVs) Heads of Contracting Activity; (4) changes that involve implementation of statutes or government-wide mandates enacted or issued since December 2006; (5) necessary conforming changes, such as addition of new or revised definitions; and (6) deletion of outdated material.

The majority of the HHSAR revisions fall into the first category, *i.e.*, they are editorial and include (1) using plain English, such as using active rather than passive voice; (2) standardizing terminology usage and formatting; (3) making minor adjustments to reflect current internal coordination procedures among departmental organizations; (4) citing current titles for various acquisition officials and organizations; and (5) providing a table that specifies the abbreviations and acronyms commonly used throughout the HHSAR.

##### II. Summary of Key Changes

The following summarizes changes that involve implementation of statutes or government-wide mandates enacted or issued since December 2006. The editorial changes are not individually summarized.

###### A. Federal-Wide and HHS Acquisition Certification Programs

The HHSAR coverage in Subpart 301.6 of requirements for training and certification of acquisition officials, as well appointment of Contracting Officers, has been rewritten to reflect the HHS implementation of the Federal Acquisition Certification Programs for contracting staff (FAC–C) (based on guidance provided by the Office of Federal Procurement Policy (OFPP) in April, 2005); Contracting Officer’s Technical Representatives (FAC–COTR) (based on the government-wide COTR certification standards established by OFPP in November, 2007), and Program/Project Managers (FAC–P/PM) (in response to the Services Acquisition Reform Act of 2003 (SARA), Public Law 108–136, and the requirements established by OFPP in April, 2007).

Implementation of the FAC–COTR program also has resulted in HHS changing the terminology it uses to describe the official who represents the requiring office after award. Where previously, HHS used only one term—Project Officer—to signify the person responsible for the pre-award and post-award responsibilities of the requiring office, the HHSAR now distinguishes between the pre-award responsibilities of the Project Officer and the post-award responsibilities of the COTR, even if the same individual performs both sets of responsibilities.

These certification programs establish prerequisites for those who seek certification, as well as for others involved in the acquisition process. For example, HHS added a new section 301.605, Contracting Officer designation of Contracting Officer Technical Representative, to specify Contracting Officer responsibilities for designation of a COTR, including documenting that a proposed COTR meets certification requirements.

Subpart 301 also addresses the HHS-unique simplified acquisition certification program (SAC–C); HHS-specific training requirements, including those for purchase card holders; and prerequisites and authorities for issuance of Contracting Officer warrants.

### *B. Improvements in the Quality of Contract Data*

Consistent with the statutory requirements of the Federal Funding and Transparency Act of 2006 (Pub. L. 109-282) and the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) and OFPP's initiative to improve the quality and timeliness of the award information stored in the Federal Procurement Data System—Next Generation, HHS is making efforts to improve the quality and timeliness of its contract data as reported in FPDS-NG, USA.Spending.gov, and Recovery.gov. To accomplish this, in Subpart 304.6, HHS has established clear lines of responsibility and accountability for the quality and timeliness of contract data.

### *C. Internal Initiatives To Provide Common Formats and Templates*

A new HHSAR Subpart—302.71—lists the areas where HHS has developed standards for documentation or approaches that provide consistency across the HHS OPDIVs. These internal business standards encompass: Acquisition planning, competition reporting, the organization and content of contract files, and market research notices.

### *D. Homeland Security Presidential Directive-12 (HSPD-12)*

A new Subpart 304.13, *Personal Identity Verification*, and section 304.1300, *Policy*, have been added to implement HSPD-12 in HHS. The HHS implementation includes applicable solicitation provisions and contract clauses and (1) reflects the implementing guidance established by Office of Management and Budget Memoranda M-05-24 and M-06-18, Federal Information Processing Standard (FIPS) Publication 201, and Federal Acquisition Regulation (FAR) 4.13; and (2) provides a consistent and systematic approach to ensure the security of HHS facilities and information systems.

### *E. Competition and Acquisition Planning*

Consistent with government-wide efforts to increase competition, in Parts 306, 307, and 308, as applicable, HHS included HHSAR coverage concerning (1) appropriate use of sources sought notices (Research and development (R&D) and non-R&D and small businesses) and requests for information (2) content requirements for Justifications for Other Than Full and Open Competition (JOFOCs) and Limited Source Justifications (LSJs), (3) the requirement to use a standard JOFOC and LSJ format, and (4) the

Contracting Officer's approval authority for JOFOCs and LSJs for acquisitions exceeding \$100,000.

HHS also—

- Specified that each HHS OPDIV competition advocate must prepare an annual Competition Advocate Report; and provided a standard format for the report's preparation.
- Updated the requirements for preparing an Annual Acquisition Plan and provided a standard template for the plan's preparation.
- Established a standard format for development of an Acquisition Plan; and provided procedures for the plan's review, coordination, and approval.
- Addressed preparation and approval of a LSJ for acquisitions awarded under the General Services Administration multiple award schedule program; and provided a standard format for preparing an LSJ.
- Addressed preparation and approval of an acquisition strategy for major information technology capital investments and, as applicable, other major investments.

### *F. Section 508 Electronic Information Technology Accessibility Standards*

In a new Subpart 315.70, HHS added coverage for acquisition of electronic information technology (EIT) products and services to implement the requirements of Section 508 of the Rehabilitation Act of 1973 [29 U.S.C. 794(d)], as amended by the Workforce Investment Act of 1998. In that subpart and, as a result of conforming changes in other parts of the HHSAR, HHS established a policy preference for commercially available products; indicated what must be addressed in solicitations, contracts, and orders, and added documentation and contract administration requirements that relate to the Section 508 accessibility standards and requirements.

### *G. Multi-Year Contracting and Awards Made During a Continuing Resolution*

HHS added a new Subpart 317.1 to address its policy on multi-year contracting and amended Subpart 332.7 to provide coverage regarding awards made during a continuing resolution.

### *H. Multi-Agency and Intra-Agency Contracts*

HHS added a new subpart 317.70 to address its expectations regarding the use of intra-agency and multi-agency contracts. Such contracting has been the subject of audit scrutiny and has been addressed by OFPP. As a result, to avoid possible misuse, HHS is stating the

conditions for use of such vehicles within HHS.

### *I. Green Purchasing Requirements*

HHS added a new subpart 323.71 to establish its requirements for green purchasing.

### *J. Earned Value Management*

HHS added a new Subpart 334.2 to implement the FAR coverage of earned value management (EVM), including: Use of full and partial EVM; use of solicitation provisions and contract clauses addressing documentation offerors must provide to demonstrate compliance with EVM system requirements; and criteria for use of pre-award or post-award integrated baseline reviews.

### *K. Other Changes*

Under section 331.101-70, *Salary Rate Limitation*, HHS provided a revised prescription for use of, and made minor revisions to, the Salary Rate Limitation clause in 352.231-70.

HHS added the following coverage in Part 339 for information technology-related acquisition:

- A new subpart, 339.70, to address the use of General Services Administration Blanket Purchase Agreements for the acquisition of independent risk analysis services, and
- A new subpart 339.1 that provides standards for security configuration, encryption, and information security.

HHS revised the coverage in Part 333 related to internal handling of protests to specify revised legal review, concurrence, and approval procedures related to protests to HHS and the Government Accountability Office before and after award.

HHS added language in section 319.270-1 concerning use of the mentor-protégé program in HHS.

HHS added a new subpart 322.8 to provide a contract clause regarding contractor cooperation in equal employment opportunity investigations.

HHS added a new subpart 370.6 to provide guidance, including a contract clause, concerning conference funding, sponsorship, and disclaimers.

HHS added a new subpart 370.7 to provide a solicitation provision and a contract clause to be used (i) in connection with the implementation of HIV/AIDS programs under the President's Emergency Plan for AIDS Relief; or (ii) when the contractor will receive funding under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003.

### III. Procedural Review Requirements

#### A. Executive Order 12866, Regulatory Planning and Review

It has been determined that this revision of the HHSAR is not a significant regulatory action. The rule does not—

(1) Have an annual effect on the economy of \$100 million or more or adversely affect, in a material way, the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

#### B. Unfunded Mandates Reform Act [2 U.S.C. 1501(7)]

It has been certified that this revision of the HHSAR does not contain a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

#### C. Regulatory Flexibility Act (5 U.S.C. 601)

The Regulatory Flexibility Act requires that a Federal agency prepare a regulatory flexibility analysis for any rule for which the agency is required to publish a general notice of rulemaking. This rule consists of a general statement of policies and procedures and amends HHS regulations for contracts. Each part of today's direct final rule is exempt from the requirement to publish a general notice of proposed rulemaking under the Administrative Procedure Act, 5 U.S.C. 553(a)(2). Therefore, the Regulatory Flexibility Act does not apply to this rulemaking.

#### D. Paperwork Reduction Act (44 U.S.C. 35)

It has been determined that this rule does not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act beyond those provided in the FAR.

#### E. Small Business Regulatory Enforcement Fairness Act

As required by the Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. 801, HHS has determined that this rule is not a major rule under 5 U.S.C. 801(2).

#### F. Executive Order 12988, Civil Justice Reform

Each agency promulgating new regulations shall adhere to the following requirements: The agency's proposed regulations shall (1) be reviewed by the agency to eliminate drafting errors and ambiguity; (2) be written to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. HHS determined that this rule meets these standards.

#### List of Subjects in 48 CFR Chapter 3, Parts 301–370

Government procurement.

■ For the reasons stated in the preamble, HHS revises 48 CFR Chapter 3, parts 301 through 370, to read as follows:

#### Title 48—Federal Acquisition Regulations System

#### CHAPTER 3—HEALTH AND HUMAN SERVICES

##### SUBCHAPTER A—GENERAL

PART 301—HHS ACQUISITION REGULATION SYSTEM  
 PART 302—DEFINITIONS OF WORDS AND TERMS  
 PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST  
 PART 304—ADMINISTRATIVE MATTERS

##### SUBCHAPTER B—COMPETITION AND ACQUISITION PLANNING

PART 305—PUBLICIZING CONTRACT ACTIONS  
 PART 306—COMPETITION REQUIREMENTS  
 PART 307—ACQUISITION PLANNING  
 PART 308—REQUIRED SOURCES OF SUPPLIES AND SERVICES  
 PART 309—CONTRACTOR QUALIFICATIONS  
 PART 310—MARKET RESEARCH  
 PART 311—DESCRIBING AGENCY NEEDS  
 PART 312—ACQUISITION OF COMMERCIAL ITEMS

##### SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

PART 313—SIMPLIFIED ACQUISITION PROCEDURES  
 PART 314—SEALED BIDDING  
 PART 315—CONTRACTING BY NEGOTIATION  
 PART 316—TYPES OF CONTRACTS  
 PART 317—SPECIAL CONTRACTING METHODS

##### SUBCHAPTER D—SOCIOECONOMIC PROGRAMS

PART 319—SMALL BUSINESS PROGRAMS

PART 322—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS  
 PART 323—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE  
 PART 324—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

##### SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS

PART 327—PATENTS, DATA, AND COPYRIGHTS  
 PART 328—BONDS AND INSURANCE  
 PART 330—COST ACCOUNTING STANDARDS  
 PART 331—CONTRACT COST PRINCIPLES AND PROCEDURES  
 PART 332—CONTRACT FINANCING  
 PART 333—PROTESTS, DISPUTES, AND APPEALS

##### SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING

PART 334—MAJOR SYSTEM ACQUISITION  
 PART 335—RESEARCH AND DEVELOPMENT CONTRACTING  
 PART 337—SERVICE CONTRACTING—GENERAL  
 PART 339—ACQUISITION OF INFORMATION TECHNOLOGY

##### SUBCHAPTER G—CONTRACT MANAGEMENT

PART 342—CONTRACT ADMINISTRATION

##### SUBCHAPTER H—CLAUSES AND FORMS

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES  
 PART 353—FORMS

##### SUBCHAPTERS I, J, K AND L ARE RESERVED

##### SUBCHAPTER M—HHS SUPPLEMENTATIONS

PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

##### SUBCHAPTER A—GENERAL

##### PART 301—HHS ACQUISITION REGULATION SYSTEM

##### Subpart 301.1—Purpose, Authority, and Issuance

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 301.103 Authority.  
 301.106 Office of Management and Budget Approval under the Paperwork Reduction Act.

**Subpart 301.2—Administration**

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**Subpart 301.4—Deviations From the FAR**

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301.607-72 Applicability.  
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301.607-74 Certification transfers.  
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301.607-76 FAC-P/PM application process.  
301.607-77 Input and maintenance of FAC-P/PM information.  
301.607-78 Governance.  
301.607-79 Contracting Officer designation of a Program/Project Manager as the Contracting Officer's Technical Representative.  
301.608 Training Requirements for Purchase Cardholders, Approving Officials, and Agency/Organization Program Coordinators.

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

**Subpart 301.1—Purpose, Authority, and Issuance**

**301.101 Purpose.**

(a) The Department of Health and Human Services (HHS) Acquisition Regulation (HHSAR) establishes uniform HHS acquisition policies and procedures that conform to the *Federal Acquisition Regulation (FAR)* System.  
(b) The HHSAR implements *FAR* policies and procedures and provides additional policies and procedures that supplement the *FAR*.  
(c) The HHSAR contains HHS policies and procedures that govern the acquisition process or otherwise control acquisition relationships between HHS' contracting activities and contractors.

**301.103 Authority.**

(b) The Assistant Secretary for Financial Resources (ASFR) prescribes the HHSAR under the authority of 5 U.S.C. 301 and section 205(c) of the *Federal Property and Administrative Services Act of 1949*, as amended (40 U.S.C. 486(c)), as delegated by the Secretary.  
(c) The HHSAR is issued in the Code of Federal Regulations (CFR) as *Chapter 3 of Title 48, Department of Health and Human Services Acquisition Regulation*. It may be referenced as "48 CFR Chapter 3."

**301.106 Office of Management and Budget approval under the Paperwork Reduction Act.**

(a) The Paperwork Reduction Act of 1980 (44 U.S.C 3501 *et seq.*) imposes a requirement on Federal agencies to obtain approval from the Office of Management and Budget (OMB) before collecting the same information from 10 or more members of the public.  
(b) The following OMB control numbers apply to the information collection and recordkeeping requirements contained in this chapter:

HHSAR segment No.	OMB control No.
315.4 .....	0990-0139
342.7101 .....	0990-0131
352.233-70 .....	0990-0133
352.270-1 .....	0990-0129
352.270-2 .....	0990-0129
352.270-3 .....	0990-0129
352.270-5 .....	0990-0130
352.270-8 .....	0990-0128
352.270-9 .....	0990-0128
370.1 .....	0990-0129
370.2 .....	0990-0129

(c) The Contracting Officer shall insert the clause in 352.201-70, Paperwork Reduction Act, in solicitations, contracts, and orders that include a

requirement to collect the same information from 10 or more persons.

**Subpart 301.2—Administration**

**301.270 Executive Committee for Acquisition.**

(a) The Associate Deputy Assistant Secretary for Acquisition (Associate DAS for Acquisition) has established the Executive Committee for Acquisition (ECA) to facilitate the planning, development, and implementation of HHS acquisition policies and procedures and to share successful acquisition practices.

(b) The ECA consists of members and alternates from the following organizations:

- (1) ASFR/Office of Grants and Acquisition Policy and Accountability (OGAPA)/Division of Acquisition (DA).
- (2) Agency for Healthcare Research and Quality (AHRQ).
- (3) Biomedical Advanced Research and Development Authority (BARDA).
- (4) Centers for Disease Control and Prevention (CDC).
- (5) Centers for Medicare and Medicaid Services (CMS).
- (6) Food and Drug Administration (FDA).
- (7) Health Resources and Services Administration (HRSA).
- (8) Indian Health Service (IHS).
- (9) National Institutes of Health (NIH).
- (10) Program Support Center (PSC).
- (11) Substance Abuse and Mental Health Services Administration (SAMHSA).

(c) The Associate DAS for Acquisition is the Chair of the ECA. The Chair will call all meetings and direct all ECA activities.

**Subpart 301.4—Deviations From the FAR**

**301.403 Individual deviations.**

Contracting activities shall prepare requests for individual deviations to either the *FAR* or HHSAR in accordance with 301.470.

**301.404 Class deviations.**

Contracting activities shall prepare requests for class deviations to either the *FAR* or HHSAR in accordance with 301.470.

**301.470 Procedure.**

(a) Contracting activities shall prepare deviation requests in memorandum form and forward them through the Head of the Contracting Activity (HCA) to the Associate DAS for Acquisition. The Associate DAS for Acquisition (non-delegable) is the official authorized to approve all deviation requests.

Contracting activities may request a deviation telephonically or by e-mail in an exigent situation, but shall confirm the request by memorandum as soon as possible.

(b) A deviation request shall clearly set forth the—

(1) Nature of the deviation, including what contract(s)/contractor(s) is involved;

(2) Identification of the *FAR* or HHSAR citation from which the deviation is needed;

(3) Circumstances under which the deviation will be used;

(4) Intended effect of the deviation;

(5) Period of applicability;

(6) Rationale for the deviation (**NOTE:** The Contracting Officer shall include a copy of pertinent background papers, such as a contractor's request, as part of the deviation request.); and

(7) Suggested wording for the deviation, if applicable.

### Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

#### 301.602 Contracting Officers.

##### 301.602-3 Ratification of unauthorized commitments.

(b) Policy.

(1) The Government is not bound by agreements with, or contractual commitments made to, prospective contractors by individuals who do not have delegated contracting authority. However, an authorized official may later ratify and execute otherwise proper contracts that were made by individuals without contracting authority or by Contracting Officers in excess of their delegated authority. The ratification shall be in the form of a written document that clearly states that ratification of a previously unauthorized act is intended.

(2) The HCA is the official authorized to ratify an unauthorized commitment—but see paragraph (b)(3) of this section.

(3) The HCA may redelegate ratification authority for actions up to \$100,000 to the Chief of the Contracting Office (CCO). No other redelegations are authorized.

(c) Limitations.

(5) The concurrence of legal counsel concerning an unauthorized commitment is optional. If a contracting activity determines that a legal review is necessary, the HCA or CCO shall coordinate the request for ratification with the Office of General Counsel (OGC), General Law Division (GLD).

(e) Procedures.

(1) The individual who is responsible for the unauthorized commitment shall provide the reviewing Contracting

Officer all records and documents concerning the commitment and a complete written statement of facts, including a description of the requirement; the estimated or agreed upon price; the funds citation; an explanation of why the contracting office was not used and why the proposed contractor was selected; a list of other sources considered; and a statement as to whether the contractor has commenced work or an item has been delivered.

(2) The Contracting Officer shall review the submitted material and, if the Contracting Officer determines that the ratification request has merit, prepare it for ratification. The Contracting Officer shall forward the ratification document and related materials to the HCA or CCO, as appropriate, with any comments or information which the approving official should consider in evaluating the ratification request.

(3) If the HCA or CCO approves the ratification request, the Contracting Officer shall issue a purchase order or contract, as appropriate, upon return of the approved ratification document and file.

##### 301.603 Selection, appointment, and termination of appointment of Contracting Officers.

###### 301.603-1 General.

(a) The HCA (non-delegable) shall select, appoint, and terminate the appointment of Contracting Officers—*i.e.*, those individuals who are authorized to obligate the Government to the expenditure of funds for contracts and orders with dollar values that exceed (or are expected to exceed) the micro-purchase threshold. The procedures for selecting and appointing Contracting Officers apply to HHS employees. HCAs may not issue HHS Contracting Officer warrants to contractor personnel. OPDIVs shall follow local procedures in the event that the signature of another authorized official, in addition to that of the HCA, is required to appoint or terminate the appointment of Contracting Officers.

(b) The HCA shall use *Standard Form (SF) 1402*, "Certificate of Appointment," (also known as a warrant) to appoint personnel, whether in the General Schedule (GS) 1102 series or other series, as Contracting Officers. The SF 1402 shall indicate the Contracting Officer's warrant level—*i.e.*, maximum dollar signature authority (*e.g.*, \$1 million or "unlimited") and any other limitations or restrictions. The HCA shall make changes to a Contracting Officer appointment (other than a

termination of an appointment as provided in *301.603-4*) by issuing a revised SF 1402. *FAR 1.603-1* prescribes the requirements for preparing and maintaining Contracting Officer warrants.

(c) Before an HCA may appoint an individual as a Contracting Officer, the individual must be certified in accordance with either the Federal Acquisition Certification in Contracting (FAC-C) program or the HHS Simplified Acquisition Certification (SAC) program, as appropriate, at the level required for the warrant authority requested. See *301.603-72* and the HHS Contracting Workforce Training and Certification Handbook.

(d) The dollar amount of an individual transaction determines whether a Contracting Officer has the authority to sign it in accordance with the delegated authority specified on the SF 1402. For new or follow-on awards, the dollar amount of an individual transaction is the amount obligated at the time of contract or order award plus any potential option amounts or future funding amounts established by the transaction. However, under an existing contract or order, when an option is subsequently exercised or a contract or order is otherwise modified to add funding, the dollar amount of the modification (individual transaction) determines whether a Contracting Officer has the necessary delegated authority to sign it.

(e) For individuals that will exercise acquisition authorities (other than solely purchase card authorities) at or below the micro-purchase threshold, the HCA may—

(1) Use a document other than the SF 1402, such as a memorandum, that indicates a maximum dollar signature authority for individual transactions; and

(2) Determine training requirements for individuals who will exercise acquisition authorities at dollar levels below the micro-purchase threshold level.

###### 301.603-2 Selection and appointment.

Contracting activities shall provide nominations for appointment of Contracting Officers through appropriate acquisition channels to the HCA for review. The HCA shall appoint an individual as a Contracting Officer only when a valid organizational need is demonstrated and after considering such factors as volume of actions, complexity of work, and structure of the requesting organization. The HCA shall also ensure that a Contracting Officer candidate meets the FAC-C or HHS SAC certification requirements, as

appropriate. Consistent with *FAR 1.603-2*, the HCA shall determine the documentation required when the requested appointment and authority will not exceed the micro-purchase threshold.

#### **301.603-3 Interim appointments.**

If it is essential to appoint an individual as a Contracting Officer who does not yet fully meet the FAC-C or HHS SAC certification requirements for the signature authority sought, the HCA (non-delegable) may make an interim appointment for up to 2 years. If an extension of time has been granted, but the individual does not complete the certification requirements by the extended date, the HCA's approval for the interim appointment will automatically terminate on that date.

#### **301.603-4 Termination of appointments.**

The HCA shall terminate or revoke Contracting Officer appointments in accordance with *FAR 1.603-4*.

#### **301.603-70 Delegation of Contracting Officer responsibilities.**

(a) Contracting Officers may re-delegate their acquisition responsibilities that do not involve the obligation or deobligation of funds, but involve the expenditure of previously obligated funds (such as approval of contractor scientific meeting travel and subcontract consent) to acquisition staff (for example, those in the GS-1100 series) by means of a written memorandum that clearly delineates the delegation and its limits. *See 301.604* for responsibilities that Contracting Officers may delegate to technical personnel.

(b) Contracting Officers may designate individuals as ordering or approving officials to make purchases or place/approve orders under blanket purchase agreements (BPAs), indefinite-delivery, indefinite quantity (IDIQ) contracts, or other pre-established mechanisms. Ordering officials are not Contracting Officers.

#### **301.603-71 Waivers to warrant standards.**

There may be an unusual circumstance that requires issuance of a warrant to an individual who does not fully meet the FAC-C or HHS SAC certification program requirements. Contracting activities shall provide any request for a waiver of the FAC-C program requirements and policies in writing to the Senior Procurement Executive (SPE), through the HCA, for review and approval. The SPE (non-delegable) will either approve or disapprove in writing the request for waiver. The HCA (non-delegable) may

approve or disapprove a waiver of the HHS SAC program requirements.

#### **301.603-72 FAC-C and HHS SAC certification requirements.**

(a) The FAC-C certification program is available to all acquisition staff who are/will be involved as Contracting Officers or Contract Specialists in acquisitions exceeding the simplified acquisition threshold. Personnel who, as part of prior certification programs, have completed some or all of the required training or have attained certification thereunder are not required to re-take training courses, but shall follow FAC-C training requirements when considering additional or required core training, if needed. *See 301.603-74* for information regarding retention of certification, including the requirement to earn continuous learning points (CLPs). FAC-C certification also does not apply to—

- (1) The SPE;
- (2) Senior level officials responsible for delegating acquisition authority;
- (3) Personnel who are not in the GS-1102 series whose warrants are used to acquire emergency goods and services; or
- (4) Personnel who are not in the GS-1102 series whose warrants are so limited as to be outside the scope of this program, as determined by the Chief Acquisition Officer (CAO). (**Note:** The HHS CAO has determined that individuals with warrants which are limited to simplified acquisitions are deemed to be outside the scope of the FAC-C program.)

(b) HHS does not require personnel with Contracting Officer warrants issued prior to January 1, 2007 to be FAC-C certified unless they are seeking a change in authority on or after that date. Individuals applying for a new Contracting Officer warrant or an increase in warrant authority on or after January 1, 2007, regardless of GS series, *must* be FAC-C certified at the level appropriate for the warrant authority sought. To obtain an unlimited warrant, FAC-C Level III certification is required. (*Note:* New Contracting Officer warrants are defined in the Office of Federal Procurement Policy's (OFPP's) FAC-C memorandum, dated January 20, 2006, as warrants issued to employees for the *first time* at a department or agency.)

(c) The FAC-C certification is based on three sets of requirements: Education, training, and experience, and the requirements are cumulative—*i.e.*, an individual must meet the requirements of each previous certification level before attaining a higher level certification. The FAC-C certification requirements, including

additional HHS-specific training requirements for certain types of acquisitions, are specified in the HHS Contracting Workforce Training and Certification Handbook.

(d) HHS SAC certification is based on three sets of requirements: Training, experience, and satisfactory performance rating. Personnel who are involved in the award of simplified acquisitions must meet the appropriate HHS SAC certification requirements. (**Note:** While personnel who are FAC-C certified are not required to obtain HHS SAC certification in order to award simplified acquisitions, they should obtain appropriate training before doing so.) The HHS SAC certification requirements, including additional HHS-specific training requirements for certain types of acquisitions, are specified in the HHS Contracting Workforce Training and Certification Handbook.

#### **301.603-73 Additional HHS training requirements.**

HHS acquisition personnel are required to complete, as applicable, the additional training requirements specified below. These courses may be used as electives for the purpose of satisfying FAC-C requirements or as continuous learning for maintenance of FAC-C or SAC certifications.

(a) *Earned value management training.* Effective January 1, 2010, all personnel in the GS-1102 series who are responsible for, or may become responsible for, the award or administration of any contract to which earned value management (EVM) is applied pursuant to *334.201(a)* or *(b)* must successfully complete an EVM training course before they commence administration of the contract or are authorized to award the contract. After completion of the initial course, a refresher course is required every 2 years. This course is in addition to the training requirements for FAC-C certification at the specified levels. Determination of course suitability shall be made by the Operating Division (OPDIV) HCA, in conjunction with HHS' Office of the Chief Information Officer (OCIO) or Office of Facilities Management and Policy (OFMP), as appropriate. To be eligible, the basic and refresher courses must each be 8 hours or more in length.

(b) *Performance based acquisition training.* Effective January 1, 2010, all GS-1102s, who award or administer service contracts, are required to complete a Performance-Based Acquisition (PBA) course prior to assuming such responsibilities. Refresher training in PBA is required

every 4 years. To be eligible, a course must be 8 hours or more in length. Determination of course suitability shall be made by the HCA.

(c) *Federal appropriations law training.* Effective January 1, 2010, all GS-1102s and GS-1105s are required to complete both HHS University's classroom-based and on-line Federal appropriations law course, by January 1, 2011 (for current employees) and within 1 year of entering on duty (for new employees). Employees are required to take the HHS University on-line course as refresher training every year. Determination of course equivalency shall be made by the HCA.

(d) *Green purchasing training.* Effective January 1, 2010, all GS-1102s and GS-1105s are required to complete green purchasing training by January 1, 2011 (for current employees) and within 1 year of entering on duty (for new employees). Refresher training is required every 2 years. To be eligible, a course must be 4 hours or more in length. Determination of course suitability shall be made by the HCA.

(e) *Section 508 training.* Effective January 1, 2010 (or when the HHS Office on Disability so requires), all GS-1102s, GS-1105s, and GS-1106s who award or administer acquisitions that exceed the micro-purchase threshold and involve electronic information technology (EIT) products or services (subject to Section 508 of the Rehabilitation Act of 1973 and pertinent HHSAR provisions), must complete all applicable training courses sponsored by the HHS Office on Disability. For information on frequency, timing, and duration of the training requirement, personnel shall consult with the HHS Office on Disability.

(f) *Training policy exceptions.*

(1) *EVM training.* In the event that there is an urgent requirement for a Contracting Officer/Contract Specialist to award or administer a project to which EVM will be applied, and the individual has not yet met the EVM training requirement, the HCA (non-delegable) may authorize the individual to perform the position duties, provided that the individual meets the training requirement within 9 months from the date of assignment to the contract. If the individual does not complete the training requirement within 9 months, the HCA's approval for the individual's assignment to the contract will automatically terminate on that date. The Contract Specialist is not required to take the class as long as the Contract Specialist is working under the direction of a Contracting Officer who has taken an EVM course.

(2) *Other additional HHS training.* The HCA (non-delegable) may grant a time extension of up to 9 months to an individual to complete the PBA, Federal appropriations law, green purchasing, and Section 508 training requirements, including completion of refresher training. If the individual does not complete the training requirement within the extension period, the HCA's approval will automatically terminate on that date.

#### **301.603-74 Requirement for retention of FAC-C and HHS SAC certification.**

To maintain FAC-C certification, all warranted Contracting Officers, regardless of series, as well as Contract Specialists, must earn 80 CLPs every 2 years. To maintain HHS SAC certification, all individuals with delegated Contracting Officer authority, including those in the GS-1102, GS-1105, GS-1106, and non-1100 series, must earn a minimum of 40 hours (CLPs) every 2 years after completing all mandatory training requirements. FAC-C and HHS SAC certification will expire if the CLPs are not earned every 2 years (from the date of initial certification or re-certification) and, if applicable, may result in a loss of warrant authority. (Note: The certification programs' continuous learning requirement applies to all applicable personnel, including those who were certified under prior certification programs.)

#### **301.604 Training and certification of Contracting Officers' Technical Representatives.**

##### **301.604-70 General.**

In accordance with the Federal Acquisition Certification for Contracting Officers' Technical Representatives (FAC-COTR) program, HHS has established a training program for certification and designation of personnel as COTRs—see HHS' Federal Acquisition Certification for Contracting Officers' Technical Representative Program Handbook, dated January 2009, for information on the methods for earning FAC-COTR certification. See also 302.101(c) for further information regarding the definition of a COTR and when designation of a COTR is appropriate. All references to COTRs also apply to their alternates.

##### **301.604-71 HCA authorities and responsibilities.**

(a) HCAs are authorized to determine (1) equivalencies for the Basic Contracting Officer's Technical Representative Course; (2) course prerequisites; and (3) approve completion of CLP continuous learning activities, education, and training for

maintenance of COTR certification. This authority does not apply to EVM training—see 301.603-73. Course equivalencies must meet the Federal Acquisition Institute's (FAI's) required COTR competencies. HCAs may re-delegate the authorities in (1) and (2) to OPDIV Acquisition Career Managers (ACMs) or other comparable officials.

(b) In addition to the authorities specified in 301.604-71(a), HCAs or their designees (except where the authority is shown as non-delegable) are responsible for—

(1) Reviewing a candidate's qualifications to be a COTR;

(2) Granting, suspending, denying, and revoking COTR certifications and their continuance;

(3) Authorizing (non-delegable) an individual to perform COTR duties on an interim basis for up to 90 days—see 301.604-73; and

(4) Determining (non-delegable) on a case-by-case basis whether to postpone (for up to 90 days) withdrawal of any interim COTR delegation for failure of a candidate to qualify for certification—see 301.604-73.

##### **301.604-72 Requirements for certification maintenance.**

Maintaining HHS FAC-COTR certification requires at least 40 relevant CLPs every 2 years. See Appendix A of OFPP's FAC-COTR memorandum, dated November 26, 2007, and HHS' Federal Acquisition Certification for Contracting Officers' Technical Representative Program Handbook, dated January 2009, for information on CLPs.

##### **301.604-73 Certification policy exception.**

(a) In the event that an individual who is not currently certified under HHS' FAC-COTR program is urgently required to serve as a COTR, the head of the sponsoring program office (Program Manager) or designee (e.g., the immediate supervisor) may request, and the HCA (non-delegable) may authorize, the individual to perform the designated duties on an interim basis for up to 6 months, provided that—

(1) The individual agrees to become certified during that period and provides evidence of training course registration; and

(2) Prior to assignment to the contract, the individual meets with the cognizant Contracting Officer to discuss the role and specific responsibilities of a COTR and the interrelationships, as applicable, among the Project Officer, Contracting Officer, Program/Project Manager, and COTR functions.

(b) If an extension has been granted, but the individual does not complete



the training by the extended date, the HCA's approval for the individual's assignment to the contract will automatically terminate on that date.

**301.604–74 Additional COTR training requirements.**

HHS COTRs are required to complete, as applicable, the training requirements specified below.

(a) *Earned value management training.* Effective January 1, 2010, all COTRs assigned to any contract to which EVM is applied pursuant to 334.201(a) or (b) must successfully complete an EVM training course before assuming their COTR duties. In conjunction with ASFR/OGAPA/DA, HHS' OCIO [for information technology (IT)] and OFMP (for construction/facilities), are authorized to designate appropriate EVM courses. At least 8 hours of EVM training is required every 2 years.

(b) *Performance-based acquisition training.* Effective January 1, 2010, all COTRs assigned to a service contract are required to successfully complete a PBA course. To be eligible, a course must be 8 hours or more in length. Determination of course suitability shall be made by the HCA or designee. At least 8 hours of refresher training in PBA is required every 4 years.

(c) *Federal appropriations law training.* Effective January 1, 2010, all COTRs are required to successfully complete HHS University's classroom-based or on-line Federal appropriations law course within 3 years after an initial certification is issued. COTRs are required to take the HHS University on-line appropriations law course as refresher training every 4 years.

(d) *Green purchasing training.* Effective January 1, 2010, all COTRs are required to complete green purchasing training within the first certification period. The individual's immediate supervisor shall make the determination of course suitability. At least 4 hours of refresher training is required every 4 years.

(e) *Training policy exceptions.*

(1) *EVM training.* In the event that there is an urgent requirement for a COTR to administer a contract to which EVM will be applied, and the individual has not yet met the EVM training requirement, the HCA (non-delegable) may authorize the individual to perform the position duties, provided that the individual meets the training requirement within 9 months from the date of assignment to the contract. If the individual does not complete the training requirement within 9 months, the HCA's approval for the individual's assignment to the contract will

automatically terminate on that date. In addition, during any extension period, the COTR must work under the direction of a COTR, or Program/Project Manager who has taken an EVM course.

(2) *Other additional HHS training.* The HCA (non-delegable) may grant a time extension of up to 9 months to a COTR to complete the PBA, Federal appropriations law, and green purchasing training requirements, including completion of refresher training. If the individual does not complete the training requirement within the extension period, the HCA's approval will automatically terminate on that date.

**301.605 Contracting Officer designation of Contracting Officer Technical Representative.**

The Contracting Officer shall ensure that a COTR candidate is currently certified under HHS' FAC-COTR program before delegating authority to that individual to act as a COTR. Even if an individual is FAC-COTR-certified, a candidate becomes a COTR only when a Contracting Officer provides in writing the authorities the individual may exercise for a specified contract or order. Authority for such designations rests solely with the Contracting Officer. The Contracting Officer shall retain in the contract or order file the individual's active FAC-COTR certificate. In the event that the HCA has granted an exception—see 301.604–73, the Contracting Officer shall include the HCA's approval in the file.

**301.606 Training requirements for Project Officers.**

**301.606–70 General.**

HHS has established a program for training personnel for certification and designation as Project Officers. See 302.101(g) for further information regarding the definition of a Project Officer and when designation of a Project Officer is appropriate. All references to Project Officers also apply to their alternates. Program Managers or their designees are authorized to designate individuals to serve as Project Officers. (Note: If an individual will also serve as the COTR for a proposed project, the individual shall comply with the training certification requirements for COTRs—see 301.604.)

**301.606–71 Project Officer training.**

Before an individual may perform the duties of a Project Officer, including development of an Acquisition Plan (AP) or other acquisition request documentation—see 307.71, for a proposed project, the Program Manager or designee shall designate an

individual as a Project Officer in writing by means of a memorandum to the Project Officer candidate with a copy to the cognizant Contracting Officer. A Project Officer must successfully complete HHS University's Basic Contracting Officer's Technical Representative Course or equivalent and any OPDIV-specific course prerequisites. The Project Officer must provide a course completion certificate to the Contracting Officer with any AP or other acquisition request documentation submitted. See HHS guidance on the training requirement for technical proposal evaluators in 315.305(a)(3)(ii).

**301.606–72 Delegation of authority to HCAs.**

HCAs are authorized to determine equivalencies for the Basic Contracting Officer's Technical Representative Course and any OPDIV-specific course prerequisites. This authority may be re-delegated to OPDIV acquisition ACMs or other comparable officials.

**301.606–73 Training policy exception.**

(a) In the event that an individual who has not successfully completed the required training course is urgently required to serve as a Project Officer, the Program Manager or designee may authorize the individual to perform the designated duties on an interim basis for up to 6 months, provided that—

(1) The individual agrees to take the Basic Contracting Officer's Technical Representative course during that period and provides evidence of course registration; and

(2) The individual meets, prior to assignment to the project, with the cognizant Contracting Officer to discuss the specific role and responsibilities of a Project Officer and the interrelationships, as applicable, among the Project Officer, Contracting Officer, Program/Project Manager, and COTR functions.

(b) If an extension of time has been granted, but the individual fails to complete the training by the extended date, the Program Manager's or designee's approval for the individual's assignment to the project will automatically terminate on that date.

**301.606–74 Additional Project Officer training requirements.**

HHS Project Officers are required to complete, as applicable, the training requirements specified below.

(a) *Earned value management training.* All Project Officers assigned to any contract project to which EVM is applied pursuant to 334.201(a) or (b) must successfully complete an EVM



training course before assuming their Project Officer duties. In conjunction with ASFR/OGAPA/DA, HHS' OCIO (for IT) and OFMP (for construction/facilities) are authorized to designate appropriate EVM courses.

(b) *Performance-based acquisition training.* Effective January 1, 2010, all Project Officers assigned to a service contract are required to successfully complete a PBA course. To be eligible, a course must be 8 hours or more in length. Determination of course suitability shall be made by the HCA or designee. At least 8 hours of refresher training in PBA is required every 4 years.

(c) *Federal appropriations law training.* Effective January 1, 2010, all Project Officers are required to successfully complete HHS University's classroom-based or on-line Federal appropriations law course. Project Officers are required to take the HHS University on-line appropriations law course as refresher training every 4 years.

(d) *Green purchasing training.* Effective January 1, 2010, all Project Officers are required to complete green purchasing training. The individual's immediate supervisor shall make the determination of course suitability. At least 4 hours of refresher training is required every 4 years.

(e) *Training policy exceptions.*

(1) *EVM training.* In the event that there is an urgent requirement to assign a Project Officer to a contract project to which EVM will be applied, and the individual has not yet met the EVM training requirement, the HCA (non-delegable) may authorize the individual to perform the position duties, provided that the individual meets the training requirement within 3 months from the date of submission of the AP or other acquisition request documentation to the contracting office. If the individual does not complete the training requirement within the extension period, the HCA's approval for the individual's assignment to the project will automatically terminate on that date. In addition, during any extension period, the Project Officer must work under the direction of a Project Officer, COTR, or Program/Project Manager who has taken an EVM course.

(2) *Other additional HHS training.* The HCA (non-delegable) may grant a time extension of up to 9 months to a Project Officer to complete the PBA, Federal appropriations law, and green purchasing training requirements, including completion of refresher training. If the individual does not complete the training requirement within the extension period, the HCA's

approval will automatically terminate on that date.

**301.607 Certification of Program and Project Managers.**

**301.607-70 General.**

In accordance with the Federal Acquisition Certification—Program and Project Managers (FAC-P/PM) program, HHS has established a certification program for Program or Project Managers. See HHS' Federal Acquisition Certification—Program and Project Managers Handbook (P/PM Handbook) for information on the methods for earning FAC-P/PM certification.

**301.607-71 FAC-P/PM levels and requirements.**

(a)(1) The FAC-P/PM certification program specifies three different levels of certification, depending on the core competency, training, and experience required to manage different types of acquisitions—

- (i) Entry/Apprentice—Level I;
- (ii) Mid-level/Journeyman—Level II; and
- (iii) Senior/Expert—Level III.

(2) Each FAC-P/PM certification level is independent of the others—*i.e.*, applicants for the Senior/Expert level need not have been certified at the Mid-level/Journeyman or Entry/Apprentice levels. General and specific core competencies, training, and required experience vary by certification level. (*Note:* Individuals certified under the FAC-P/PM program meet the general competency and experience standards for P/PM certification. However, IT Program and Project Managers should attain/demonstrate IT-specific P/PM requirements. See Appendix C, Federal Acquisition Certification—Program and Project Managers—Information Technology Technical Competencies, in the P/PM Handbook for additional information.

(b)(1) *Competencies.* An applicant can satisfy the competency requirements through:

- (i) Successful completion of training;
- (ii) Completion of comparable education or certification programs;
- (iii) Demonstration of knowledge, skills, and abilities; or
- (iv) Any combination of these three.

(2) The FAI describes the following three sets of general core competencies on its Web site:

(3) *General Business Competencies:* Includes decision-making, interpersonal skills, oral communication, team-building, and writing.

(4) *Technical Competencies:* Includes contracting, financial management, quality assurance, and risk management.

(5) *Essential Competencies and Proficiencies:* Includes management processes, systems engineering, test and evaluation, contracting, and business.

(6) Specific core competencies also apply to the three certification levels. See Chapter 2, Federal Acquisition Certification—Program and Project Managers—Requirements and Performance Accountability, in the P/PM Handbook for additional information.

(c) *Training.* (1) Suggested training includes coursework, varying from 16–24 hours in duration, in:

- (i) Acquisition;
- (ii) Project management;
- (iii) leadership and interpersonal skills;
- (iv) Government-specific training; and
- (v) Earned value management and cost estimating.

(2) The depth of the training for each course required may vary by certification level.

(d) *Experience.* Experience requirements vary by certification level. For example, for certification at the Entry/Apprentice—Level I, at least 1 year of project management experience within the last 5 years is required. The Mid-level/Journeyman—Level II requires at least 2 years of program or project management experience within the last 5 years. The Senior/Expert—Level III requires at least 4 years of program and project management experience on *Federal* projects within the last 5 years.

(e) *Additional OPDIV guidance.* OPDIVs may issue supplemental guidance and requirements for selection and assignment of Program and Project Managers and require additional skills and competencies to meet organizational or mission needs. However, OPDIVs may not reduce the requirements specified in the P/PM Handbook.

**301.607-72 Applicability.**

(a) The FAC-P/PM certification prerequisites and continuous learning requirements apply to all HHS employees who seek to obtain a FAC-P/PM certification. Although obtaining a FAC-P/PM certification qualifies employees to serve as a Program or Project Manager, it does not ensure their selection or designation as such. (*Note:* Contractors and their employees are not eligible to be certified or to serve as Program or Project Managers.)

(b) Mandatory certification is limited to major and non-major IT and construction capital investment acquisitions. Consistent with OFPP guidance, HHS requires FAC-P/PM Level III certification for Program and

Project Managers responsible for major IT and construction capital investments—*i.e.*, those requiring preparation of an OMB Exhibit 300, HHS Form 300, or equivalent. An individual must obtain FAC–P/PM Level III certification within 1 year from the date of being assigned to such a major capital investment. Also, HHS requires that an individual obtain FAC–P/PM Level II or I certification for non-major IT and construction—*i.e.*, tactical or supporting, capital investments, respectively, within 2 years from the date of being assigned to such a non-major capital investment. *See* Appendix A, Federal Acquisition Certification—Program and Project Managers—HHS Projects and Programs with Associated Certification Levels, in the P/PM Handbook for additional information regarding major and non-major IT and construction capital investments. FAC–P/PM certification for other types of investments [*e.g.*, advanced research and development (R & D)] is encouraged, but is not mandatory.

#### **301.607–73 Certification waivers.**

(a) Waivers to certification requirements may be approved in certain situations. Waivers for additional time to complete certification requirements are not necessary for the first year following an assignment to a major IT or construction capital investment and for 2 years following an assignment to a non-major capital investment. For waivers beyond those periods (for up to 1 additional year), the HHS Chief Information Officer (CIO) (for IT programs and projects) and the Deputy Assistant Secretary for Facilities Management and Policy (DASfMP) (for construction programs and projects) are delegated authority to approve waiver requests. The HHS CAO is the only individual authorized to approve waiver requests for additional time beyond the initial 1-year waiver period.

(b) Approval of a waiver request does not relieve an individual from meeting the certification requirements. Also, unlike FAC–P/PM certifications, waivers issued by other Federal departments and agencies do not transfer to HHS, since a waiver is agency-specific.

#### **301.607–74 Certification transfers.**

(a) HHS recognizes and accepts FAC–P/PM certifications issued by other Federal departments and agencies. In addition, HHS complies with FAI determinations as to which certifications by organizations outside the Federal government are eligible for full or partial consideration under FAC–P/PM. *See* FAI's Web site, and Chapter

3, Federal Acquisition Certification—Program and Project Managers—Application and Certification Procedures, in the P/PM Handbook for additional information.

(b) A certification transfer should not be initiated when an individual, who holds a current FAC–P/PM certification from another Federal department or agency, becomes an HHS employee. Instead, the individual must apply for recertification (which will result in issuance of an HHS certification) at the time the candidate's immediate supervisor performs the bi-annual assessment to determine whether the individual has met the HHS FAC–P/PM CLP requirements.

#### **301.607–75 Maintenance of FAC–P/PM certification.**

(a) FAC–P/PM certification lasts for 2 years. To maintain FAC–P/PM certification, HHS Program and Project Managers are required to earn 80 CLPs of skills currency every 2 years, starting from the date of their initial certification or recertification, and document completion of all training. If the required CLPs are not earned within each 2-year period, a FAC–P/PM certification will lapse. Lapsed certifications may be reinstated when 80 CLPs have been accumulated.

(b) Continuous learning activities related to FAC–P/PM include, but are not limited to—

(1) Training activities, such as teaching, self-directed study, and mentoring;

(2) Courses completed to achieve certification at the next higher level;

(3) Professional activities, such as attending/speaking/presenting at professional seminars/symposia/conferences, publishing papers, and attending workshops;

(4) Educational activities, such as formal training and formal academic programs; and

(5) Experience, such as developmental or rotational assignments.

*See* Appendix F, Federal Acquisition Certification—Program and Project Managers—Guidance on Meeting Requirements for Continuous Learning Points, in the P/PM Handbook for additional information.

#### **301.607–76 FAC–P/PM application process.**

The P/PM Handbook contains application procedures and forms to be completed for basic certification; certification transfer; certification through fulfillment; recertification; and certification waiver. Applicants for HHS FAC–P/PM certification actions shall comply with the requirements and

procedures specified in the P/PM Handbook and refer any questions to their OPDIV ACM for resolution.

#### **301.607–77 Input and maintenance of FAC–P/PM information.**

FAI's Acquisition Career Management Information System (ACMIS) is HHS' system of record for the FAC–P/PM program. Program and Project Manager candidates and certified Program and Project Managers are responsible for entering, maintaining, and updating their FAC–P/PM training and CLP data in ACMIS. OPDIV ACMs shall periodically review ACMIS records for quality assurance purposes.

#### **301.607–78 Governance.**

The Departmental ACM, in ASFR/OGAPA/DA, serves as the Departmental FAC–P/PM Program Manager and is responsible for administering the program. To support the overall management of the FAC–P/PM certification program at the OPDIV level, Executive Officers and their HCAs may either use their existing ACM or designate an additional ACM, whose professional background includes program and project management. *See* Appendix B, Federal Acquisition Certification—Program and Project Managers—Roles and Responsibilities, in the P/PM Handbook for additional information.

#### **301.607–79 Contracting Officer designation of a Program/Project Manager as the Contracting Officer's Technical Representative.**

Personnel who are FAC–P/PM certified, at any level, meet the requirements for FAC–COTR certification and are, therefore, not required to obtain FAC–COTR certification to serve as a COTR for an HHS acquisition. However, for those individuals serving as a Program or Project Manager under a FAC–P/PM certification waiver—*see* 301.607–73, the Contracting Officer shall ensure that the individual meets the requirements of HHS' FAC–COTR program before delegating authority to that individual to act as a COTR. *See* 301.605 for additional information regarding the Contracting Officer's designation of a COTR.

#### **301.608 Training Requirements for Purchase Cardholders, Approving Officials, and Agency/Organization Program Coordinators.**

Training requirements for purchase cardholders, Approving Officials, and Agency/Organization Program Coordinators are listed in the following table:

HHS PURCHASE CARD TRAINING PROGRAM, BY AUTHORITY LEVEL

Authority <sup>a</sup>	Program participant	Required training <sup>b</sup>
Up to \$3,000 .....	Prospective/newly appointed purchase cardholders and Approving Officials.	Basic purchase card training (HHS University course or an OPDIV equivalent course). Yearly refresher purchase card training.
\$3,001 to \$25,000 .....	Purchase card holders and Approving Officials ..... Prospective/newly appointed purchase cardholders and Approving Officials.	<ul style="list-style-type: none"> <li>• Basic purchase card training (HHS University course or an equivalent).</li> <li>• Basic simplified acquisition procedures (e.g., DAU's CON 237).</li> <li>• Advanced simplified acquisition procedures or Appropriations law.</li> </ul>
\$25,001 to \$100,000 .....	Purchase card holders and Approving Officials ..... Prospective/newly appointed purchase cardholders and Approving Officials.	<ul style="list-style-type: none"> <li>• Basic purchase card training (HHS University course or an OPDIV equivalent course).</li> <li>• Basic simplified acquisition procedures (e.g., DAU's CON 237).</li> <li>• Advanced simplified acquisition procedures or Appropriations law.</li> <li>• CON 100 (Shaping Smart Business Arrangements).</li> <li>• CON 110 (Mission Support Planning).</li> </ul>
Not applicable .....	Purchase cardholders and Approving Officials ..... Prospective/newly appointed Agency/Organization Program Coordinators.	<ul style="list-style-type: none"> <li>• Basic purchase card training (HHS University course or an OPDIV equivalent course).</li> <li>• Basic simplified acquisition procedures or DAU's CON 237.</li> <li>• Advanced simplified acquisition procedures or appropriations law.</li> <li>• CON 100 (Shaping Smart Business Arrangements).</li> <li>• CON 110 (Mission Support Planning).</li> </ul>
	Agency/Organization Program Coordinators .....	Yearly refresher purchase card training (attendance at GSA's annual training conference satisfies refresher training).

<sup>a</sup> Cardholders and Approving Officials with authorized increases in delegation of procurement authority (DPA) have up to 3 months to complete the training requirements for the new DPA.  
<sup>b</sup> CON 237, CON 100, and CON 110 are available at the DAU Web site at <http://www.dau.mil/registrar/enroll.asp>. CON 100 is also offered through HHS University (see Web site at: <http://learning.hhs.gov>).

**PART 302—DEFINITIONS OF WORDS AND TERMS**

**Subpart 302.1—Definitions**

Sec.  
302.101 Definitions.

**Subpart 302.2—Definitions Clause**

302.201 Contract clause.

**Subpart 302.70—Common HHSAR Acronyms and Abbreviations**

302.7000 Common HHSAR acronyms and abbreviations.

**Subpart 302.71—HHS Standard Templates and Formats**

302.7100 HHS standard templates and formats.

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

**Subpart 302.1—Definitions**

**302.101 Definitions.**

(a) *Agency head or head of the Agency*, unless otherwise stated, means the head of the OPDIV for: AHRQ; CDC; CMS; FDA; HRSA; IHS; NIH; SAMHSA; and ASFR for the Office of the Secretary (OS), including PSC. The Assistant Secretary for Preparedness and Response (ASPR) is the head of the agency for BARDA contracting functions.

(b) *Chief of the Contracting Office* is typically a mid-level management official, usually an office director, division director, or branch chief, who manages and monitors the daily contract operations of an OPDIV or major component of an OPDIV. The CCO is subordinate to the HCA, except where the same individual is the HCA and CCO.

(c) *Contracting Officer's Technical Representative* is a Federal employee whom a Contracting Officer has designated in writing to act as the Contracting Officer's representative in monitoring and administering specified aspects of contractor performance *after* award of a contract or order that exceeds the simplified acquisition threshold. (Note: In accordance with local procedures, OPDIVs may designate COTRs for contracts or orders estimated to be less than the simplified acquisition threshold.) These activities may include verifying that:

- (1) The contractor's performance meets the standards set forth in the contract;
- (2) The contractor meets the contract/order's technical requirements by the specified delivery date(s) or within the period of performance; and

(3) The contractor performs within the fixed price or cost ceiling stated in the contract or order. COTRs must meet the training and certification requirements specified in 301.604.

(d) *Head of the contracting activity* is an official who has overall responsibility for managing a contracting activity—i.e., the organization within an OPDIV or other HHS organization which has been delegated broad authority regarding the conduct of acquisition functions.

(1) The HHS HCAs are as follows:

- AHRQ: Director, Division of Contracts Management
- BARDA: Director, Acquisition Management System
- CDC: Director, Procurement and Grants Office
- CMS: Director, Office of Acquisition and Grants Management
- FDA: Director, Office of Acquisitions and Grant Services
- HRSA: Director, Office of Acquisition Management and Policy
- IHS: Director, Division of Acquisition Policy
- NIH: Director, Office of Acquisition and Logistics Management
- PSC: Director, Strategic Acquisition Service
- SAMHSA: Director, Division of Contracts Management

(2) Each HCA shall conduct an effective and efficient acquisition program; establish adequate controls to ensure compliance with applicable laws, regulations, procedures, and the dictates of good management practices; and conduct periodic reviews to evaluate and determine the extent of adherence to prescribed policies and regulations and the need for guidance and training.

(3) HCAs may redelegate their authorities to the extent that redelegation is not prohibited by the terms of their respective delegations of authority, by law, by the FAR, by the HHSAR, or by other regulations. To ensure proper control of redelegated acquisition authorities, HCAs shall maintain a file containing successive delegations of HCA authority through the Contracting Officer level.

(e) *Program Manager* is a Federal employee whom an OPDIV official or designee one level above the head of the sponsoring program office has designated in writing to act as a Program Manager for a group of related major or non-major IT or construction capital investments—see HHS FAC-P/PM Program Handbook. See also Appendix D, Relationship between Program Management and Project Management, of OFFP memorandum entitled “The Federal Acquisition Certification for Program and Project Managers,” dated April 25, 2007. Program Managers must meet the FAC-P/PM certification requirements in 301.607. A Program Manager may also be delegated authority to act as the COTR for a major or non-major IT or construction capital investment—see 301.604.

(f) *Project Manager* is a Federal employee whom a head of the

sponsoring program office (Program Manager) or designee has designated in writing to act as a Project Manager for a major or non-major IT or construction capital investment—see HHS FAC-P/PM Program Handbook. See also Appendix D, Relationship between Program Management and Project Management, of OFFP memorandum entitled “The Federal Acquisition Certification for Program and Project Managers,” dated April 25, 2007. Project Managers must meet the FAC-P/PM certification requirements in 301.607. A Project Manager may also be delegated authority to act as the COTR for a major or non-major IT or construction capital investment—see 301.604.

(g) *Project Officer* is a Federal employee whom a head of the sponsoring program office (Program Manager) or designee has designated in writing to act as a Project Officer and provide guidance, information, and assistance to the Contracting Officer for all technical aspects of a proposed project before award of a contract or order that is estimated to exceed the simplified acquisition threshold. (Note: In accordance with local procedures, OPDIVs may designate Project Officers for contracts or orders estimated to be less than the simplified acquisition threshold.) Project Officers must meet the training requirements in 301.606. Project Officers are often delegated authority to also act as the COTR on a contract or order—see 301.604.

**Subpart 302.2—Definitions Clause**

**302.201 Contract clause.**

The Contracting Officer shall insert the clause in FAR 52.202-1, Definitions, in solicitations and contracts, except as

cited below. This is an authorized FAR deviation.

(a) In accordance with FAR 52.202-1(a)(1), the Contracting Officer shall insert paragraph (a) in 352.202-1 in place of paragraph (a) of the FAR clause.

(b) In accordance with FAR 52.202-1(a)(1), the Contracting Officer shall insert paragraph (b), or its alternate in 352.202-1, to the end of the FAR clause. The Contracting Officer shall insert paragraph (b) when a fixed-priced contract is contemplated and the alternate to paragraph (b) when a cost-reimbursement contract is contemplated.

**Subpart 302.70—Common HHSAR Acronyms and Abbreviations**

**302.7000 Common HHSAR acronyms and abbreviations.**

(a) The HHSAR cites numerous acquisition-related and organizational acronyms and abbreviations. Each of these is established where first cited in the text, following the use of the unabbreviated term, and are used in subsequent subparts of that part or any other part of the HHSAR.

(b) The table below cites, for reference purposes, the most commonly used acronyms and abbreviations—i.e., those that have applicability to multiple parts of the HHSAR, and where they are first cited. They are listed alphabetically. The HHSAR also contains other acronyms and abbreviations, which because they are cited only in one HHSAR part, subpart, section, or in reference to a particular topic, are not listed in the table. An example is DCIS (Departmental Contracts Information System) cited in subpart 304.602.

Acronym/abbreviation	Term	Where first cited in the HHSAR
A & E	Architect and engineer (contracts)	304.803-70(b).
AHRQ	Agency for Healthcare Research and Quality	301.270(b).
AP	Acquisition Plan	301.606-71.
ASFR	Assistant Secretary for Financial Resources (in OS)	301.103(b).
Associate DAS for Acquisition	Associate Deputy Assistant Secretary for Acquisition (in OS/ASFR/OGAPA/DA)	301.270(a).
BARDA	Biomedical Advanced Research and Development Authority	301.270(b).
BPA or BPAs	Blanket Purchase Agreement(s)	301.603-70(b).
CA	Competition Advocate	306.202(a).
CAO	Chief Acquisition Officer (for HHS)	301.603-72(a)(4).
CCO	Chief of the Contracting Office	301.602-3(b)(3).
CDC	Centers for Disease Control and Prevention	301.270(b).
CFR	Code of Federal Regulations	301.103(c).
CIO	Chief Information Officer (for HHS)	301.607-73(a).
CMS	Centers for Medicare and Medicaid Services	301.270(b).
COTR	Contracting Officer's Technical Representative	301.604-70.
D&F	Determination and Findings	306.202(b)(1).
DA	Division of Acquisition (in ASFR) in OS	301.270(b).
DASFMP	Deputy Assistant Secretary for Facilities Management and Policy	301.607-73(a).
DAS/GAPA	Deputy Assistant Secretary for Grants and Acquisition Policy and Accountability.	309.403.
EIT	Electronic information technology	301.603-73(e).
EVM	Earned value management	301.603-73(a).

Acronym/abbreviation	Term	Where first cited in the HHSAR
FAR	Federal Acquisition Regulation	301.101(a).
FDA	Food and Drug Administration	301.270(b).
FedBizOpps	Federal Business Opportunities	305.205(a).
FSS	Federal Supply Schedule	304.803–70(b).
GLD	General Law Division (typically referred to with “OGC”)	301.602–3(c)(5).
GSA	General Services Administration	304.803–70(b).
GWAC	Government-wide acquisition contract	304.803–70(b).
HCA	Head of the Contracting Activity	301.470(a).
HHS	(Department of) Health and Human Services	301.101(a).
HHSAR	Health and Human Services Acquisition Regulation	301.101(a).
HRSA	Health Resources and Services Administration	301.270(b).
HUBZone	Historically Underutilized Business Zone	305.205(a)(2).
IDIQ	indefinite-delivery, indefinite-quantity (contract type)	301.603–70(b).
IHS	Indian Health Service	301.270(b).
IT	information technology	301.604–74(a).
JOFOC	Justification for Other than Full and Open Competition	306.303–1(b)(1).
NIH	National Institutes of Health	301.270(b).
OCIO	Office of the Chief Information Officer (for HHS)	301.603–73(a).
OFMP	Office of Facilities Management and Policy (for HHS)	301.603–73(a).
OGAPA	Office of Grants and Acquisition Policy and Accountability	301.270(b).
OGC	Office of the General Counsel	301.602–3(c)(5).
OIG	Office of the Inspector General	303.104–7(a)(2)(i).
OMB	Office of Management and Budget	301.106.
OPDIV	Operating Division	301.603–73(a).
OS	Office of the Secretary	302.101(a).
OSDBU	Office of Small and Disadvantaged Business Utilization (in OS)	307.104(a)(4).
Pub. L.	Public Law	304.604.
PWS	performance work statement (typically cited with SOW)	304.1300(c).
PSC	Program Support Center (in OS)	301.270(b).
R&D	research and development	301.607–72(b).
RFI	Request for Information	305.205(a).
SAMHSA	Substance Abuse and Mental Health Services Administration	301.270(b).
SBS	Small Business Specialist (in OSDBU)	307.104(a)(4).
SF	Standard Form	301.603–1(b).
SOW	statement of work [inclusive of specification(s)] and typically cited with PWS	304.1300(c).
SPE	Senior Procurement Executive—i.e., Associate DAS for Acquisition	301.603–71.
STAFFDIV	Staff Division (in OS)	311.7001(b).

**Subpart 302.71—HHS Standard Templates and Formats**

**302.7100 HHS standard templates and formats.**

HHS has developed standard templates and formats for preparation of

various acquisition documents, reports, and plans. The templates and formats, which contain instructions for their completion, may be accessed on the ASFR/OGAPA/DA Internet Web site. A complete listing of the standard

templates and formats and where they are referenced in the text are cited in the table below:

Title of template/format	HHSAR reference
Acquisition Plan	307.7103.
Acquisition Plan Waiver Request	307.7101(b)(2).
Acquisition Strategy	307.104–70.
Annual Acquisition Plan	307.104(a)(5).
Competition Advocate Report	306.502(b).
Contract File Checklists	304.803–70.
FedBizOpps R & D Sources Sought Notice	305.205(a)(3).
FedBizOpps Request for Information	315.201(e)(4).
FedBizOpps Small Business Sources Sought Notice	319.202–2(a)(3).
FedBizOpps Sources Sought Notice	310.001(a)(3)(iv).
Justification for Other than Full and Open Competition	306.303–1(b)(1).
Limited Source Justification	308.405–6(g)(1)(i).
Request for Information	315.201(e)(4).

**PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST**

**Subpart 303.1—Safeguards**

Sec.

- 303.101 Standards of conduct.
- 303.101–3 Agency regulations.
- 303.1047–7 Violations or possible violations of the Procurement Integrity Act.
- 303.1003 Requirements.

**Subpart 303.2—Contractor Gratuities to Government Personnel**

- 303.203 Reporting suspected violations of the Gratuities clause.

**Subpart 303.3—Reports of Suspected Antitrust Violations**

303.303 Reporting suspected antitrust violations.

**Subpart 303.4—Contingent Fees**

303.405 Misrepresentations or violations of the Covenant Against Contingent Fees clause.

**Subpart 303.6—Contracts With Government Employees or Organizations Owned or Controlled by Them**

303.602 Exceptions.

**Subpart 303.7—Voiding and Rescinding Contracts**

303.704 Policy.

**Subpart 303.8—Limitation on the Payment of Funds to Influence Federal Transactions**

303.808–70 Solicitation provision and contract clause.

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

**Subpart 303.1—Safeguards**

303.101 Standards of conduct.

303.101–3 Agency regulations.

(a)(3) The HHS Standards of Conduct are prescribed in 45 CFR part 73.

**303.104–7 Violations or possible violations of the Procurement Integrity Act.**

(a)(1) The Contracting Officer shall submit to the HCA for review and approval the determination (along with supporting documentation) that a reported violation or possible violation of the statutory prohibitions has no impact on the pending award or selection of a contractor for award.

(2) The Contracting Officer shall refer the determination that a reported violation or possible violation of the statutory prohibitions has an impact on the pending award or selection of a contractor, along with all related information available, to the HCA, if the HCA is in the Senior Executive Service (SES), or to another SES official designated by the OPDIV. That individual shall—

(i) Refer the matter immediately to the Associate DAS for Acquisition for review, who may consult with OGC–GLD and the Office of the Inspector General (OIG), as appropriate; and

(ii) Determine the necessary action in accordance with *FAR 3.104–7(c) and (d)*. The HCA shall obtain the approval or concurrence of the Associate DAS for Acquisition before proceeding with an action.

(b) The HCA (non-delegable) shall act with respect to actions taken under the FAR clause *52.203–10*, Price or Fee Adjustment for Illegal or Improper Authority.

**303.1003 Requirements.**

(b) The Contracting Officer, when notified of a possible contractor violation of Federal criminal law, in accordance with FAR 3.1003(b), shall—

(1) Notify the OIG at <http://www.oig.hhs.gov/fraud/hotline>, 1–800–HHS–TIPS (1–800–447–8477), or [HHSTips@oig.hhs.gov](mailto:HHSTips@oig.hhs.gov);

(2) Notify the HCA; and

(3) Cooperate with any investigation by the OIG; and in coordination with the HCA, OIG, OGC and the affected program office, pursue appropriate remedies.

(c)(2) The Contracting Officer shall specify the title of HHS' hotline poster ("Report Fraud") and the Web site where the poster can be obtained ([http://oig.hhs.gov/fraud/hotline/OIG\\_Hotline\\_Poster.pdf](http://oig.hhs.gov/fraud/hotline/OIG_Hotline_Poster.pdf)) in subparagraph (b)(3) of the clause at *FAR 52.203–14*.

**Subpart 303.2—Contractor Gratuities to Government Personnel****303.203 Reporting suspected violations of the Gratuities clause.**

HHS personnel shall report suspected violations of the Gratuities clause to the Contracting Officer, who will in turn report the matter to the OGC Ethics Division for disposition. The OGC Ethics Division shall identify, and notify the Contracting Officer of, the form and content of the required report.

**Subpart 303.3—Reports of Suspected Antitrust Violations****303.303 Reporting suspected antitrust violations.**

(h) The HCA shall provide a copy of the draft OPDIV report of suspected antitrust violations to the SPE. If the SPE concurs with the draft report, the SPE will provide it to the OGC–GLD for its review. If the OGC–GLD concurs with the draft report, the SPE will provide the signed OGC–approved report to the Attorney General.

**Subpart 303.4—Contingent Fees****303.405 Misrepresentations or violations of the Covenant Against Contingent Fees clause.**

(a) HHS personnel shall promptly report suspected misrepresentations or violations of the Covenant Against Contingent Fees clause to the Contracting Officer.

(b)(4) The HCA shall provide a copy of the draft OPDIV report of suspected covenant against contingency fees misrepresentations or violations to the SPE. If the SPE concurs with the draft report, the SPE will provide it to the OGC–GLD for its review. If the OGC–

GLD concurs with the draft report, the SPE will provide the signed OGC–approved report to the Attorney General.

**Subpart 303.6—Contracts With Government Employees or Organizations Owned or Controlled by Them****303.602 Exceptions.**

The HCA (non-delegable) is the official authorized to approve an exception to the policy stated in *FAR 3.601*.

**Subpart 303.7—Voiding and Rescinding Contracts****303.704 Policy.**

(a) For purposes of implementing *FAR subpart 3.7*, the HCA (non-delegable) shall exercise the authorities granted to the "agency head or designee."

**Subpart 303.8—Limitation on the Payment of Funds to Influence Federal Transactions****303.808–70 Solicitation provision and contract clause.**

The Contracting Officer shall insert the clause in *352.203–70*, Anti-lobbying, in solicitations and contracts that exceed the simplified acquisition threshold.

**PART 304—ADMINISTRATIVE MATTERS****Subpart 304.6—Contracting Reporting****Subpart 304.8—Government Contract Files**

Sec.

304.602 General.

304.604 Responsibilities.

304.803–70 Contract/order file organization and use of checklists.

304.804–70 Contract closeout audits.

**Subpart 304.13—Personal Identity Verification**

304.1300 Policy.

**Subpart 304.70—Acquisition Instrument Identification Numbering System**

304.7000 Scope of subpart.

304.7001 Numbering acquisitions.

**Subpart 304.71—Review and Approval of Proposed Contract Awards**

304.7100 Policy.

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

**Subpart 304.6—Contract Reporting****304.602 General.**

HHS' Departmental Contracts Information System (DCIS) captures and stores HHS' Individual Contract Award Reports (ICARs) and forwards copies of them to the Federal Procurement Data System—Next Generation (FPDS–NG).

All HHS contracting activities shall use the DCIS, in accordance with the most current version of the "User Manual for the Enhanced Departmental Contracts Information System," (DCIS Users' Manual) available at <http://dcis.hhs.gov>. For the purposes of this policy, reporting shall include inputting and submitting report data through DCIS into FPDS-NG.

**304.604 Responsibilities.**

In order for HHS to meet its reporting requirements and ensure compliance with the Federal Funding Accountability and Transparency Act (Transparency Act), Public Law (Pub. L.) 109-282, HHS acquisition officials and staff must report their contract information accurately and timely. Ensuring accuracy and timeliness also requires effective and efficient data verification and validation at the time of and following reporting.

Following are descriptions of the organizational roles and responsibilities associated with contract reporting, including data input, oversight, and quality control; training of acquisition staff on reporting responsibilities; and operating, managing, and maintaining DCIS.

(a) *ASFR/OGAPA/DA*. The ASFR/OGAPA/DA shall do the following:

- (1) Oversee and provide policy guidance for OPDIV contract reporting by—
  - (i) Establishing and implementing an effective HHS-wide ICAR data verification and validation program; and
  - (ii) Identifying cross-cutting trends through periodic testing of selected ICAR data, including Transparency Act data fields.
- (2) Ensure that DCIS is properly managed and maintained, including—
  - (i) Verifying that data included therein meets FPDS-NG and Transparency Act accuracy and timeliness standards;
  - (ii) Updating the DCIS Users' Manual periodically; and
  - (iii) Prescribing standard HHS-wide DCIS training.

(3) Certify annually that HHS ICAR information is complete and accurate.

(b) *HCA*. Each HCA (non-delegable) shall—

(1) Ensure that all reportable ICAR information is collected, submitted, and received within the time frames and under the circumstances specified in *FAR Subpart 4.6*.

**Note:** Each CCO shall prepare and submit accurate ICAR data in accordance with HCA guidance.;

(2) Provide continuing oversight, including implementing an OPDIV-level data verification and validation program, to ensure ICAR data quality and timeliness;

(3) Establish a continuous training program for acquisition staff to ensure the quality and timeliness of ICAR data; and

(4) Certify annually to HHS' SPE that OPDIV ICAR information is complete and accurate.

(c) *Contracting Officer*. As part of a normal file review, required under *304.7101*, the Contracting Officer shall—

(1) Ensure that all reportable contracts and orders, including BPA orders and modifications thereto, are reported;

(2) Review and approve proposed ICAR data for completeness and accuracy prior to signing contracts/orders and modifications; and

(3) Correct all DCIS data discrepancies before signing the associated contract, order, or modification.

(d) *OPDIV DCIS coordinator/focal point*. The OPDIV DCIS coordinator/focal point shall—

(1) Identify data errors and ensure their timely correction as part of the DCIS quality control process;

(2) Conduct remedial staff training, as appropriate, to improve data accuracy and timeliness; and

(3) Represent the OPDIV as a member of the DCIS Configuration Committee.

(e) *DCIS Configuration Committee*. The DCIS Configuration Committee is composed of the HHS DCIS manager, other ASFR/OGAPA/DA acquisition management staff, as required; and each

OPDIV's DCIS coordinator/focal point. The Committee shall ensure that the DCIS is properly maintained and shall evaluate and recommend changes to DCIS to improve its functionality, features, and quality control, as appropriate.

**Subpart 304.8—Government Contract Files**

**304.803-70 Contract/order file organization and use of checklists.**

(a) To provide a consistent approach to the organization and content of HHS contract and order files, OPDIVs shall use the folder filing system and accompanying file checklists specified in *304.803-70(b)*, in accordance with the guidance therein and the instructions specified as "Contract and Order File Folders, Checklists, and Instructions. The checklists are available on the ASFR/OGAPA/DA Internet.

(b) The checklist requirements apply to files for (i) negotiated, sealed-bid, and Architect-Engineer (A & E) acquisitions; (ii) orders awarded and BPAs established under General Services Administration (GSA) Federal Supply Schedule (FSS) contracts; (iii) orders placed under all types of indefinite-delivery contracts, including task orders under Government-wide Acquisition Contracts (GWACs); and (iv) modifications under the types of acquisitions specified in (i), (ii), and (iii). Simplified acquisitions, including those for commercial items, are exempt from these checklist requirements. However, HHS contracting activities shall adhere to the simplified acquisition file documentation and retention requirements of *FAR 13.106-3(b)*. For commercial item acquisitions using the negotiated or sealed bid methods, HHS contracting activities shall use the applicable checklist.

(1) A complete contract or order file may consist of the following folders that are titled as indicated below for the specified acquisition methods:

Acquisition method	Folder title	Folder title	Folder title	Folder title
Negotiated .....	Presolicitation to Award ....	Unsuccessful Proposals ....	Administration and Close-out.	Reports and Deliverables.
Sealed-bid .....	Presolicitation to Award ....	Unsuccessful Bids .....	Administration and Close-out.	N/A.
A & E .....	Preannouncement to Award.	Unsuccessful Qualifications Statements.	Administration and Close-out.	Reports and Deliverables.
Task orders .....	Presolicitation to Award ....	Unsuccessful Proposals ....	Administration and Close-out.	Reports and Deliverables.
GSA FSS .....	Presolicitation to Award ....	Unsuccessful Quotations/ Oral Presentations.	Administration and Close-out.	N/A.



(2) Although the use of the checklists is mandatory, each OPDIV contracting office is permitted to make certain checklist changes or additions as specified in "Use and modification of checklists" under "File checklists and tab dividers" in the instructions.

(3) OPDIVs using or planning to use electronic filing capabilities shall adhere to the folder and tab nomenclature requirements identified herein to the maximum extent practicable.

#### **304.804-70 Contract closeout audits.**

(a) Contracting Officers shall rely, to the maximum extent possible, on single audits to close physically completed cost-reimbursement contracts with colleges and universities, hospitals, non-profit organizations, and State and local governments. In addition, where appropriate, a sample of these contracts or an individual contract may be selected for audit, in accordance with paragraph (b) of this section.

(b) Contracting Officers shall request contract closeout audits on physically completed, cost-reimbursement, contracts with for-profit organizations in accordance with the following:

(1) The OIG and the Associate DAS for Acquisition, in conjunction with the OPDIV's cost advisory/audit focal point, determine which contracts or contractors will be audited, which audit agency will perform the audit, and the type and scope of closeout audit to be performed. These decisions are based on the needs of the customer, risk analysis, return on investment, and the availability of audit resources. When an audit is warranted prior to closing a contract, the Contracting Officer shall submit the audit request to the OIG's Office of Audit Services, through the OPDIV's cost advisory/audit focal point.

(2) Except where a Contracting Officer suspects misrepresentation or fraud, the Contracting Officer shall not request contract closeout field audits, if the cost of performance is likely to exceed the potential cost recovery. Contracting Officers may close contracts that are not selected for a field audit on the basis of a desk review, subject to any later on-site audit findings. In those situations, the release executed by the contractor shall contain the following statement: "The Contractor agrees, pursuant to the clause in this contract entitled "Allowable Cost" or "Allowable Cost and Fixed Fee," as appropriate, that it

will refund to the Government the amount of any sustained audit exceptions resulting from any audit made after final payment."

#### **Subpart 304.13—Personal Identity Verification**

##### **304.1300 Policy.**

(a) Definitions. The following definitions apply to this subpart:

(1) *Access*: "Physical" entry to and/or exit from a facility/area of a facility (such as a building or room in a building) or "logical" entry into an information system, such as a researcher up-loading data/information through a secure Web site or a contractor accessing an HHS-controlled information system from its own facility. It does not include access to a public Web site, whether by an HHS contractor or member of the public, because such Web sites do not require permission to access. In the case of sensitive data/information that exists in hard copy, "access" means providing a contractor the right to view or use written/typed data or information for the purpose described in a contract.

(2) *Long-term*: Greater than 6 months in duration.

(3) *Routine*: On a regular, non-intermittent basis, which is at least once per week during the contract or order period of performance.

(4) *Sensitive data/information*: As defined by the Computer Security Act of 1987, any data/information, "the loss, misuse, or unauthorized access to or modification of which, could adversely affect the national interest or the conduct of Federal programs, or the privacy to which individuals are entitled under section 552a of the Title 5 of U.S.C. (the Privacy Act), but which has not been specifically authorized under criteria established by an Executive order or an act of Congress to be kept secret in the interest of national defense or foreign policy." Examples include individuals' social security numbers; other personal identification information, such as individuals' health, medical, or psychological information; proprietary research data; and confidential legal data.

(5) *Short-term*: Six (6) months or less in duration.

(b) Homeland Security Presidential Directive (HSPD-12), entitled, "Policy for a Common Identification Standard for Federal Employees and Contractors,"

was issued on August 27, 2004, to enhance security and reduce identity fraud related to contractor physical access to Federally-controlled facilities and/or logical access to Federally-controlled information systems.

(1) The HSPD-12 requirements related to routine, long-term physical access to HHS-controlled facilities and logical access to HHS-controlled information systems, including contractor personnel background checks/investigations (termed herein as "more stringent" access procedures), apply to all solicitations and new contracts or orders for services, including services incidental to supply contracts/orders, regardless of dollar amount, where the contractor will require such access (*FAR* 4.1303). In addition, HHS has determined that, when a contractor has routine, long-term access to sensitive data/information, whether it exists in an HHS-controlled information system or in hard copy, that data/information must also be protected and controlled in accordance with HSPD-12's more stringent access procedures—see *304.1300(e)*.

(2) When a contractor's access to HHS-controlled facilities, information systems, and/or sensitive data/information is of routine but short-term duration, an OPDIV shall use the applicable guidance cited in OMB memorandum M-05-24 related to "short-term" access to determine appropriate protections and limit/control contractor access—see *304.1300(f)*. However, if the Project Officer determines greater access controls are necessary, an OPDIV may protect and control facilities, information systems, and/or sensitive data/information in accordance with HSPD-12's more stringent access procedures.

(3) When a contractor's access to HHS-controlled facilities, information systems, and/or sensitive data/information is not routine, regardless of duration, HHS has determined that OPDIVs shall use the applicable guidance cited in OMB memorandum M-05-24 related to "occasional visitors" to determine appropriate protections and limit/control contractor access—see *304.1300(g)*.

(4) *Summary table of contractor access circumstances and HSPD-12 requirements.*

Type of access	HSPD-12 access procedures required	HSPD-12 security notice required in solicitation/contract SOW/PWS? [see 304.1300(e)]
Routine, long-term, physical access to HHS-controlled facilities.	More stringent access procedures apply .....	YES.
Routine, long-term logical access to an HHS-controlled information system that does not contain sensitive HHS data/information.	More stringent access procedures apply .....	YES.
Routine, long-term access to sensitive HHS data/information, whether it exists in an HHS-controlled information system (logical access) or in hard copy.	More stringent access procedures apply .....	YES.
Routine, short-term access to HHS-controlled facilities, information systems, and/or sensitive HHS data/information.	If greater access controls are deemed necessary, more stringent access procedures apply.	YES.
If greater access controls are <i>not</i> deemed necessary, applicable guidance cited in OMB memorandum M-05-24 related to "short-term" access to determine appropriate protections and limit/control contractor access.	NO, but contractor staff must be provided with the OPDIV documentation on the rules of behavior and consequences for violation [see 304.1300(f)].	
Non-routine access, regardless of duration, to HHS-controlled facilities, information systems, and/or sensitive HHS data/information.	Applicable guidance cited in OMB memorandum M-05-24 related to "occasional visitors" to determine appropriate protections and limit/control contractor access.	NO, but contractor staff must be provided with the OPDIV "occasional visitor" policy and procedures [see 304.1300(g)].

(c) As part of the acquisition planning process, the Project Officer shall determine whether, based on the nature of the requirement, contractor personnel may require access to HHS-controlled facilities and/or information systems, including sensitive data/information, in order to perform the contract/order Statement of Work (SOW)/Performance Work Statement (PWS). If contractor access is required, the Project Officer must assess, based on information available at that point in the process, the type, frequency, and duration of such access. Following that determination, the Project Officer shall consult with OPDIV and/or local building and IT security officials/staff, and officials/staff involved with personnel security, including the designated personnel security representative, to determine appropriate security requirements and, as necessary, adjust project requirements to minimize security and access issues. The Project Officer shall comply with HSPD-12 and the following implementing guidance in making these judgments and determinations:

(1) OMB memorandum M-05-24, Implementation of Homeland Security Presidential Directive (HSPD) 12—Policy for a Common Identification Standard for Federal Employees and Contractors, dated August 5, 2005.

(2) National Institutes of Standards and Technology Federal Information Processing Standard Publication (FIPS PUB) 201, dated February 25, 2005, which can be accessed at: <http://csrc.nist.gov/publications/>.

(3) FAR (FAR 4.13 and 52.204-9).

(4) Any HHS and OPDIV implementation thereof.

(d) If, as part of the acquisition planning process, the Project Officer determines that contractor access will not be required, the Project Officer should so state in the AP (or other acquisition request document)—see 307.7101. If an AP does not address access issues or indicates contractor access is not required, and it appears an acquisition may involve access requirements, the Contracting Officer shall request that the Project Officer address or reconsider the initial access determination. The Project Officer's determination shall be final.

(e) If HSPD-12's more stringent access procedures are expected to apply, because access will be routine and of long-term duration, or is routine and of short-term duration, but greater access controls are deemed necessary, the Project Officer shall include the following "HHS-Controlled Facilities and Information Systems Security" notice in a separate, clearly designated "Security" section of the SOW/PWS. (Note: The Contracting Officer is responsible for tailoring the language in the solicitation and contract/order in accordance with the instructions provided below.)

"XXX Security.

**HHS-Controlled Facilities and Information Systems Security**

(a) To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3). (b) To gain routine physical access to an HHS

facility, logical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigation procedures contained in the following documents:

- (1) HHS Information Security Program Policy.
- (2) HHS Office of Security and Drug Testing, Personnel Security/Suitability Handbook, dated February 1, 2005.
- (3) HHS HSPD-12 Policy Document, v. 2.0.
- (4)

**Note:** Based upon information provided by the Project Officer, the Contracting Officer shall insert references to OPDIV and/or local procedural guideline(s), if any; indicate if they are readily accessible to the public; and, if so, specify where they may be found. If they are not readily accessible, the Contracting Officer shall attach a copy to the solicitation and contract and reference the guideline(s) here.

(c) This contract/order will entail the following position sensitivity level(s):

**Note:** At the time of solicitation, based upon information provided by the Project Officer, the Contracting Officer shall specify all known levels. If the position sensitivity levels are not known at that time, the Contracting Officer shall insert the words "To Be Determined at the Time of Award." However, the Contracting Officer must include the definitive position sensitivity levels in the awarded contract/order.

(d) The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type

of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions—*i.e.*, those above non-sensitive, require more extensive documentation and investigation.

**Note:** The Contracting Officer shall include the following sentence in each *solicitation* as the concluding sentence in paragraph (d): “As part of its proposal, and if the anticipated position sensitivity levels are specified in paragraph (c) above, the Offeror shall notify the Contracting Officer of (1) its proposed personnel who will be subject to a background check/investigation and (2) whether any of its proposed personnel who will work under the contract have previously been the subject of national agency checks or background investigations.”

(The Contracting Officer shall include the following sentence in each *contract/order* as the concluding sentence in paragraph (d) in lieu of the solicitation language: “The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.”)

(e) Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays—*see* FAR 52.249-14.

**Note:** The Contracting Officer shall include the following sentence in each *solicitation* as the concluding sentence in paragraph (e): “Accordingly, if position sensitivity levels are specified in paragraph (c), the Offeror shall ensure that the employees it proposes for work under this contract have a reasonable chance for approval.” The Contracting Officer shall include the following sentence in each *contract/order* as the concluding sentence in paragraph (e) in lieu of the solicitation language: “Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.”

(f) Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s).

(g) The Contractor shall include language similar to this “HHS-Controlled Facilities and Information Systems Security” language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

(h) The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

(i) Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.”

(f) When a contractor's access to HHS-controlled facilities, information systems, and/or sensitive data/information is of routine, but short-term duration, and greater access controls are not deemed necessary, the Contracting Officer and Project Officer shall use the applicable guidance cited in OMB memorandum M-05-24, dated August 5, 2005, specifically Attachment A, “HSPD-12 Implementation Guidance for Federal Departments and Agencies,” to ensure that—

(1) Adequate OPDIV access controls are applied, and a contractor is granted only limited/controlled access to facilities, systems, and/or sensitive data/information, consistent with the requirements of the acquisition;

(2) Contractor staff are provided with clear OPDIV documentation on the rules of behavior and consequences of their violation before being granted access to facilities, systems, and/or sensitive data/information;

(3) Contractor security violations are documented and reported to the appropriate OPDIV authority within 24 hours of their occurrence; and

(4) Identity credentials issued to contractor staff are visually and electronically distinguishable from credentials issued to individuals to whom the more stringent HSPD-12 access procedures apply.

**Note to paragraph (f):** However, as indicated in 304.1300(e), if the Project Officer determines greater access controls are necessary, an OPDIV may protect and control facilities, information systems, and/or sensitive data information in accordance with HSPD-12's more stringent access procedures.

(g) When a contractor's access to HHS-controlled facilities, information systems, and/or sensitive data/information is not routine, regardless of duration, the Contracting Officer and Project Officer shall use the applicable guidance cited in OMB memorandum M-05-24, dated August 5, 2005, specifically Attachment A, “HSPD-12 Implementation Guidance for Federal Departments and Agencies,” related to “occasional visitors” to determine appropriate protections and limit/control contractor access to ensure that—

(1) Adequate OPDIV access controls are applied, and the contractor is granted only limited/controlled access to facilities, systems, and/or sensitive

data/information, consistent with the requirements of the acquisition; and  
(2) OPDIV visitor policies, including contractor personnel identity badging requirements, are enforced and are provided to the contractor.

### Subpart 304.70—Acquisition Instrument Identification Numbering System

#### 304.7000 Scope of subpart.

This subpart prescribes policy and procedures for assigning identification numbers to contracts and related instruments, including solicitation documents, purchase orders, and delivery orders. The HCA (non-delegable) shall establish a numbering system within an OPDIV.

#### 304.7001 Numbering acquisitions.

(a) *Acquisitions which require numbering.* Contracting activities shall number the following acquisitions and related instruments in accordance with the system prescribed in paragraphs (b), (c) and (d) of this section:

(1) Contracts, including letter contracts, that exceed the micro-purchase threshold or the acquisition of personal property or nonpersonal services. (*Note:* The Contracting Officer shall also assign the letter contract number to the superseding definitized contract.)

(2) Basic ordering agreements (BOAs) and BPAs.

(3) Requests for proposals and invitations for bids.

(4) Requests for quotations.

(b) *Numbering system for contracts.* The Contracting Officer shall assign a number consisting of the following to all contracts which require numbering (paragraph (a)(1) of this section):

(1) The three-digit identification code (HHS) of the Department.

(2) A one-digit alphabetic identification code of the servicing agency.

AHRQ: A  
BARDA: O  
CDC: D  
CMS: M  
FDA: F  
HRSA: H  
IHS: I  
NIH: N  
PSC: P  
SAMHSA: S

(3) The three-digit numeric identification code assigned by ASFR/OGAPA/DA to the contracting office within the servicing agency.

(4) A four-digit fiscal year designation (*e.g.*, 2009, 2010).

(5) A five-digit alphanumeric tracking number, the content of which is

determined by the contracting office within the servicing agency.

(6) A one-digit code describing the type of contract action. For example, the National Cancer Institute, NIH, may number its first contract for fiscal year 2009 as HHSN261200900001C. (*Note:* When more than one code may apply in a specific situation, or for additional codes, refer to the DCIS Users' Manual or consult with the cognizant DCIS coordinator/focal point for guidance on which code governs.):

- A Commercial Item Acquisitions (including purchases using simplified acquisition procedures in accordance with the FAR subpart 13.5 Test program)
- C New Definitive Contract
- P Purchases using simplified acquisition procedures (other than commercial items)
- I IDC
- O BOA
- B BPA
- F Facilities Contract
- U Contracts placed with or through other Government departments, GSA contracts, or against mandatory source contracts such as AbilityOne and Federal Prison Industries (UNICOR)
- L Lease Agreement
- W Government-wide Acquisition Contract (GWAC)
- E Letter Contract
- G Federal Supply Schedule
- M Micro-purchase
- Q Multi-agency contract

(c) *Numbering system for orders.* The Contracting Officer shall assign order numbers (e.g., task order numbers) to orders issued under contracts. The order number shall be up to a seventeen-digit number consisting of the following:

(1) The three-digit identification code (HHS) of the Department.

(2) A one-digit numeric identification code of the servicing agency:

AHRQ: A  
 BARDA: O  
 CDC: D  
 CMS: M  
 FDA: F  
 HRSA: H  
 IHS: I  
 NIH: N  
 PSC: P  
 SAMHSA: S

(3) The three-digit numeric identification code assigned by ASFR/OGAPA/DA to the contracting office within the servicing agency.

(4) An alphanumeric tracking number, up to ten characters, the content of which is determined by the contracting office within the servicing agency.

(d) *Numbering system for solicitations.* The HCA is responsible for developing a numbering system for solicitations listed in paragraphs (a)(3) and (a)(4) of this section.

(e) *Assignment of identification codes.* ASFR/OGAPA/DA shall assign each

contracting office a three-digit identification code. HCAs shall request from ASFR/OGAPA/DA the assignment of codes for newly established contracting offices. A listing of the contracting office identification codes currently in use is contained in the DCIS Users' Manual, available at <http://dcis.hhs.gov>.

#### Subpart 304.71—Review and Approval of Proposed Contract Actions

##### 304.7100 Policy.

(a) The HCA (non-delegable) shall establish review and approval procedures for proposed contract actions to ensure that—

(1) Contractual documents are in conformance with law, established policies and procedures, and sound business practices;

(2) Contract awards properly reflect the mutual understanding of the parties; and

(3) The Contracting Officer is informed of deficiencies and items of questionable acceptability, and takes corrective action.

(b) The HCA shall designate acquisition officials to serve as reviewers. Each HCA shall establish the criteria for determining which contracts to review.

(c) Officials assigned responsibility for review and approval of contract actions shall possess qualifications in the field of acquisition commensurate with the level of review performed. However, if an official is to serve as the Contracting Officer and sign the contractual document, an appropriate official at least one level above the Contracting Officer shall perform the review and approval function.

(d) The Contracting Officer shall review all contractual documents, regardless of dollar value, prior to award to ensure the requirements of paragraph (a) of this section are met.

#### SUBCHAPTER B—COMPETITION AND ACQUISITION PLANNING

#### PART 305—PUBLICIZING CONTRACT ACTIONS

##### Subpart 305.2—Synopsis of Proposed Contract Actions

Sec.

305.202 Exceptions.

305.205 Special situations.

##### Subpart 305.3—Synopsis of Contract Awards

305.303 Announcement of contract awards.

##### Subpart 305.5—Paid Advertisements

305.502 Authority.

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

#### Subpart 305.2—Synopsis of Proposed Contract Actions

##### 305.202 Exceptions.

(b) When the Contracting Officer deems an advance notice is not appropriate or reasonable, the Contracting Officer shall prepare a memorandum citing all pertinent facts and details and send it through appropriate acquisition channels, including the HCA, to Associate DAS for Acquisition requesting an exception to synopsis. The Associate DAS for Acquisition shall review the request and decide whether an exception is appropriate and reasonable. If it is, the Associate DAS for Acquisition shall take the necessary coordinating actions required by *FAR 5.202(b)*. ASFR/OGAPA/DA shall promptly notify the contracting office of the Associate DAS for Acquisition's determination on the request.

##### 305.205 Special situations.

(a) An OPDIV may issue an advance notice, entitled "Research and Development Sources Sought," in Federal Business Opportunities (FedBizOpps), in accordance with the requirements of *FAR 5.205(a)*. The primary purpose of an R & D Sources Sought notice is to identify all potential sources, regardless of organizational type and size classification, and determine their capabilities to fulfill a potential Government requirement. The notice is not intended to solicit technical, scientific, or business information for project planning purposes regarding existing or possible solutions. In the latter instance, a Request for Information (RFI) may be used—see *FAR 15.201(e)* and *315.201(e)*.

(1) When using an R & D Sources Sought notice, an OPDIV shall not request that potential sources provide more than the minimum information necessary—see *FAR 10.001(b)*, to determine whether they have the apparent capability to perform a requirement and, therefore, whether they should be included in any future competition. The notice and the information received shall not be used to determine how well respondents can perform a requirement, which can only be evaluated in response to a solicitation. Accordingly, the notice shall not be used to—

(i) Obtain capability statements that are evaluated and determined acceptable or unacceptable;

(ii) Require cost/price proposals or detailed technical solutions;

(iii) Identify a prospective sole source; or

(iv) Exclude small business concerns.  
 (2) While not the primary intent of an R & D Sources Sought notice, in addition to seeking information regarding all potential qualified R & D sources, the notice may request that respondents provide information regarding their organizational size classification. For example, the notice may ask respondents to identify whether they are small businesses; Historically Underutilized Business (HUB) Zone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses in order to determine the appropriate acquisition method, including whether a set-aside is possible. However, such a notice shall not be used solely to determine the size classification of respondents for a proposed R & D acquisition. In such instances, a "Small Business Sources Sought" notice may be used (*see* 319.202-2), in lieu of the procedures in this section.

(3) OPDIVs shall follow the standard HHS instructions for completing an R & D Sources Sought notice. The template for the notice is available on the ASFR/OGAPA/DA Internet Web site. The Contracting Officer shall post the notice in FedBizOpps by selecting and completing a Sources Sought notice, accessible on the FedBizOpps "Notices" page at: <http://www.fedbizopps.gov>. Additional information may be included in the notice in accordance with OPDIV procedures. The Contracting Officer shall document, in the form of a memorandum to the file, the results of the review by technical personnel of information submitted in response to the notice, including whether each respondent appears to be capable of performing the requirement. The Contracting Officer shall attach a copy of the analysis provided by the technical personnel to the memorandum.

(4) In instances where a sufficient number of sources has not been identified to compete for a non-R & D project, an OPDIV may use the procedures specified in 310.001, including the issuance of a "Sources Sought" notice, as appropriate, in lieu of the procedures in this section.

### Subpart 305.3—Synopses of Contract Awards

#### 305.303 Announcement of contract awards.

(a) *Public Announcement.* The Contracting Officer shall report awards over \$3.5 million, not otherwise exempt under FAR 5.303, to the Office of the

Assistant Secretary for Legislation (OASL) (Congressional Liaison). The Contracting Officer shall provide a copy of the contract or award document face page to the referenced office prior to the day of award or in sufficient time to allow OASL to make an announcement by 5 p.m. Washington, DC time on the day of award. The Contracting Officer may also provide notification by e-mail or facsimile.

### Subpart 305.5—Paid Advertisements

#### 305.502 Authority.

The Contracting Officer may advertise or place notices in newspapers and periodicals to announce that the contracting office is seeking proposals, quotations, or bids, as appropriate.

### PART 306—COMPETITION REQUIREMENTS

#### Subpart 306.2—Full and Open Competition after Exclusion of Sources

Sec.

306.202 Establishing or maintaining alternative sources.

#### Subpart 306.3—Other Than Full and Open Competition

306.302 Circumstances permitting other than full and open competition.

306.302-1 Only one responsible source and no other supplies or services will satisfy agency requirements.

306.302-7 Public interest.

306.303 Justifications.

306.303-1 Requirements.

306.304 Approval of the justification.

#### Subpart 306.5—Competition Advocates

306.501 Requirement.

306.502 Duties and responsibilities.

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

#### Subpart 306.2—Full and Open Competition after Exclusion of Sources

#### 306.202 Establishing or maintaining alternative sources.

(a) The reference to the agency head in FAR 6.202 (a) shall mean the appropriate Competition Advocate (CA) cited in 306.501.

(b)(1) The Contracting Officer shall prepare the required determination and findings (D & F) based on the data provided by program personnel. The appropriate CA (non-delegable) shall sign the D & F.

### Subpart 306.3—Other Than Full and Open Competition

#### 306.302 Circumstances permitting other than full and open competition.

#### 306.302-1 Only one responsible source and no other supplies or services will satisfy agency requirements.

(a)(2)(iv) Follow-on contracts for the continuation of R & D studies on long-term social and health programs, research studies, or clinical trials may be deemed to be available only from the original source when it is likely that award to any other source would result in unacceptable delays in fulfilling HHS' or the OPDIV's requirements.

(b) *Application.*

(5) when the head of the sponsoring program office has determined that the activity must acquire only specified makes or models of technical equipment or parts to meet the activity's program responsibility to test and evaluate certain kinds and types of products, and only one source is available. (**Note:** This criterion is limited to testing and evaluation purposes only and not for initial outfitting or repetitive acquisitions. Project Officers shall support the use of this criterion with citations from their agency's legislation and the technical rationale for the item of equipment required.)

#### 306.302-7 Public interest.

(a) *Authority.*

(2) Agency head, in this instance, means the Secretary.

(c) *Limitations.* The Contracting Officer shall prepare a written request for approval and provide it through appropriate acquisition channels, including the HCA and Associate DAS for Acquisition, to the Secretary. The request shall include a D & F for the Secretary's signature that contains all pertinent information to support the justification for exercising the exemption to competition and a letter for the Secretary's signature notifying Congress of the determination to award a contract under the authority of 41 U.S.C. 253(c)(7).

#### 306.303 Justifications.

#### 306.303-1 Requirements.

(b) The responsible Program Office must provide a written justification whenever it requests that goods or services be acquired without obtaining full and open competition. The justification must be submitted with the AP or other acquisition request document—*see* Subpart 307.71. The Project Officer has responsibility for preparing the justification with

assistance, as necessary, from the Contracting Officer.

(1) Justifications for acquisitions at or below the simplified acquisition threshold may be in the form of a paragraph or paragraphs contained in the requisition or other acquisition request document. Justifications for acquisitions in excess of the simplified acquisition threshold shall be in the form of a separate, self-contained document, prepared in accordance with *FAR 6.303* and *306.303*, and titled "Justification for Other Than Full and Open Competition" (JOFOC). HHS requires use of a standard format for a JOFOC. The template for the justification is available on the ASFR/OGAPA/DA Internet Web site. Additional information may be included in the JOFOC template in accordance with OPDIV procedures.

(2) Regardless of the dollar amount of the acquisition, justifications shall—

(i) Fully describe what is to be acquired;

(ii) Provide a specific explanation of why it is not feasible to obtain full and open competition;

(iii) Be supported by verifiable facts, rather than untested or unsubstantiated opinions or conclusions; and

(iv) Be written in a manner to permit an individual without technical knowledge of the requirement to understand the supporting rationale.

(3) Preliminary arrangements with, or verbal or written commitments to, a proposed sole-source contractor shall be avoided given the statutory requirement to obtain full and open competition to the maximum extent practicable.

(4) Justifications for orders to be placed under FSS contracts that limit consideration of contractors shall comply with *FAR 8.405-6* and *308.405-6*.

#### **306.304 Approval of the justification.**

*Certification, concurrence, and approval requirements.* The Project Officer, the Project Officer's immediate supervisor, the head of the sponsoring program office, and the Contracting Officer shall certify that the justification is accurate and complete by signing the JOFOC. For acquisitions in the dollar amount cited in *FAR 6.304(a)(2)* through *(a)(4)*, the CCO, if applicable, and the HCA shall indicate their review of, and concurrence with, the justification by signing the JOFOC.

(a) The approving officials for JOFOCs are as follows:

(1) The Contracting Officer shall exercise this approval authority unless a higher approval level is required by OPDIV procedures.

(2) The CAs are listed in *306.501*. This approval authority is not delegable.

(3) The CA shall exercise this approval authority, except where the individual designated as the CA does not meet the requirements of *FAR 6.304(a)(3)(ii)*. This approval authority is not delegable.

(4) HHS' SPE is the Associate DAS for Acquisition.

(c) A class justification shall be processed in the same manner as an individual justification. A class justification may consist of contracts/orders for the same or related supplies and services or other contract/order actions that require essentially identical justifications.

### **Subpart 306.5—Competition Advocates**

#### **306.501 Requirement.**

The HHS CA is the Director, Strategic Acquisition Service, PSC. The CAs for each of HHS' contracting activities are as follows:

AHRQ: Director, Office of Performance Accountability, Resources and Technology  
BARDA: Chief of Mission Support and Acquisition Policy

CDC: Chief Information Officer

CMS: Chief Operating Officer

FDA: Deputy Commissioner for Administration

HRSA: Associate Administrator, Office of Operations

IHS: Director, Office of Management Services  
NIH: Senior Scientific Advisor for Extramural Research, Office of Extramural Research (R&D) and Senior Advisor to the Director (other than R&D)

PSC: Director, Strategic Acquisition Service

SAMHSA: Executive Officer

#### **306.502 Duties and responsibilities.**

(a) Each OPDIV CA shall prepare an annual Competition Advocate Report (CAR), covering the prior fiscal year, in accordance with the requirements of *FAR 6.502(b)(2)* and *306.502(b)*, and provide it to the HHS CA not later than November 16 of each year or the next business day, if the due date falls on a non-business day. NIH's two CAs shall prepare and sign a joint report covering their respective areas of responsibility.

(b) HHS requires that each CAR be prepared in a standard format. The template for the report is available on the ASFR/OGAPA/DA Internet Web site. As long as the standard headings are included and required information is addressed, the OPDIV may include additional information in accordance with OPDIV procedures.

(1) The CAR shall be based on information and data for all acquisitions that exceed the micro-purchase threshold for the applicable fiscal year,

unless otherwise noted in the standard format.

(2) Each OPDIV CA shall obtain the information and data needed for preparation of the CAR from the responsible HCA and/or the CCO, as appropriate, who shall assist the CA in preparing the CAR.

(3) Prior to forwarding the CAR to the HHS CA, each OPDIV CA shall provide the CAR to the responsible HCA, who shall review and approve it for accuracy and completeness.

(c) The HHS CA shall consolidate all OPDIV CARs and provide an HHS-wide CAR that addresses all requirements of *FAR 6.502(b)* to the HHS SPE and the CAO by December 20 of each year or the next business day, if the due date falls on a non-business day.

## **PART 307—ACQUISITION PLANNING**

### **Subpart 307.1—Acquisition Planning**

Sec.

307.104 General procedures.

307.104-70 Acquisition strategy.

307.104-71 Purpose and timing.

307.105 Contents of written acquisition plans.

307.108-70 Telecommuting of contractor employees.

#### **Subpart 307.70—Considerations in Selecting an Award Instrument.**

307.7000 Scope of subpart.

307.7001 Distinction between acquisition and assistance.

307.7002 Procedures.

#### **Subpart 307.71—Acquisition Plan.**

307.7100 Scope of subpart.

307.7101 Policy.

307.7102 Content.

307.7103 Format.

307.7104 Review and certification.

307.7105 Transmittal.

307.7106 Acquisition milestones.

307.7107 Responsibilities.

307.7108 Statement of work.

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

### **Subpart 307.1—Acquisition Planning**

#### **307.104 General procedures.**

(a) Each contracting activity shall prepare an Annual Acquisition Plan (AAP) as far in advance of each fiscal year as possible, in accordance with the following:

(1) The AAP shall contain all anticipated acquisition actions for the coming fiscal year that exceed the simplified acquisition threshold, including new acquisitions and contract/order modifications. The AAP must include—

(i) The aggregate dollars planned for simplified acquisitions by quarter;

(ii) Any long lead-time acquisitions that will be awarded in future fiscal years (*see* paragraph (c) below); and

(iii) Proposed multi-agency and intra-agency contracts—*see* 317.70.

(2) The HCA or the CCO, as appropriate, shall prepare the AAP and obtain the information needed for its preparation from the responsible program planning/budget office and/or the program offices.

(3) Contracting activities shall use the AAP for reporting purposes and workload scheduling and monitoring.

(4) The HCA/CCO and Small Business Specialist (SBS) in the Office of Small and Disadvantaged Business Utilization (OSDBU) shall review the AAP at least quarterly, with input from the cognizant program office, and modify it, as appropriate, during the fiscal year, with updated information, particularly regarding the specific acquisition method the contracting activity plans to use.

(5) HHS requires use of a standard format for an AAP. The template for the plan is available on the ASFR/OGAPA/DA Internet Web site. For the data elements specified in the AAP format, the HCA/CCO may include information in addition to that required by the standard instructions accompanying the format.

(b) As early as possible following completion of the AAP, the Contracting Officer shall initiate discussions with the assigned Project Officer, in consultation with the OSDBU SBS, for each action that exceeds the simplified acquisition threshold. As appropriate, the discussions shall include—

(1) Determining the intended acquisition strategy and contract/order type, including the use of options;

(2) Reviewing the SOW, if available, for adequacy and ensuring that a PWS is used for services, where practicable;

(3) Evaluating the potential for, and maximizing the use of, competitive procedures;

(4) Performing market research, identifying potential sources, and determining set-aside potential and small business subcontracting opportunities;

(5) Assessing the availability of commercial items;

(6) Determining required clearances/approvals and supporting documentation; and

(7) Preparing an acquisition milestone schedule;

(8) Determining the best multi- or intra-agency contracting activity to assist in awarding a contract on the requiring organization's behalf, if applicable; and

(9) Determining in the case of direct ordering that the chosen acquisition vehicle is the best way to obtain the required product or service, if a vehicle

other than those listed in 317.7002(b) is proposed.

(c) The HCA or designee (not lower than the CCO) shall establish standard lead-times for processing various types of acquisitions and applicable fiscal year deadlines for receipt of requirements to allow for well-planned and timely awards. The Project Officer shall initiate planning, to the extent possible, for certain requirements, such as major capital IT investments, major capital construction investments, and R & D projects that require peer review, at least 24 months before planned award, given the clearance/approval requirements and lead-time required for such complex acquisitions.

(d) The outcome of the discussions referenced in paragraph (b) above shall be an agreement concerning the acquisition approach and documentation required. For those actions that require development of a written AP—*see* 307.7101, for which the Project Officer has ultimate responsibility, these discussions shall also result in an agreement concerning—

(1) Which elements of the AP the Contracting Officer will assist the Project Officer in preparing; and

(2) The date (as specified in the milestone schedule) the Project Officer will provide the AP to the CCO or designee.

#### **307.104–70 Acquisition strategy.**

Program and Project Managers responsible for major IT capital investments (and for any other investments designated by the HHS CIO, DASFMF, the CAO, or the cognizant HCA) shall prepare an acquisition strategy using the HHS acquisition strategy template. The template for the acquisition strategy is available on the ASFR/OGAPA/DA Internet Web site. Program and Project Managers must initiate the acquisition strategy for major IT capital investments as part of the planned investment's business case, usually during the Enterprise Performance Life Cycle concept phase.

#### **307.104–71 Purpose and timing.**

(a) The purpose of an acquisition strategy is to describe the overall approach for acquiring capabilities needed to fulfill investment/programmatic objectives. Acquisition strategy development requires identification of issues and risks that might impact an acquisition(s) to allow early action to eliminate or mitigate the issues and risks.

(b) An acquisition strategy differs from an AP with respect to the timing

of its development and the level of detail required.

(1) An acquisition strategy is established at the inception (concept phase) of an investment/acquisition to support the business case, identify and mitigate risks, and begin the acquisition planning process. An acquisition strategy addresses the major issues surrounding business objectives, competitive forces, and various risks that need to be considered.

(2) An acquisition strategy is a living document used throughout the investment's life-cycle. It should be continuously updated with the active involvement of the Program or Project Manager and the Contracting Officer at appropriate points, as plans for the investment/acquisition mature. An acquisition strategy ultimately will result in an AP—*see* 307.71.

(3) An AP, which is required to support proposed acquisitions expected to exceed \$500,000 (inclusive of options, with certain exceptions)—*see* 307.7101, is developed closer to the time of solicitation. The AP addresses not only those issues in the acquisition strategy, but also the tactical details of how the acquisition will be executed.

#### **307.105 Contents of written acquisition plans.**

*FAR 7.105* specifies the content requirements of a written AP. Subpart 307.71 incorporates and supplements those requirements.

#### **307.108–70 Telecommuting of contractor employees.**

(a) SOWs/PWSs shall permit offerors or contractors to specify their own place(s) of performance (hence authorize their employees to telecommute), except as follows:

(1) The Project Officer may restrict place of performance (hence restrict an offeror's or contractor's telecommuting) for any part of an SOW/PWS, after determining that the work or any portion thereof must be performed at a specified place of performance; or security would be compromised. The Project Officer must document this determination in writing and send a copy of the determination, along with the SOW/PWS, to the Contracting Officer. The Project Officer must also address in an HHS AP (or other acquisition request document) any performance requirements or security considerations that restrict place of performance—*see* 307.71.

(2) In accordance with *FAR 7.108(a)*, if the Contracting Officer concurs with the Project Officer's determination in (a)(1) above, then the Contracting Officer must sign the Project Officer's



determination; include it in the official contract file; and specify any prohibition against telecommuting in the solicitation and resultant contract.

(3) In accordance with *FAR 7.108(a)*, if the Contracting Officer decides to restrict a place of performance that the Project Officer did not restrict, then the Contracting Officer must document in writing the determination to preclude telecommuting in part or in whole; include the determination in the official contract file; and specify any prohibition against telecommuting in the solicitation and resultant contract.

(b) If the Contracting Officer disagrees with the Project Officer's determination in (a)(1) above, then the Contracting Officer shall return both the SOW/PWS and determination to the Project Officer for further consideration.

(c) The Contracting Officer shall ensure that authorized telecommuting of contractor employees does not result in increased cost or price to the Government.

#### **Subpart 307.70—Considerations in Selecting an Award Instrument**

##### **307.7000 Scope of subpart.**

This subpart provides guidance on the appropriate selection of award instruments to fulfill program needs consistent with 31 U.S.C. 6301–6308. This subpart explains the use of the contract as the award instrument for acquisition relationships and a grant or cooperative agreement as instruments for financial assistance relationships.

##### **307.7001 Distinction between acquisition and assistance.**

(a) 31 U.S.C. 6301–6308 requires the use of contracts to acquire property or services for the direct benefit or use of the Government and grants or cooperative agreements to transfer money, property, services, or anything of value to eligible entities to accomplish a public purpose of support or stimulation authorized by Federal statute.

(b) OPDIVs shall use a contract as the legal instrument to reflect a relationship between the Government and an entity whenever the—

(1) Principal purpose of the instrument is the acquisition, by purchase, lease, or barter, of property or services for the direct benefit or use of the Government; or

(2) Government determines in a certain situation that specific needs can be satisfied best by using the acquisition process. However, this authority does not permit circumventing the criteria for use of acquisition or assistance instruments. Use of this authority is

restricted to extraordinary circumstances and requires the Associate DAS for Acquisition's prior approval.

(c) OPDIVs shall use a grant or cooperative agreement as the legal instrument to reflect a relationship between the Government and an entity whenever the principal purpose of the relationship is the transfer of money, property, services, or anything of value to accomplish a public purpose of support or stimulation authorized by Federal statute.

(1) OPDIVs shall use a grant when no substantial programmatic involvement is anticipated between the Government and the recipient during performance of the contemplated activity.

(2) OPDIVs shall use a cooperative agreement when substantial programmatic involvement is anticipated between the Government and the recipient during performance of the contemplated activity.

(d) As a general rule, OPDIVs shall use contracts for the following purposes:

(1) Evaluation (including research of an evaluative nature) of the performance of Government programs or projects or grantee activity initiated by the funding agency for its direct benefit or use.

(2) Technical assistance rendered to the Government, or on behalf of the Government, to any third party, including those receiving grants or cooperative agreements.

(3) Surveys, studies, and research which provide specific information desired by the Government for its direct activities, or for dissemination to the public.

(4) Consulting services or professional services of all kinds if provided to the Government or, on behalf of the Government, to any third party.

(5) Training projects where the Government selects the individuals or specific groups whose members are to be trained or specifies the content of the curriculum (not applicable to fellowship awards).

(6) Production of publications or audiovisual materials the Government requires primarily for the conduct of its direct operations.

(7) Design or development of items for Government use or pursuant to agency definition or specifications.

(8) Conferences conducted on the Government's behalf.

(9) Generation of management information or other data for Government use.

##### **307.7002 Procedures.**

(a) OPDIV program officials shall use existing budget and program planning procedures to propose new activities

and major changes in ongoing programs. OPDIV program officials shall meet with the HCA and the Chief Grants Management Officer, or their designees, as necessary, to determine whether award is to be made through the acquisition or assistance process. This determination shall normally occur prior to the time when the AAP is reviewed and approved so that the AAP will reflect all known proposed contract actions. The HCA shall fully document a shift from one award instrument to another in the appropriate files to show a fundamental change in program purpose that unequivocally justifies the rationale for the shift.

(b) The Contracting Officer shall confirm the appropriateness of the use of the contract instrument when reviewing the AP or other acquisition request document.

(c) OPDIVs shall ensure that the choice of instrument is in accordance with 31 U.S.C. 6301–6308 and applicable HHS policies. If, however, there are major individual transactions or programs which contain elements of both acquisition and assistance in such a way that they cannot be characterized as having a principal purpose of one or the other instrument, OPDIVs shall obtain guidance from ASFR/OGAPA/DA, through appropriate acquisition channels, including the HCA, before proceeding with a determination.

(d) Any public notice, program announcement, solicitation, or request for applications or proposals, or request for quotations shall indicate whether the intended relationship will be one of acquisition or financial assistance and specify the award instrument the OPDIV will use.

#### **Subpart 307.71—Acquisition Plan**

##### **307.7100 Scope of subpart.**

*FAR 7.102* requires acquisition planning for all acquisitions. This subpart establishes: (a) when a written AP is required; (b) its contents and format; and (c) the need for review of the AP to certify that it is accurate, complete, and in the proper format. This subpart also establishes the documentation requirements for those acquisitions not requiring an AP.

##### **307.7101 Policy.**

(a) An AP is required for all acquisitions, to be placed by an HHS contracting office, expected to exceed \$500,000 (inclusive of options) with the following exceptions:

- (1) Letter contracts.
- (2) Unsolicited proposals.
- (3) Regulated utility services available from only one source.

(4) Proposals under the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs.

(5) Acquisition of commercial items/services—see *FAR 2.101*, including orders placed under FSS contracts meeting the definition of a commercial item/service, and not exceeding \$5.5 million [\$11 million for acquisitions as described in *FAR 13.500(e)*].

(6) Task orders or delivery orders of any dollar amount placed under—

(i) An IDIQ contract, other than a GWAC; or

(ii) A BPA, provided there is an approved acquisition planning document for the original action, and there is no significant deviation from that plan.

(7) Orders of any dollar amount placed under HHS-wide strategic sourcing vehicles.

(8) Contract/order modifications that—

(i) Exercise options;

(ii) Only provide additional funding; or

(iii) Make changes authorized by the Changes clause.

(9) Assisted acquisitions processed pursuant to an interagency agreement. However, the OPDIV must comply with the requirements specified in *317.5* Interagency Agreements under the Economy Act and *317.70*, Multi-agency and Intra-agency Contracts.

(b) In urgent or other justifiable cases, such as an emergency acquisition—see *FAR Part 18*, the HCA may waive, in writing, the requirement for completion of an AP. An HCA shall not approve a waiver request based on the lack of advance planning.

(1) The Project Officer, the Project Officer's immediate supervisor, the head of the sponsoring program office, the Contracting Officer, and other signatories shall sign the waiver request in accordance with OPDIV policies. In OPDIVs where a CCO(s) is designated, as defined in *302.101*, the cognizant CCO also shall sign the waiver request.

(2) HHS has established a standard format for preparing an AP waiver request. The template for the waiver request is available on the ASFR/OGAPA/DA Internet Web site. Contracting activities shall use this format when requesting a waiver.

(3) The OPDIV shall provide ASFR/OGAPA/DA a copy of any approved waiver request within 5 business days after HCA approval.

(c) For those acquisitions not requiring an AP, other than assisted acquisitions processed pursuant to an interagency agreement—see *317.5* and *317.70*, the Project Officer shall provide

an acquisition request document (e.g., memorandum, requisition, or other form of transmittal) to the CCO or designee, requesting completion of the required action. The request must include, as applicable: a SOW/PWS (including deliverables and reporting requirements); a certified funding document; source selection strategy and criteria; necessary clearances, approvals, and justifications (e.g., a JOFOC); a milestone schedule; and an independent Government cost estimate.) In addition, OPDIVs shall use the content requirements of the AP as a reference in determining what other information and documentation is necessary to support the intended acquisition. Alternatively, OPDIVs may prescribe use of an AP for acquisitions excepted under *307.7101(a)(i) through (a)(viii)*.

#### **307.7102 Content.**

In accordance with *307.105*, the *FAR*, *HHSAR*, and other Federal requirements that OPDIVs must consider in developing an AP, as well as its format, are stipulated in *307.7103*. An AP shall address each applicable element. As indicated in the instructions, elements that are not applicable to an individual acquisition shall be marked "N/A." The scope and depth of an AP may vary depending on the nature, complexity, and estimated cost of the proposed acquisition. As a result of new or revised *FAR* requirements or other Federal directives, the—

(a) HCA or designee may make any needed interim changes to the AP;

(b) HCA or designee shall notify ASFR/OGAPA/DA of the need for revision(s) to the acquisition; and

(c) ASFR/OGAPA/DA shall update the AP, which would supersede any interim HCA (or designee) changes made to the acquisition plan for future acquisitions.

#### **307.7103 Format.**

(a) HHS has established a standard format for preparing an AP. The template for the AP is available on the ASFR/OGAPA/DA Internet Web site.

(b) OPDIVs may use the prescribed format without modification or use it as a guideline, as long as the format used by the OPDIV complies with the requirements specified in subparagraphs (c) and (d) below.

(c) An AP must consist of seven (7) parts with standard headings, as follows:

Part I Transmittal and Approval Form.

Part II Summary Sheet.

Part III Project Considerations and Information.

Part IV Clearance/Approval Checklist.

Part V Acquisition Milestone Schedule.

Part VI Independent Government Cost Estimate.

Part VII Attachments.

(d) Within each of the seven parts, there are required components that an OPDIV cannot modify and specific areas where OPDIVs can make changes. The table in the *Requirements and Responsibilities* section of the AP cites the titles, paragraph/subparagraph headings, narrative, and other requirements that must appear in each part of an AP in the specified format, as well as permissible modifications.

#### **307.7104 Review and certification.**

Before the Project Officer transmits the AP to the CCO or designee—see *307.7105*, the head of the sponsoring program office (typically a Division Director or equivalent), Project Officer, Funds Certification Official, Contracting Officer, and other signatories in accordance with OPDIV policies, shall review the AP and certify that it provides all required information in the prescribed format and the following:

(a) Vague and ambiguous language has been eliminated.

(b) A thorough technical review of the SOW/PWS has been completed.

(c) The project is structured by phases or tasks, as appropriate.

(d) Methods are available to assess the contractor's performance.

(e) The acquisition mechanism is appropriate—*i.e.*, the principal purpose of the project is to acquire supplies or services for the direct benefit or use of the Government.

(f) The planned obligation of appropriated funds for the project satisfies a *bona fide* need of the requiring office arising in the fiscal year for which the appropriation was made.

#### **307.7105 Transmittal.**

The Project Officer shall convey the signed AP to the CCO or designee by providing a completed Part I—Transmittal and Approval Form, with other parts of the AP attached, no later than the date agreed to in the acquisition milestone schedule, unless the officials establish a different date by mutual agreement.

#### **307.7106 Acquisition milestones.**

The Contracting Officer shall retain the acquisition milestone schedule in the contract file and update/revise it to track progress of the acquisition. The milestone schedule signatories (see the *Requirements and Responsibilities* section of the AP—Part V of the table) shall mutually agree to any revisions to the milestone dates that will impact meeting the scheduled award date. Milestone schedule signatories shall

report a failure to meet established milestones to a higher level official in accordance with OPDIV procedures.

**307.7107 Responsibilities.**  
The following table summarizes the responsibilities of the various

organizations and officials for acquisition planning:

Acquisition planning	Responsible organization/official	HHSAR reference
Make necessary interim changes to the AP and notify ASFR/OGAPA/DA of changes needed.	OPDIV HCA or designee .....	307.7102.
Update the AP to reflect new or revised FAR and other Federal directives.	ASFR/OGAPA/DA .....	307.7102.
Prepare the AAP and update it quarterly, as appropriate.	OPDIV-HCA/CCO .....	307.104, subparagraph (a).
Establish standard acquisition lead-times and deadlines for receipt of requirements for award in an applicable fiscal year.	OPDIV-HCA/CCO .....	307.104, subparagraph (d).
Identify and plan requirements, particularly complex, long lead-time acquisitions, well in advance of the fiscal year in which they are to be awarded.	OPDIV-Project Officer .....	307.104, subparagraph (d).
(i) Participate in acquisition planning; (ii) prepare the AP; and (iii) provide the AP to the Contracting Officer.	OPDIV-Project Officer .....	(i) 307.104, subparagraph (c); (ii) 307.104, subparagraph (e); and (iii) 307.7105.
(i) Participate in acquisition planning; and (ii) assist the Project Officer in AP preparation.	OPDIV-Contracting Officer .....	(i) 307.104, subparagraph (c); (ii) 307.104, subparagraph (e).
Waive requirement for development of an AP when justified.	OPDIV-HCA .....	307.7101, subparagraph (b).
Review and certify that an AP is complete, accurate, and in the proper format.	OPDIV-Head of the Sponsoring Program Office, Project Officer, Funds Certification Official, Contracting Officer, and other signatories in accordance with OPDIV policies.	307.7104
Meet established acquisition milestone dates .....	OPDIV-Project Officer and Contracting Officer .....	307.7106.

**307.7108 Statement of work.**

(a) *General.* An SOW describes the work or services a contractor is to perform in reaching an end result without describing the method that the contractor shall use, unless the method of performance is critical or required in order to obtain successful performance. An SOW shall be clear and concise; completely define the responsibilities of both the contractor and the Government; and be worded to make misinterpretation virtually impossible.

(b) *Term (level of effort) form and completion form SOWs.* Term-form (level of effort) SOWs essentially require the furnishing of technical effort, which may include a report thereof, while completion-form SOWs require development of tangible items designed to meet specific performance and/or design characteristics—see FAR 16.306(d) for this distinction.

(1) *Term (or level of effort).* A term or level of effort-form SOW is appropriate for research where the objective is to discover the feasibility of later development or to gather general information. A term or level of effort-form SOW specifies that some number of labor hours be expended on a particular course of research or that a certain number of tests be run, without reference to any intended conclusion.

(2) *Completion.* A completion-form SOW is appropriate for development work where the feasibility of producing an end item is already known. A

completion-form SOW may describe what is to be achieved through the contracted effort, such as development of new methods, new end items, or other tangible results.

(c) *Phasing.* Individual research, development, or demonstration projects frequently lie well beyond the present state of the art and entail procedures and techniques of great complexity and difficulty. Under these circumstances, a contractor, no matter how carefully selected, may be unable to deliver the desired result. Moreover, the job of evaluating the contractor's progress is often difficult. Such a contract is frequently phased and often divided into stages of accomplishment, each of which the contractor must complete and the Contracting Officer approve before the contractor may proceed to the next phase or stage. Phasing makes it necessary to develop methods and controls, including reporting requirements for each phase of the contract and criteria for evaluation of the report submitted, that will provide, at the earliest possible time, appropriate data for making decisions relative to future phases. A phased contract, such as one for an R & D or demonstration project, may include stages of accomplishment. Within each phase, there may be a number of tasks that the SOW should include. When phases of work can be identified, the SOW shall provide for phasing and the solicitation shall require offerors to submit

proposed costs by phases. The resultant contract shall reflect costs by phases, require the contractor to identify incurred costs by phases, establish delivery schedules by phase, and require the written acceptance of each phase. The Contracting Officer shall not allow contractors to incur costs for phases that are dependent upon successful completion of earlier phases until the Contracting Officer provides written acceptance of the prior work.

(d) *Elements of the SOW.* The elements of the SOW may vary with the objective, complexity, size, and nature of the acquisition. In general, the SOW shall include the following:

(1) *Purpose of the project.* This includes a general description of the objectives of the project and the desired results.

(2) *Background information.* This includes a brief history of the project and the importance of the project to the overall program objectives.

(3) *A detailed description of the technical requirements.* The SOW shall provide sufficient detail to accurately reflect the Government's requirement. It shall state what is to be accomplished without prescribing the method the contractor is to use and shall include performance standards, if applicable. See 307.104(b)(2) and FAR 37.602 for guidance on preparation of a PWS. An SOW may include tasks and subtasks. The degree of breakout depends on the size and complexity of the project. An

SOW shall indicate whether the tasks are sequential or concurrent.

(4) *Reference material.* This includes an explanation of all reference material a contractor needs to carry out the project; the applicability of the reference material; and a statement as to where potential offerors can obtain the material.

(5) *Level of effort.* When a level of effort is necessary, the SOW shall specify the number and type of personnel required, if known, and the type and degree of expertise.

(6) *Special requirements (as applicable).* This includes providing, in a separate section, any unusual or special contractual requirements that may affect performance. For example, the SOW shall specify separately the work requirements to implement information security management requirements—see 339.71 for additional information.

(7) *Deliverables and reporting requirements.* This includes clearly and completely describing all deliverables and reports, including the time frame for completion, the format, and the required number of copies.

## PART 308—REQUIRED SOURCES OF SUPPLIES AND SERVICES

### Subpart 308.4—Federal Supply Schedules

Sec.  
308.404 Use of Federal Supply Schedules.  
308.405–6 Limited source justification and approval.

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

### Subpart 308.4—Federal Supply Schedules

#### 308.404 Use of Federal Supply Schedule.

(f) *Technical Evaluation.* When conducting a technical evaluation of quotations or proposals received under *FAR Part 8*, the provisions of 315.305(a)(3) apply.

#### 308.405–6 Limited source justification and approval.

(g) (1) As required by *FAR 8.405–1* or *8.405–2*, the responsible program office must provide a written justification whenever it requests an acquisition under the FSS program that restricts consideration of the number of schedule contractors or to an item peculiar to one manufacturer. The justification must be submitted with the AP or other acquisition request document—see 307.71. The Project Officer has responsibility for preparing the justification with assistance, as necessary, from the Contracting Officer.

(i) Justifications for orders at or below the simplified acquisition threshold may be in the form of a paragraph or

paragraphs contained in the requisition or other acquisition request document. Justifications for orders in excess of the simplified acquisition threshold shall be in the form of a separate, self-contained document, prepared in accordance with *FAR 8.405–6(g)* and *308.405–6(g)*, and titled “Limited Source Justification” (LSJ). HHS requires use of a standard format for an LSJ. The template for the justification is available on the ASFR/OGAPA/DA Internet Web site.

Additional information may be included in the LSJ template in accordance with OPDIV procedures.

(ii) Regardless of dollar amount of the acquisition, justifications shall—

(A) Fully describe what is to be acquired;

(B) Cite specific reasons that explain why it is necessary to restrict consideration of sources;

(C) Be supported by verifiable facts rather than untested or unsubstantiated opinions or conclusions; and

(D) Be written in a manner to permit an individual without technical knowledge of the requirement to understand the supporting rationale.

(iii) Preliminary arrangements with, or verbal or written commitments to, a proposed contractor shall be avoided given the requirement to obtain competition for FSS orders using the procedures in *FAR Subpart 8.4*—see also *FAR 6.102(d)(3)*.

(iv) Justifications for non-FSS orders to be awarded without full and open competition shall comply with *FAR 6.303* and *306.303*.

(h) *Justification approvals. Certification, concurrence, and approval requirements.* The Project Officer, the Project Officer’s immediate supervisor, the head of the sponsoring program office, and the Contracting Officer shall certify that the justification is accurate and complete by signing the LSJ. For acquisitions in the dollar amount cited in *FAR 8.405–6(h)(2) through (h)(4)*, the CCO, if applicable, and the HCA shall indicate their review of, and concurrence with, the justification by signing the LSJ. The approving officials for LSJs are as follows:

(1) The Contracting Officer shall exercise this approval authority unless a higher approval level is required by OPDIV procedures.

(2) The CAs are listed in 306.501. This approval authority is not delegable.

(3) The CA shall exercise this approval authority, except where the individual designated as the competition advocate does not meet the requirements of *FAR 8.405–6(h)(3)(ii)*. This approval authority is not delegable.

(4) The HHS SPE is the Associate DAS for Acquisition.

## PART 309—CONTRACTOR QUALIFICATIONS

### Subpart 309.4—Debarment, Suspension, and Ineligibility

Sec.  
309.403 Definitions.  
309.404 List of parties excluded from Federal procurement and non-procurement programs.  
309.405 Effect of listing.  
309.406 Debarment.  
309.406–3 Procedures.  
309.407 Suspension.  
309.407–3 Procedures.  
309.470 Reporting of suspected causes for debarment or suspension or the taking of evasive actions.  
309.470–1 Situations where reports are required.  
309.470–2 Contents of reports.

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

### Subpart 309.4—Debarment, Suspension, and Ineligibility

#### 309.403 Definitions.

*Acquiring agency’s head or designee*, as used in the *FAR*, means, unless otherwise stated in this subpart, the HCA. The HCA may make the required justifications or determinations and take the necessary actions specified in *FAR 9.405*, *9.406* and *9.407*, only after obtaining the written approval of the debarring or suspending official, as appropriate.

*Debarring official* means the Deputy Assistant Secretary for Grants and Acquisition Policy and Accountability (DAS/GAPA).

*Initiating official* means the Contracting Officer, the HCA, the Associate DAS for Acquisition, or the Inspector General (IG).

*Suspending official* means the DAS/GAPA.

#### 309.404 List of parties excluded from Federal procurement and non-procurement programs.

(c) The ASFR/OGAPA/DA shall perform the actions required by *FAR 9.404(c)*.

(4) The ASFR/OGAPA/DA shall maintain all documentation the initiating official submits to recommend the debarment or suspension action and all correspondence and other pertinent documentation generated during the review.

#### 309.405 Effect of listing.

(a) The HCA (non-delegable) may, with the written concurrence of the debarring or suspending official, make the determinations referenced in *FAR 9.405(a)* regarding contracts.

(1) If a Contracting Officer considers it necessary to award a contract, or consent to a subcontract with a debarred or suspended contractor, the Contracting Officer shall prepare a determination, including all pertinent documentation, and submit it through appropriate acquisition channels to the HCA. The documentation shall include the date by which approval is required and a compelling reason for the proposed action. Compelling reasons for award of a contract or consent to a subcontract with a debarred or suspended contractor include the following:

(i) Only the cited contractor can provide the property or services.

(ii) The urgency of the requirement dictates that HHS conduct business with the cited contractor.

(2) If the HCA decides to approve the requested action, the HCA shall request the concurrence of the debarring or suspending official and, if given, shall inform the Contracting Officer in writing of the decision within the required time period.

#### **309.406 Debarment.**

##### **309.406-3 Procedures.**

(a) *Investigation and referral.* When an apparent cause for debarment becomes known, the initiating official shall prepare a report containing the information required by 309.470-2, along with a written recommendation, and forward it through appropriate acquisition channels, including the HCA, to the Associate DAS for Acquisition in accordance with 309.470-1. The debarring official shall initiate an investigation.

(b) *Decision making process.* The debarring official shall review the results of the investigation, if any, and make a written determination whether or not debarment procedures shall commence. The ASFR/OGAPA/DA shall promptly send a copy of the determination through appropriate acquisition channels to the initiating official and the Contracting Officer. If the debarring official determines that debarment procedures shall commence, the debarring official shall consult with OGC-GLD and then notify the contractor in accordance with FAR 9.406-3(c). If the proposed action is not based on a conviction or judgment and the contractor's submission in response to the notice raises a genuine dispute over facts material to the proposed debarment, the debarring official shall arrange for fact-finding hearings and take the necessary action specified in FAR 9.406-3(b)(2). The debarring official shall also ensure that written

findings of facts are prepared and shall base the debarment decisions on the facts as found, after considering information and argument submitted by the contractor and any other information in the administrative record. The OGC-GLD shall represent HHS at any fact-finding hearing and may present witnesses for HHS and question any witnesses presented by the contractor.

#### **309.407 Suspension.**

##### **309.407-3 Procedures.**

(a) *Investigation and referral.* When an apparent cause for suspension becomes known, the initiating official shall prepare a report containing the information required by 309.470-2 along with a written recommendation and forward it through appropriate acquisition channels, including the HCA, to the suspending official in accordance with 309.470-1. The suspending official shall initiate an investigation.

(b) *Decision making process.* The suspending official shall review the results of the investigation, if any, and make a written determination whether or not suspension shall occur. ASFR/OGAPA/DA shall send a copy of the determination through appropriate acquisition channels to the initiating official and the Contracting Officer. If the suspending official determines that suspension is necessary, the suspending official shall consult with OGC-GLD and then notify the contractor in accordance with FAR 9.407-3(c). If the action is not based on an indictment, and, subject to the provisions of FAR 9.407-3(b)(2), the contractor's submission in response to the notice raises a genuine dispute over facts material to the suspension, the suspending official shall, after imposing the suspension, arrange for fact-finding hearings and take the necessary actions specified in FAR 9.407-3(b)(2).

#### **309.470 Reporting of suspected causes for debarment or suspension or the taking of evasive actions.**

##### **309.470-1 Situations where reports are required.**

The Contracting Officer shall forward a report, incorporating the information required by 309.470-2, through appropriate acquisition channels, including the HCA, to the Associate DAS for Acquisition whenever a contractor—

(a) Has committed, or is suspected of having committed, any of the acts described in FAR 9.406-2 or FAR 9.407-2; or

(b) Is suspected of attempting to evade the prohibitions of debarment or suspension imposed under this subject, or any other comparable regulation, by changes of address, multiple addresses, formation of new companies, or by other devices.

#### **309.470-2 Contents of reports.**

The Contracting Officer shall coordinate each report prepared under 309.470-1 with OGC-GLD and include the following information, when available:

(a) Contractor name and address.

(b) Name of the principal officers, partners, owners, or managers.

(c) All known affiliates, subsidiaries, or parent firms, and the nature of the affiliation.

(d) Description of the contract or contracts concerned, including the contract number and office identifying numbers or symbols; the amount of each contract; the amount paid to the contractor and the amount still due; and the percentage of work completed and to be completed.

(e) The status of vouchers.

(f) Whether contract funds have been assigned pursuant to the Assignment of Claims Act, as amended, (31 U.S.C. 3727, 41 U.S.C. 15), and, if so assigned, the name and address of the assignee and a copy of the assignment.

(g) Whether any other contracts are outstanding with the contractor or any affiliates, and, if so, the amount of the contracts, whether these funds have been assigned pursuant to the Assignment of Claims Act, as amended, (31 U.S.C. 3727, 41 U.S.C. 15), and the amounts paid or due on the contracts.

(h) A complete summary of all available pertinent evidence.

(i) A recommendation as to the continuation of current contracts.

(j) An estimate of damages, if any, sustained by the Government as a result of the contractor's action, including an explanation of the method used in making the estimate.

(k) The comments and recommendations of the Contracting Officer and statements indicating whether the contractor should be suspended or debarred, whether any limitations are necessary, and the period of any proposed debarment.

(l) As an enclosure, a copy of the contract(s) or pertinent excerpts therefrom, appropriate exhibits, testimony or statements of witnesses, copies of assignments, and other relevant documentation or a written summary of any information for which documentation is not available.

**PART 310—MARKET RESEARCH**

Sec.  
310.001 Policy.

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

**310.001 Policy.**

(a) OPDIVs are encouraged to conduct market research, to the maximum extent practicable, consistent with the urgency, complexity, and dollar value of a proposed acquisition, as well as their past experience with the same or similar requirements.

(3) (i) An OPDIV may issue an advance notice, entitled "Sources Sought" in FedBizOpps in accordance with the requirements of *FAR Part 5*, whenever a sufficient number of sources has not been identified to obtain adequate competition for a non-R & D project. The primary purpose of a Sources Sought notice is to identify all potential sources, regardless of organizational type and size classification, and determine their capabilities to fulfill a potential Government requirement. The notice is not intended to solicit technical, scientific, or business information for project planning purposes regarding existing or potential solutions. In the latter instance, an RFI may be used—see *FAR 15.201(e)* and *315.201(e)*.

(ii) When using a Sources Sought notice, an OPDIV shall not request that potential sources provide more than the minimum information necessary—see *FAR 10.001(b)*, to determine whether they have the apparent capability to perform a requirement and, therefore, whether they should be included in any future competition. The notice and the information received shall not be used to determine how well respondents can perform a requirement, which can only be evaluated in response to a solicitation. Accordingly, the notice shall not be used to—

(A) Obtain capability statements that are evaluated and determined acceptable or unacceptable;

(B) Require cost/price proposals or detailed technical solutions;

(C) Identify a prospective sole source; or

(D) Exclude small business concerns.

(iii) While not the primary intent of a Sources Sought notice, in addition to seeking information regarding all potential qualified sources, the notice may request that respondents provide information regarding their organizational size classification. For example, the notice may ask respondents to identify whether they are small businesses; HUBZone small businesses; service-disabled, veteran-

owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses in order to determine the appropriate acquisition method, including whether a set-aside is possible. However, such a notice shall not be used solely to determine the size classification of respondents for a proposed non-R & D acquisition. In such instances, a "Small Business Sources Sought" notice may be used—see *319.202–2*, in lieu of the procedures in this section.

(iv) OPDIVs shall follow the standard HHS instructions for completing a Sources Sought notice. The Contracting Officer shall post the notice in FedBizOpps by selecting and completing a Sources Sought notice. The template for the notice is available on the ASFR/OGAPA/DA Internet Web site. Additional information may be included in the notice in accordance with OPDIV procedures. The Contracting Officer shall document, in the form of a memorandum to the file, the results of the review by technical personnel of information submitted in response to the notice, including whether each respondent appears to be capable of performing the requirement. The Contracting Officer shall attach a copy of the analysis provided by the technical personnel to the memorandum.

(v) In instances where a sufficient number of sources has not been identified to compete for an R & D project, OPDIVs may use the procedures specified in *305.205*, including the issuance of an "R & D Sources Sought" notice, as appropriate, in lieu of the procedures in this section.

**PART 311—DESCRIBING AGENCY NEEDS****Subpart 311.70—Section 508 Accessibility Standards**

Sec.

311.7000 Defining electronic information technology requirements.

311.7001 Section 508 accessibility standards for HHS Web site content and communication materials.

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

**Subpart 311.70—Section 508 Accessibility Standards****311.7000 Defining electronic information technology requirements.**

HHS staff that define agency needs for EIT products and services, including EIT deliverables such as electronic documents and reports, and perform market research to meet those needs, shall document EIT requirements,

identify the applicable Section 508 accessibility standards, and document the market research. OPDIVs may develop procedures for these activities, based on the level of agency investment and risk, and shall ensure any procedures developed are in conformance with *FAR Part 10*. Procedures for defining EIT requirements may, but are not required to, include the use of the Buy Accessible Wizard (<http://www.buyaccessible.gov>), managed by GSA, or other Federal agency tools.

**311.7001 Section 508 accessibility standards for HHS Web site content and communications materials.**

(a) Section 508 of the Rehabilitation Act of 1973 [29 U.S.C. 794(d)], as amended by the Workforce Investment Act of 1998, (Section 508) specifies the accessibility standards that apply to all new solicitations and new or existing contracts or orders, regardless of dollar amount, for communications products and services that require a contractor or consultant to produce content in any format that is specifically intended for publication on, or delivery via, an HHS-owned or -funded Web site.

(b) Accordingly, before forwarding a request to the contracting/ordering office for the acquisition of communications products and services, including content in any format, such as reports, documents, charts, posters, presentations (such as Microsoft PowerPoint), or video material that is specifically intended for publication on, or delivery via, an HHS-owned or -funded Web site, the Project Officer shall consult with the OPDIV/STAFF Division (DIV) Section 508 Official or Coordinator, as necessary, to determine the applicability of Section 508, identify applicable Section 508 accessibility standards, and resolve any related issues.

(c) Based on those discussions, the Project Officer shall provide a statement in the AP (or other acquisition request document)—see *307.7101*, as to the applicability of Section 508. If Section 508 applies to an acquisition, the Project Officer shall include the following "HHS Section 508 Accessibility Standards Notice" language in a separate, clearly designated section of the SOW/PWS, and any additional information applicable to the acquisition's Section 508 accessibility standards [e.g., the list of applicable accessibility standards of the Architectural and Transportation Barriers Compliance Board (Access Board) Final Rule (36 CFR Part 1194)]. If an AP does not address these issues, and it appears an acquisition involves

Section 508, or if the discussion of Section 508 applicability to the acquisition is inadequate or incomplete, the Contracting Officer shall request that the Project Officer modify the AP accordingly.

### HHS Section 508 Accessibility Standards Notice (September 2009)

This contract is subject to Section 508 of the Rehabilitation Act (the Act) of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board (Access Board) Electronic and Information Accessibility Provisions (36 CFR Part 1194). Section 508 of the Act requires that, unless an exception applies, all communications products and services that require a contractor or consultant to produce content in any format that is specifically intended for publication on, or delivery via, a Federally owned or Federally funded Web site permit the following:

(1) Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities.

(2) Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

**Note:** Information about Section 508 of the Act is available at <http://www.section508.gov/>. The complete text of Section 508 can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

Accordingly, regardless of format, all Web content or communications materials specifically produced for publication on, or delivery via, HHS Web sites, including text, audio, or video, under this contract shall conform to applicable Section 508 accessibility standards. Remediation of any materials that do not comply with the applicable accessibility standards of 36 CFR Part 1194 as set forth herein shall be the responsibility of the Contractor.

The following Section 508 accessibility standards apply to the content or communications material identified in this SOW or PWS:

**Note:** The Project Officer shall list the applicable accessibility standards of the Access Board Final Rule (36 CFR Part 1194) (e.g., “36 CFR 1194.21(a)–(j).” Most Web-based text and communication must meet the accessibility standards in 36 CFR 1194.22, “Web-based intranet and Internet information and applications.” Additionally,

36 CFR 1194.41, “Information, documentation and support,” and 36 CFR 1194.24 “Video and multimedia products” apply to all written, graphical, or broadcast video materials or products produced for HHS, including training. 36 CFR 1194.41(c) specifies that support services for products shall accommodate the communication needs of end-users with disabilities.

## PART 312—ACQUISITION OF COMMERCIAL ITEMS

### Subpart 312.1—Acquisition of Commercial Items—General

Sec.  
312.101 Policy

### Subpart 312.2—Special Requirements for the Acquisition of Commercial Items.

312.202(d) Market research and description of agency need.

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

### Subpart 312.1—Acquisition of Commercial Items—General

#### 312.101 Policy.

(a) It is HHS policy to leverage its buying power, reduce acquisition administrative costs, and develop long-term, mutually beneficial partnerships with best-in-class providers of products and services. Accordingly, HHS has implemented a Strategic Sourcing Program through which it awards BPAs or other contract vehicles to achieve savings for commercial items and services across HHS and make the acquisition process more efficient. OPDIVs shall use HHS’ strategic sourcing vehicles to the maximum extent possible—see the HHS strategic sourcing portion of the ASFR/OGAPA/DA intranet site for further information.

### Subpart 312.2—Special Requirements for the Acquisition of Commercial Items

#### 312.202(d) Market research and description of agency need.

Whenever an OPDIV/STAFFDIV requires EIT products and services subject to Section 508 of the Rehabilitation Act of 1973, as amended, commercially available products and services shall be acquired to the maximum extent possible while ensuring Section 508 compliance. Consistent with paragraph 4.3.1 of the HHS Section 508 policy—see Section 508 policy on the HHS Office on Disability Web site, if products and services are commercially available that meet some but not all of the applicable Section 508 accessibility standards, and no commercially available products or services meet all of the applicable Section 508 accessibility standards, an OPDIV/STAFFDIV shall acquire the

products and services that best meet the applicable Section 508 accessibility standards. Commercial nonavailability exception determinations for EIT products and services that do not meet some or all of the applicable Section 508 accessibility standards shall be processed in accordance with 339.203.

## SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

### PART 313—SIMPLIFIED ACQUISITION PROCEDURES

Sec.  
313.003 Policy.

### Subpart 313.1—Procedures.

313.106–2 Evaluation of quotations or offers.

### Subpart 313.3—Simplified Acquisition Methods

313.301 Government-wide commercial purchase card.  
313.303 Blanket purchase agreements.  
313.303–5 Purchases under blanket purchase agreements.

### Subpart 313.5—Test Program for Certain Commercial Items

313.501 Special documentation requirements.

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

#### 313.003 Policy.

EIT products and services, including EIT deliverables such as electronic documents and reports, acquired pursuant to FAR Part 13 shall comply with Section 508 of the Rehabilitation Act of 1973, as amended. Consistent with paragraph 4.3.1 of the HHS Section 508 policy—see Section 508 policy on HHS Office on Disability Web site, if products and services, including commercially available items, meet some but not all of the applicable Section 508 accessibility standards, and no commercially available products or services meet all of the applicable Section 508 accessibility standards, an OPDIV/STAFFDIV shall acquire the products and services that best meet the applicable Section 508 accessibility standards. Commercial nonavailability exception determinations for EIT products and services that do not meet some or all of the applicable Section 508 accessibility standards shall be processed in accordance with 339.203.

### Subpart 313.1—Procedures

313.106–2 Evaluation of quotations or offers.

(b)(5) Technical Evaluation. When conducting a technical evaluation of quotations or proposals received under FAR Part 13, the provisions of 315.305(a)(3) apply.



**Subpart 313.3—Simplified Acquisition Methods****313.301 Government-wide commercial purchase card.**

(b) HHS' procedures for the use and control of the Government-wide commercial purchase card may be found in the HHS Purchase Card Program Guide, available on the ASFR/OGAPA/DA Web site.

(1) ASFR/OGAPA/DA has overall responsibility for monitoring the OPDIVs' implementation of the HHS purchase card program to foster compliance with FAR 13.301; OMB Circular A-123, Appendix B, "Improving the Management of Government Charge Card Programs;" GSA's SmartPay Program guidance; and HHS Purchase Card program standards.

(2) The OPDIVs, through their designated Agency/Organization Program Coordinators, are responsible for establishing the necessary local procedures and appropriate training requirements to ensure effective implementation of the HHS purchase card program.

(3) OPDIVs shall refer to 313.003 and the HHS Purchase Card Program Guide for information regarding acquiring EIT products and services subject to Section 508 of the Rehabilitation Act of 1973, as amended.

**313.303 Blanket purchase agreements.****313.303-5 Purchases under blanket purchase agreements.**

(e)(5) HHS personnel that sign delivery documents, invoices, *etc.*, verifying the receipt of an item or service shall forward such documents to the fiscal office or other paying office that the OPDIV designates. The fiscal or other paying officer shall use the signed document, invoice, *etc.*, as the basis for payment. Alternatively, OPDIVs may use electronic methods to document, and transmit to the paying office, the receipt, inspection, and acceptance of items or services for payment purposes, provided such methods are authorized in local fiscal procedures. Contracting offices shall establish procedures to ensure that funds are available prior to placement of orders.

**Subpart 313.5—Test Program for Certain Commercial Items****313.501 Special documentation requirements.**

(a) (1)

(i) The justification requirements of 306.303-1(b) and 306.303-1(b)(1) through (b)(4) apply to proposed noncompetitive acquisitions placed under FAR Subpart 13.5.

(ii) The HHS standard format for JOFOCs cited in 306.303-1(b)(1) shall be used to support noncompetitive acquisitions in excess of the simplified acquisition threshold placed under FAR Subpart 13.5.

(iii) The certification, concurrence, and approval requirements cited in 306.304 for JOFOCs apply to applicable noncompetitive acquisitions placed under FAR Subpart 13.5.

(2)

(i) The Contracting Officer shall exercise this approval authority unless a higher approval level is required by OPDIV procedures.

(ii) The CAs are listed in 306.501. This approval authority is not delegable.

(iii) The CA shall exercise this approval authority, except where the individual designated as the competition advocate does not meet the requirements of FAR 6.304(a)(3)(ii). This approval authority is not delegable.

(iv) The HHS SPE is the Associate DAS for Acquisition.

**PART 314—SEALED BIDDING****Subpart 314.1—Use of Sealed Bidding**

Sec.

314.103 Policy.

**Subpart 314.2—Solicitation of Bids**

314.202 General rules for solicitation of bids.

314.202-7 Facsimile bids.

**Subpart 314.4—Opening of Bids and Award of Contract**

314.404 Rejection of bids.

314.404-1 Cancellation of invitations after opening.

314.407 Mistakes in bids.

314.407-3 Other mistakes disclosed before award.

314.407-4 Mistakes after award.

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

**Subpart 314.1—Use of Sealed Bidding****314.103 Policy.**

EIT products and services, including EIT deliverables such as electronic documents and reports, acquired using sealed-bid procedures shall comply with Section 508 of the Rehabilitation Act of 1973, as amended. Consistent with paragraph 4.3.1 of the HHS Section 508 policy—see Section 508 policy on HHS Office of Disability Web site, if products and services, including commercially available items, meet some but not all of the applicable Section 508 accessibility standards, and no commercially available products or services meet all of the applicable Section 508 accessibility standards, an OPDIV/STAFFDIV shall acquire the products and services that best meet the applicable Section 508 accessibility

standards. Commercial nonavailability exception determinations for EIT products and services that do not meet some or all of the applicable Section 508 accessibility standards shall be processed in accordance with 339.203.

**Subpart 314.2—Solicitation of Bids****314.202 General rules for solicitation of bids.****314.202-7 Facsimile bids.**

(c) If the HCA (non-delegable) determines that the contracting activity will allow use of facsimile bids and proposals, the HCA shall prescribe internal procedures, in accordance with the FAR 14.202-7, to ensure uniform processing and control.

**Subpart 314.4—Opening of Bids and Award of Contract****314.404 Rejection of bids.****314.404-1 Cancellation of invitations after opening.**

(c) The HCA or CCO (non-delegable) shall make the agency head determinations specified in FAR 14.404-1.

**314.407 Mistakes in bids.****314.407-3 Other mistakes disclosed before award.**

(e) The CCO (non-delegable) has the authority to make determinations under paragraphs (a), (b), (c), and (d) of FAR 14.407-3.

(f) OGC-GLD shall concur in each proposed determination.

(i) The CCO shall submit directly to OGC-GLD cases in which the evidence is not clear and convincing or is otherwise doubtful.

**314.407-4 Mistakes after award.**

(c) The HCA or the CCO (non-delegable), in consultation with OGC-GLD, has the authority to make administrative determinations in connection with mistakes in bid alleged after award.

(d) OGC-GLD shall concur in each proposed determination.

**PART 315—CONTRACTING BY NEGOTIATION****Subpart 315.2—Solicitation and Receipt of Proposals and Information**

Sec.

315.201 Exchanges with industry before receipt of proposals.

315.204-5 Part IV—Representations and instructions.

315.208 Submission, modification, revision, and withdrawal of proposals.

315.209 Solicitation provisions and contract clauses.

**Subpart 315.3—Source Selection.**

- 315.303–70 Policy.
- 315.304 Evaluation factors and significant subfactors.
- 315.305 Proposal evaluation.
- 315.306 Exchanges with offerors after receipt of proposals.
- 315.307 Proposal revisions.
- 315.370 Finalization of details with the selected source.
- 315.371 Contract preparation and award.
- 315.372 Preparation of negotiation memorandum.

**Subpart 315.4—Contract Pricing**

- 315.404 Proposal analysis.
- 315.404–2 Information to support proposal analysis.
- 315.404–4 Profit.

**Subpart 315.6—Unsolicited Proposals**

- 315.605 Content of unsolicited proposals.
- 315.606 Agency procedures.
- 315.606–1 Receipt and initial review.
- 315.609 Limited use of data.

**Subpart 315.70—Acquisition of Electronic Information Technology**

- 315.7000 Section 508 accessibility standards.

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

**Subpart 315.2—Solicitation and Receipt of Proposals and Information****315.201 Exchanges with industry before receipt of proposals.**

(e)(1) An OPDIV may issue an advance notice, entitled “Request for Information,” in accordance with the requirements of *FAR 15.201(e)*, whenever it requires technical, scientific, and/or business information and input from the marketplace for project planning purposes regarding the availability of existing or potential solutions. An RFI may be used for any type of requirement, but is particularly appropriate for complex projects involving R & D, IT, construction, and other highly technical requirements. An RFI may also be issued to identify issues about the Government’s requirements and the planned acquisition strategy. Use of an RFI generally is appropriate under the following conditions:

(i) It is not clear whether the purpose and performance requirements of a potential or planned project are feasible, achievable, and complete.

(ii) It is not certain that a solution, technical approach, or product needed to accomplish a potential or planned project exists or can be developed, particularly in the case of a new, highly specialized/unique Government program mandate.

(iii) It is necessary to test the marketplace to determine if there are questions or concerns regarding the use of a new or innovative acquisition strategy or instrument previously

untreated to accomplish a potential or planned project.

(iv) It is necessary to determine the general effort or time (estimate or rough order of magnitude) that may be required to accomplish a potential or planned project.

**Note:** This type of information may be requested, only if it is necessary, broad in scope, and required for planning purposes. Detailed estimates must not be requested.

(v) It is necessary to ensure that unduly restrictive technical or business/acquisition requirements are not made part of any resultant solicitation so that maximum competition is generated.

(2) When using an RFI, an OPDIV shall not request that potential sources provide more than the minimum information necessary—*see FAR 10.001(b)*, to obtain the input required. The notice and the information received shall not be used to determine how well respondents can perform a requirement, which can only be evaluated in response to a solicitation. Accordingly, the notice shall not be used to—

- (i) Obtain capability statements that are evaluated and determined acceptable or unacceptable;
- (ii) Require cost/price proposals or detailed technical solutions;
- (iii) Identify a prospective sole source; or

(iv) Exclude small business concerns.

(3) While not the primary intent of an RFI, an OPDIV may additionally request that respondents provide information regarding their organizational size classification and capabilities when the OPDIV is uncertain whether any organization, acting individually or in partnership with others, can satisfy the requirement. For example, the notice may ask respondents to identify whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or a small disadvantaged businesses. However, an RFI shall not be used solely to determine the availability of qualified sources for a proposed project or to determine their size classification. In such instances, as applicable, an R & D Sources Sought notice, Sources Sought notice, or Small Business Sources Sought notice may be used—*see HHSAR 305.205, 310.001, and 319.202–2*.

(4) OPDIVs shall follow the standard HHS instructions for completing an RFI. The template for an RFI is available on the ASFR/OGAPA/DA Internet Web site. The Contracting Officer shall post the notice in FedBizOpps by selecting

and completing a Special Notice, accessible on the FedBizOpps “Notices” page at: <http://www.fedbizopps.gov>. RFIs must be published, at a minimum, in FedBizOpps—*see FAR 10.002(b)(2)(iii) and 15.201(d)*.

Additional information may be included in an RFI in accordance with OPDIV procedures. The Contracting Officer shall document, in the form of a memorandum to the file, the results of the review by technical personnel of information submitted in response to the notice, including whether each respondent appears to be capable of performing the requirement. The Contracting Officer shall attach a copy of the analysis provided by the technical personnel to the memorandum.

**315.204–5 Part IV—Representations and instructions.**

(c) *Section M, Evaluation factors for award.*

(1) General.

(i) The Project Officer shall develop technical evaluation factors and submit them to the Contracting Officer as part of the acquisition plan or other acquisition request documentation for inclusion in a solicitation. The Project Officer shall indicate the relative importance or weight of the evaluation factors based on the requirements of an individual acquisition. Since the evaluation factors will serve as the standard for proposal evaluation, they require careful selection.

(ii) Only a formal amendment to a solicitation can change the evaluation factors. Evaluation of proposals shall include only those factors set forth in a solicitation.

(2) Review of evaluation factors.

(i) The Contracting Officer shall review evaluation factors to ensure they are consistent with the SOW/PWS. This review is not intended to dictate technical requirements to the program office or Project Officer, but rather to ensure that the evaluation factors are clear, concise, and fair, so that all potential offerors are fully aware of the bases for proposal evaluation and are given an equal opportunity to compete.

(ii) The Project Officer and the Contracting Officer shall review the evaluation factors to ascertain the following:

(A) The factors address the key programmatic concerns which the offerors must be aware of in preparing proposals.

(B) The factors are specifically applicable to the current acquisition and are not restatements of factors from previous acquisitions which are not relevant.

(C) The factors represent only the significant areas of importance, rather than a multitude of factors. (*Note:* All factors tend to lose importance, if too many are included; and using too many factors may prove as detrimental as using too few.)

(3) Examples of topics that form a basis for evaluation factors. Typical examples of topics that form a basis for the development of evaluation factors are listed in the following paragraphs. These examples may assist in the development of actual evaluation factors for a specific acquisition, as appropriate.

(i) Understanding of the SOW/PWS.  
 (ii) Method of accomplishing the objectives and intent of the SOW/PWS.  
 (iii) Soundness of the scientific or technical approach for executing the requirements of the SOW/PWS, including, when applicable, preliminary layouts, sketches, diagrams, other graphic representations, calculations, curves, and other data necessary for presentation, substantiation, justification, or understanding of the approach.

(iv) Special technical factors, such as experience or pertinent novel ideas in the specific branch of science or technology involved.

(v) Feasibility or practicality of successfully accomplishing the requirements (including a statement and discussion of anticipated major difficulties and problem areas, and recommended approaches for their resolution).

(vi) Availability of required special research, test, and other equipment or facilities.

(vii) Managerial capability (ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources, and to successfully manage the project, including subcontractor and/or consultant efforts, if applicable, as evidenced by the management plan and demonstrated by previous experience).

(viii) Availability, qualifications, experience, education, and competence of professional, technical, and other personnel, including proposed subcontractors and consultants (as evidenced by resumes, endorsements, and explanations of previous efforts).

(ix) Soundness of the proposed staff time or labor hours, propriety of personnel classifications (professional, technical, others), necessity for type and quantity of material and facilities proposed, validity of proposed subcontracting, and necessity of proposed travel.

(x) Quality of offeror's past performance on recent projects of similar size and scope.

(xi) Extent of proposed participation of small disadvantaged business concerns in performance of the contract.

#### **315.208 Submission, modification, revision, and withdrawal of proposals.**

(b) In addition to the provision in *FAR 52.215-1*, Instructions to Offerors—Competitive Acquisition, if an HCA determines that certain classes of biomedical or behavioral R & D acquisitions are subject to conditions other than those specified in *FAR 52.215-1(c)(3)*, the HCA may authorize for use in competitive solicitations for R & D, valued at more than the simplified acquisition threshold, the use of the provision in *352.215-70*, Late Proposals and Revisions. This is an authorized FAR deviation.

(2) When the provision at *352.215-70* is included in the solicitation and a proposal is received after the exact time specified for receipt, the Contracting Officer, with the assistance of cost and technical personnel, shall make a written determination as to whether the proposal meets the requirements of the provision at *352.215-70* and, therefore, can be considered.

#### **315.209 Solicitation provisions and contract clauses.**

(a) The Contracting Officer shall insert paragraph (e) in *352.215-1* in place of paragraph (e) in the provision in *FAR 52.215-1*, Instructions to Offerors—Competitive Acquisition, in solicitations for competitive, negotiated acquisitions valued at more than the simplified acquisition threshold. This is an authorized FAR deviation.

### **Subpart 315.3—Source Selection**

#### **315.303-70 Policy.**

(a) If an OPDIV is required by statute to use peer review for technical review of specified contracts, the requirements of those statutes, any implementing regulatory requirements, the Federal Advisory Committee Act, and as applicable, any approved HHSAR deviation(s) from this subpart take precedence over the otherwise applicable requirements of this subpart.

(1) The statutes that require such review and implementing regulations are as follows: NIH—42 U.S.C. 289a and 42 CFR Part 52h; SAMHSA—42 U.S.C. 290aa-3, and AHRQ—42 U.S.C. 299c-1.

#### **315.304 Evaluation factors and significant subfactors.**

(a) A solicitation for EIT products and services, including EIT deliverables such as electronic documents and

reports, shall include a separate technical evaluation factor (which may be in the form of a technical evaluation criterion or a mandatory qualification criterion, as appropriate) developed by the Contracting Officer, Project Officer, and the OPDIV Section 508 Coordinator to determine vendor compliance with applicable Section 508 accessibility standards. The technical evaluation panel's assessment of Section 508 accessibility standards conformance shall be based on the Section 508 Product Assessment Template—see Section 508 policy on Office of Disability Web site for the template, and on any other pertinent information that offerors provide in response to a solicitation. The HHS Office on Disability is responsible for providing technical assistance in Section 508 evaluation factor development.

(b) Before conducting negotiations or making an award, the Contracting Officer shall provide a summary of the technical evaluation panel's assessment of vendor responses to the solicitation's Section 508 evaluation factor for review by the Section 508 Official or designee. The Section 508 Official or designee shall indicate approval/disapproval of the evaluation panel's assessment. The Contracting Officer shall coordinate the resolution of any issues raised by the Section 508 Official or designee with the chair of the technical evaluation panel or Project Officer, as appropriate. The acquisition process shall not proceed unless and until the Section 508 Official or designee has approved the technical evaluation panel's assessment. The Contracting Officer shall include the assessment in the official contract file. See *339.203* regarding processing exception determination requests.

#### **315.305 Proposal evaluation.**

(a)(1) *Cost or price evaluation.*  
 (i) The Contracting Officer shall evaluate proposals in accordance with the *FAR 15.404*. The extent of cost or price analysis in each case depends on the availability of competition, contract type, the proposed amount, and technical complexity.

(A) For competitive firm-fixed-price and fixed price with economic price adjustment contracts, price analysis should be sufficient to determine price fairness and reasonableness.

(B) When competition is not adequate for the above contract types, and for cost-reimbursement and time and materials contracts, cost analysis may be required. In such cases, the Contracting Officer shall request the Project Officer's assistance in analyzing the following cost elements, if applicable, to

determine if the proposed amounts are necessary and reasonable for efficient contract performance:

(1) The number and mix of proposed labor hours relative to the technical requirements.

(2) Types, numbers and hours/days of proposed consultants.

(3) The kinds and quantities of material, equipment, supplies, and services.

(4) Kinds and quantities of IT.

(5) Logic of proposed subcontracting.

(6) Travel proposed, including number of trips, locations, purpose, and travelers.

(7) Other direct costs not specified above.

(ii) The Project Officer shall provide written comments, including the rationale for any exceptions to the cost elements. The Contracting Officer shall consider the Project Officer's comments for negotiations or to support award without discussions. The Contracting Officer shall also request assistance of a cost/price analyst, when necessary.

(2) *Past performance evaluation.*

When evaluating past performance, the Contracting Officer shall check references to obtain information concerning the performance history of offerors in compliance with *FAR 42.1502*. The Contracting Officer may require the assistance of the Project Officer as well as other Government technical personnel in performing this function.

(3) *Technical evaluation.*

(i) Technical evaluation plan.

(A) The Contracting Officer shall require a technical evaluation plan if the proposed acquisition either requires preparation of an AP—*see 307.71* or is otherwise sufficiently complex.

(B) The technical evaluation plan shall include, at a minimum, the following elements:

(1) A list of recommended technical evaluation panel members, their organizations, a list of their major consulting clients (if applicable), their qualifications, and curricula vitae (if applicable).

(2) A statement that the technical evaluation panel will include non-Federal technical proposal evaluators, if applicable, and a determination that sufficient Federal technical proposal evaluators are unavailable—*see FAR 37.204*. A determination to use non-Federal proposal evaluators shall be signed at a level no lower than the HCA. A determination is not required, however, if non-Federal evaluators will be used in accordance with *315.303-70(a)*.

(3) A statement that there is no apparent or actual conflict of interest

regarding any recommended panel member.

(4) A copy of each rating sheet, approved by the Contracting Officer, to ensure consistency with the evaluation criteria.

(5) A brief description of the general evaluation approach.

(6) A description of the methodology for evaluating key elements in the technical evaluation plan, including any solicitation evaluation factor involving the acquisition of EIT products and services subject to Section 508.

(C) Except as provided in OPDIV procedures, a program office official at least one level above the Project Officer shall approve the technical evaluation plan.

(D) The Project Officer shall provide the technical evaluation plan to the Contracting Officer for review and approval before the solicitation is issued. The Contracting Officer shall ensure that the evaluation criteria reflect the significant factors and subfactors relating to the evaluation when conducting the review of the plan.

(ii) Technical evaluation panel.

(A) General.

(1) A technical evaluation panel is required for all acquisitions subject to this subpart that require preparation of an AP. The Contracting Officer may require a technical evaluation panel for acquisitions that do not require preparation of an AP, based on the complexity of the acquisition and the role that the technical evaluation will have in the award decision.

(2) The technical evaluation process requires careful consideration regarding the size, composition, expertise, and function of the technical evaluation panel. The panel's efforts will influence the success or failure of the acquisition.

(3) At least 50 percent of the HHS personnel on a technical evaluation panel shall have successfully completed HHS University's "Basic Contracting Officer's Technical Representative" course or an equivalent course before assuming their designated role. This training requirement applies to evaluators performing the initial technical evaluation and any subsequent technical evaluations. However, this training requirement does not apply to peer review panel members.

(B) Role of the Project Officer.

(1) The Project Officer provides guidance, information, and assistance to the Contracting Officer on all technical aspects of a proposed acquisition—*see 302.101*. The Project Officer may be a voting member of the technical evaluation panel and may serve as the chairperson of the panel unless

prohibited by law or contracting activity procedures.

(2) The Project Officer shall recommend panel members who have sufficient expertise in the technical aspects of the acquisition to be able to evaluate strengths and weaknesses in proposals.

(3) The Project Officer shall ensure that persons possessing expertise and experience in addressing issues relative to sex, race, national origin, and disability are included as panel members for acquisitions to which such issues apply.

(4) The Project Officer shall submit a list of recommended panel members to a program office official at least one level higher than him/herself. This official shall review the list and select the chairperson.

(5) The Project Officer shall arrange for adequate and secure working space for the panel.

(C) Role of the Contracting Officer.

(1) The term "Contracting Officer," as used in this subpart, may be the Contracting Officer or a Contract Specialist possessing an appropriate FAC-C certification.

(2) The Contracting Officer shall not serve as a member of the technical evaluation panel, but shall—

(i) Address the initial meeting of the technical evaluation panel;

(ii) Provide assistance to the evaluators as required; and

(iii) Ensure that the scores adequately reflect the written technical report comments.

(D) Conflict of interest.

(1) If a panel member has an actual or apparent conflict of interest related to a proposal under evaluation, the individual cannot serve on the panel. If a suitable replacement is not available, the panel shall perform the review without a replacement.

(2) For the purposes of this subpart, conflicts of interest are defined in the *Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635)*, *Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services (5 CFR part 5501)*, and the *Procurement Integrity Act*. For outside evaluators serving on the technical evaluation panel, *see* paragraph (a)(3)(ii)(F) of this section.

(E) Continuity of evaluation process.

(1) The technical evaluation panel shall evaluate all original proposals; make recommendations to the chairperson regarding strengths and weaknesses of proposals; if required by the Contracting Officer, assist the Contracting Officer during communications and discussions; and

review supplemental, revised or final proposal revisions. To the extent possible, the same evaluators shall be available throughout the entire evaluation and selection process to ensure continuity and consistency in the treatment of proposals. The following are examples of circumstances when it would not be necessary for the technical evaluation panel to evaluate revised proposals submitted during the acquisition:

(i) The answers to questions do not have a substantial impact on the proposal.

(ii) Final proposal revisions are not materially different from the original proposals.

(iii) Revisions to the proposals are relatively minor and do not affect the rankings of the offerors.

(2) The Contracting Officer, with the written concurrence of the technical evaluation panel chairperson, may decide not to have the panel evaluate the revised proposals. The Contracting Officer shall fully document such a decision in the contract file.

(3) When the Contracting Officer considers technical evaluation panel meetings necessary, the attendance of evaluators is mandatory. When the chairperson determines that an evaluator's failure to attend the meetings is prejudicial to the evaluation, the chairperson shall remove or replace the individual after discussing the situation with the Contracting Officer and obtaining the Contracting Officer's concurrence and the approval of the official responsible for appointing the panel members.

(4) When continuity of the evaluation process is not possible, and new evaluators are selected or the size of the evaluation panel is reduced, each panel member shall review all proposals at the current stage of the acquisition—*i.e.*, initial proposal, final proposal revisions, *etc.* Also, the Contracting Officer shall provide guidance concerning what steps to take if an unusually large number of proposals is received, including how to determine what constitutes an unusually large number of proposals.

(F) Use of outside evaluators.

(1) Except when peer review is required by statute as provided in 315.303–70(a), decisions to disclose proposals to evaluators outside of the Government shall be made by the official responsible for appointing panel members in accordance with OPDIV procedures. The avoidance of organization conflict of interest and competitive relationships must be taken into consideration when making the decision to use outside evaluators.

(2) When a solicited proposal will be disclosed outside the Government for evaluation purposes, the following or similar conditions shall be part of the written agreement with the evaluator(s) prior to disclosure:

#### Conditions for Evaluating Proposals

The evaluator agrees to use the data (trade secrets, business data, and technical data) contained in the proposal for evaluation purposes only. The foregoing requirement does not apply to data obtained from another source without restriction. Any notice or legend placed on the proposal by either HHS or the submitter of the proposal shall be applied to any reproduction or abstract provided to the evaluator or made by the evaluator. Upon completion of the evaluation, the evaluator shall return to the Government the furnished copy of the proposal or abstract, and all copies thereof, to the HHS office which initially furnished the proposal for evaluation. Unless authorized by the HHS initiating office, the evaluator shall not contact the submitter of the proposal concerning any aspects of its contents. The evaluator's employees and subcontractors shall abide by these conditions.

(iii) Receipt of proposals.

(A) After the closing date for the receipt of proposals set in the solicitation, the Contracting Officer shall forward the technical proposals, by memorandum, to the Project Officer or chairperson for evaluation. The Contracting Officer shall retain the business proposals for evaluation.

(B) The transmittal memorandum shall include at least the following elements:

(1) A list of the names of the organizations submitting proposals.

(2) A reference to the need to preserve the integrity of the source selection process.

(3) A statement that only the Contracting Officer is authorized to conduct discussions.

(4) A requirement for a technical evaluation report in accordance with paragraph (a)(3)(vi) of this section.

(5) The establishment of a date for receipt of the technical evaluation report.

(iv) Convening the technical evaluation panel.

(A) Normally, the technical evaluation panel convenes to evaluate proposals. However, there may be situations when the panel chairperson determines that it is not feasible for the panel to convene. Whenever the panel does not convene, the panel chairperson shall closely monitor the technical review to produce acceptable results.

(B) When a panel convenes, the chairperson shall control the technical proposals provided by the Contracting Officer for use during the evaluation

process. The chairperson normally distributes the technical proposals prior to the initial panel meeting and establishes procedures for securing the proposals whenever they are not being evaluated to ensure their confidentiality. After an evaluation is completed, the chairperson shall return all proposals to the Contracting Officer.

(C) The Contracting Officer shall address the initial meeting of the panel and state the basic rules for conducting the evaluation. The Contracting Officer shall provide written guidance to the panel, if the Contracting Officer cannot attend the initial panel meeting. The guidance shall include the following elements:

(1) An explanation of the evaluation process and the role of evaluators throughout the process.

(2) The need for evaluators to read and understand the solicitation, especially the SOW/PWS and evaluation criteria, prior to reading the proposals.

(3) The need for evaluators to restrict the review to only the SOW/PWS, the evaluation criteria, and the contents of the technical proposals.

(4) The need for each evaluator to review all of the proposals.

(5) The need for evaluators to identify ambiguities, inconsistencies, errors, and deficiencies.

(6) The need for the evaluators to provide complete written documentation of the individual strengths and weaknesses for each proposal.

(7) An instruction specifying that, until an award is made, they may not disclose information concerning the acquisition to any person not directly involved in the evaluation process.

(8) An explanation of conflicts of interest.

(v) Rating and ranking of proposals. The evaluators shall individually read each proposal, describe tentative strengths and weaknesses, and independently assign preliminary scores in relation to each evaluation factor set forth in the solicitation. The evaluators may then discuss in detail the individual strengths and weakness described by each evaluator and, if possible, arrive at a common understanding of the major strengths and weaknesses and the potential for correcting each offeror's weakness(es). Each evaluator shall assign a final score to each proposal, and the technical evaluation panel shall collectively rank the proposals. Normally, ranking is the result of adding the numerical scores assigned to the evaluation factors and determining the average for each offeror. The evaluators shall then identify

whether each proposal is acceptable or unacceptable. The technical evaluation panel shall not employ predetermined cutoff scores.

(vi) Technical evaluation report. The chairperson shall prepare a technical evaluation report and provide it to the Contracting Officer, who shall maintain it as a permanent record in the contract file. The report shall reflect the ranking of the proposals and identify each proposal as acceptable or unacceptable. The report shall also include a narrative evaluation specifying the strengths and weaknesses of each proposal, and any reservations, qualifications, or areas to be addressed that might bear upon the selection of sources for negotiation and award. The report shall include concrete technical reasons supporting any determination of unacceptability of a proposal and, for acceptable proposals, include specific points and questions for discussions or negotiations. The technical evaluation report shall also include a copy of each signed rating sheet, unless the Contracting Officer determines, in accordance with FAR 15.305(a)(3)(ii), and 315.305(a)(3)(vi), that the technical evaluation report includes appropriate and sufficiently detailed supporting narrative (with specific references to particular portions of offerors' proposals) to (1) fully and reasonably explain the basis for the technical evaluation panel's assessments of each proposal, including an evaluation rating of "acceptable" or "unacceptable; and (2) support any recommendation to include or not include a proposal in the competitive range. However, when peer review of proposals is required as provided in 315.303-70(a), OPDIVs shall follow applicable peer review guidelines and practices regarding the submission, maintenance, and disposal of reviewer rating sheets.

**315.306 Exchanges with offerors after receipt of proposals.**

(d) *Exchanges with offerors after establishment of the competitive range.* The Project Officer or technical evaluation panel shall develop technical questions as part of the technical evaluation report. The questions shall disclose the ambiguities, weaknesses, and deficiencies of offeror(s)' proposals. The Contracting Officer, with the assistance of the Project Officer or panel as required, shall prepare the management, past performance, and cost or price questions. The method of requesting offerors in the competitive range to submit additional information may vary depending on the complexity of the questions, the extent of additional information necessary, the time needed

to analyze the responses, and the time frame for making the award. However, to the extent practicable, all questions and answers shall be in writing. The Contracting Officer shall give each offeror in the competitive range an equitable period of time for preparation of responses to questions to the extent practicable.

**315.307 Proposal revisions.**

(b) Final proposal revisions are subject to—

(1) A final evaluation of price or cost and other salient factors by the Contracting Officer and Project Officer, with assistance from a cost/price analyst, as appropriate; and

(2) An evaluation of technical factors by the technical evaluation panel, as necessary.

The technical evaluation panel may rescore and re-rank technical proposals in the competitive range and prepare a technical evaluation report. To the extent practicable, the same evaluators who reviewed the original proposals shall perform the evaluation. The Contracting Officer and Project Officer shall conduct a final evaluation of past performance. The technical evaluation panel may be involved in the final evaluation of past performance, if the panel is comprised solely of Government personnel.

**315.370 Finalization of details with the selected source.**

(a) After selection of the successful proposal, the Contracting Officer may finalize details with the selected offeror, if necessary. However, the Contracting Officer shall not introduce any factor that could have an effect on the selection process after the common cutoff date for receipt of final proposal revisions, nor shall the finalization process in any way prejudice the competitive interest or rights of the unsuccessful offerors. The Contracting Officer shall restrict finalization of details with the selected offeror to definitizing the final agreement on terms and conditions, assuming none of these factors were involved in the selection process.

(b) Whenever a change occurs in the requirements, the Contracting Officer shall reopen the competition, and provide all offerors submitting final proposal revisions an opportunity to resubmit proposals based on the revised requirements. If there is a question as to whether a change is material and would require the initiation of a new competition, the Contracting Officer shall obtain the advice of technical personnel and OGC-GLD before proceeding. Significant changes in the

offeror's cost proposal may also necessitate a reopening of a competition, if the changes alter the factors involved in the original selection process.

(c) Upon finalization of details, the Contracting Officer shall obtain a confirmation letter from the successful offeror which includes any revisions to its technical proposal, the agreed upon price or cost, and, as applicable, a certificate of current cost or pricing data.

**315.371 Contract preparation and award.**

(a) After completing any activities that may be necessary to finalize details with the selected offeror, the Contracting Officer shall—

(1) Prepare the negotiation memorandum in accordance with 315.372;

(2) Prepare the contract containing all agreed to terms and conditions and clauses required by law or regulation;

(3) Include in the contract file the pertinent documents referenced in FAR 4.803; and

(4) Obtain the appropriate approval of the proposed contract award(s) in accordance with subpart 304.71 and contracting activity procedures.

(b) After receiving the required approvals, the Contracting Officer shall—

(1) Transmit the contract to the prospective contractor for signature; and

(2) Inform the prospective contractor that the contract is not effective until the Contracting Officer transmits the fully executed contract to the contractor.

(c) The Contracting Officer shall not sign or issue the contract until the finance office certifies that the funds are available for obligation.

**315.372 Preparation of negotiation memorandum.**

The Contracting Officer shall prepare a negotiation memorandum, or summary of negotiations, to document all actions leading to award of a contract and support the source selection decision discussed in FAR 15.308. The memorandum also satisfies the requirement for preparation of a "cost/price negotiation memorandum" required by FAR 15.406-3. The memorandum shall be in sufficient detail to explain and support the rationale, judgments, and authorities upon which all actions were predicated. The memorandum shall document the negotiation process and reflect the negotiator's actions and judgments in concluding a satisfactory agreement for the Government. The memorandum shall address each item listed below. If an item is not applicable, the

memorandum shall so state. The Contracting Officer may reference information already contained in the contract file rather than reiterate it.

(a) *Description of articles and services and period of performance.* Provide a description of the articles or services, quantity, unit price, total contract amount, and period of contract performance.

(b) *Acquisition planning.* Summarize or reference any acquisition planning activities that have taken place.

(c) *Synopsis of acquisition.* Provide a statement as to whether the acquisition has or has not been publicized in accordance with *FAR Subpart 5.2*. Include a brief statement referencing the specific basis for exemption under the FAR, if applicable.

(d) *Contract type.* Provide sufficient detail to support the type of contractual instrument recommended for the acquisition. If the contract is a cost-sharing type, explain the essential cost-sharing features.

(e) *Extent of competition.* Discuss the extent to which full and open competition was solicited and obtained. Include the date of solicitation, sources solicited, and solicitation results. If a late proposal was received, discuss whether or not the late proposal was evaluated and the rationale for the decision.

(f) *Technical evaluation.* Summarize or reference the results presented in the technical evaluation report.

(g) *Business evaluation.* Summarize or reference results presented in the business report.

(h) *Past performance.* Summarize or reference results of both the past performance evaluation and reference checks.

(i) *Competitive range* (if applicable). Describe how the competitive range was determined, and indicate the offerors that were included in and excluded from the competitive range.

(j) *Cost breakdown and analysis.* Include a complete cost breakdown together with the Contracting Officer's analysis of the estimated cost by individual cost elements. The analysis shall discuss the items specified in *FAR 15.406-3* and other cost factors, such as—

(1) A comparison of cost factors proposed for the current requirement with actual factors used in earlier contracts, using the same cost centers of the same supplier or cost centers of other sources having recent contracts for the same or similar item;

(2) Any pertinent Government-conducted audit of the proposed contractor's record or any pertinent cost advisory report;

(3) Any pertinent technical evaluation inputs as to necessity, allocability and reasonableness of labor, material and other direct expenses;

(4) Any other pertinent information to fully support the basis for the cost analysis;

(5) If the contract is an incentive type, a discussion of all elements of profit and fee structure; and

(6) A justification of the reasonableness of the contractor's proposed profit or fixed fee considering the requirements of *FAR 15.404-4* and *315.404-4*.

(k) *Cost realism.* Describe the cost realism analysis performed on proposals.

(l) *Government-furnished property and facilities.* With respect to Government-furnished facilities, equipment, tooling, or other property, include the following:

(1) If the Government will not provide property, a statement to that effect.

(2) If the Government will provide property, a full description of it, its estimated dollar value, the basis of price comparison with competitors, and the basis of rental charge, if rental is involved.

(3) If a decision to furnish property has not been made, a detailed explanation.

(m) *Negotiations.* Include a statement as to the date and place of negotiations, and identify members of both the Government and contractor negotiating teams by area of responsibility. Include negotiation details relative to the SOW/PWS, terms and conditions, and special provisions. The results of cost or price negotiations shall include the information required by *FAR 31.109* and *15.406-3*. In addition, if the potential contractor provided cost or pricing data, specify the extent to which the Contracting Officer relied upon the factual cost or pricing data submitted and used it in negotiating the cost or price.

(n) *Other considerations.* Include coverage of areas such as the following:

(1) Financial data with respect to a contractor's capacity and stability.

(2) Determination of contractor responsibility.

(3) Details as to why the method of payment, such as progress payments, advance payments, *etc.*, is necessary and cite any required D & F's.

(4) Information with respect to obtaining a certificate of current cost or pricing data.

(5) Other required special approvals.

(6) If the contract represents an extension of previous work, the status of funds and performance under the prior contract(s). Also, the Project Officer

shall provide sufficient information for the Contracting Officer to determine that the Government has obtained enough actual or potential value from the work previously performed to warrant continuation with the same contractor.

(7) A statement that the Contracting Officer has explained the equal opportunity provisions of the proposed contract to the contractor, and the contractor is aware of its responsibilities. Also, state whether or not an Equal Employment Opportunity (EEO) clearance is required.

(8) If the contract is for services, a statement, in accordance with *FAR 37.103*, that the services are nonpersonal in nature.

(o) *Terms and conditions.* Identify the general and special clauses and conditions that are contained in the contract, such as option arrangements, multi-year contracting, anticipatory costs, deviations from standard clauses, *etc.* The Contracting Officer shall state the rationale for inclusion of any special terms and conditions and, where applicable, identify the document which granted approval for their use.

(p) *Recommendation.* Briefly state the basis (or bases) for recommending award.

(q) *Signature.* The Contracting Officer and the individual who prepared the negotiation memorandum must sign the document.

## Subpart 315.4—Contract Pricing

### 315.404 Proposal analysis.

#### 315.404-2 Information to support proposal analysis.

(a)(2) When some or all information sufficient to determine the reasonableness of the proposed cost or price is already available or can be obtained by phone from the cognizant audit agency, the Contracting Officer may request less-than-complete field pricing support (specifying in the request the information needed) or may waive in writing the requirement for audit and field pricing support by documenting the file to indicate what information will be used instead of the audit report and the field pricing report.

(3) When initiating audit and field pricing support, the Contracting Officer shall do so by sending a request to the cognizant Administrative Contracting Officer, with an information copy to the cognizant audit office. When field pricing support is not available, the Contracting Officer shall initiate an audit by sending, in accordance with agency procedures, two (2) copies of the request to the OIG Office of Audit Services, Regional Inspector General. In



both cases, the Contracting Officer shall, in the request—

- (i) Prescribe the extent of the support needed;
- (ii) State the specific areas for which input is required;
- (iii) Include the information necessary to perform the review, such as the offeror's proposal and the applicable portions of the solicitation, particularly those describing requirements and delivery schedules;
- (iv) Provide the complete address of the location of the offeror's financial records that support the proposal;
- (v) Identify the office having audit responsibility, if other than the HHS Regional Audit Office; and
- (vi) Specify a due date for receipt of a verbal report and the written audit report. If the time available is not adequate to permit satisfactory coverage of the proposal, the auditor shall so advise the Contracting Officer and indicate the additional time needed. The Contracting Officer shall submit one copy of the audit request letter provided to the Office of Audit Services, Regional Inspector General and a complete copy of the contract price proposal to OIG Office of Audit Services. Whenever the Office of Audit Services has conducted an audit review, the Contracting Officer shall forward two (2) copies of the memorandum of negotiation to OIG Office of Audit Services.

**315.404-4 Profit.**

(b) *Policy.*

(1) The structured approach for determining profit provides a technique for establishing a profit objective for negotiation. A profit objective is that part of the estimated contract price objective or value which, in the judgment of the Contracting Officer, constitutes an appropriate amount of profit for the acquisition being considered. This technique allows for consideration of the profit factors described in paragraph (d) of this section. The Contracting Officer's analysis of these factors shall be based on available information, such as proposals, audit data, assessment reports, and pre-award surveys. The structured approach provides a basis for documenting the profit objective. The Contracting Officer shall explain any significant departure from this objective. The amount of documentation depends on the dollar value and complexity of the proposed acquisition. The profit objective is a part of the overall negotiation objective and is directly related to the cost objective and any proposed sharing arrangement. The profit objective shall exclude factors

considered inapplicable to the acquisition.

- (ii) The Contracting Officer shall negotiate the profit objective at the same time as the other cost items and as a whole rather than as individual profit factors. The profit factor breakdown shall be part of the documentation. The Contracting Officer shall use the profit analysis factors in FAR 15.404-4(d) in lieu of the structured approach in the following circumstances:
  - (A) Contracts not expected to exceed \$100,000.
  - (B) A & E contracts.
  - (C) Management contracts for operations or maintenance of Government facilities.
  - (D) Construction contracts.
  - (E) Contracts primarily requiring delivery of material supplies by subcontractors
  - (F) Termination settlements.
  - (G) Cost-plus-award-fee contracts.

However, the Contracting Officer may perform a structured profit analysis as an aid in arriving at an appropriate fee arrangement. The Contracting Officer may make other exceptions in the negotiation of contracts having unusual pricing situations, but shall justify in writing those situations where the structured approach is determined to be unsuitable.

(c) *Contracting Officer responsibilities.* The Contracting Officer shall develop the profit objective, which shall realistically reflect the total overall effort of the contractor. The Contracting Officer shall not begin to develop the profit objective until he or she has completed a thorough review of the proposed contract work; conducted a review of all available knowledge regarding the contractor pursuant to FAR subpart 9.1, including audit data, pre-award survey reports and financial statements, as appropriate; and completed an analysis of the contractor's cost estimate and comparison with the Government's estimate or projection of cost.

(d) *Profit-analysis factors.*

(1) *Common factors.* The Contracting Officer shall consider the following factors in all cases in which profit is negotiated and shall use the weight ranges listed after each factor in all instances where the structured approach is used.

Profit factors	Weight ranges (%)
<b>Contractor Effort:</b>	
Material acquisition .....	1 to 5.
Direct labor .....	4 to 15.
Overhead .....	4 to 9.
General & Administrative (G & A).	4 to 8.

Profit factors	Weight ranges (%)
Other costs .....	1 to 5.
<b>Other Factors:</b>	
Cost risk .....	0 to 7.
Investment .....	-2 to +2.
Performance .....	-1 to +1.
Socioeconomic programs .....	-.5 to +.5.
Special situations	

(i) The Contracting Officer shall measure "Contractor Effort" by assigning a profit percentage within the designated weight range to each element of contract cost. The categories listed are for reference purposes only, but are broad and basic enough to provide guidance for other elements of cost. The Contracting Officer shall not include facilities capital cost of money. "Contractor Effort" shall include a computed total dollar profit.

(ii) The Contracting Officer shall use the total dollar profit for the "Contractor Effort" to calculate specific profit dollars for "Other Factors"—cost risk, investment, performance, socioeconomic programs, and special situations. The Contracting Officer shall multiply the total dollar profit for the "Contractor Effort" by the weight assigned to each of the elements in the "Other Factors" category. Facilities capital cost of money is not included. Form HHS 674, Structured Approach Profit/Fee Objective, shall be used.

(iii) In making a judgment of the value of each factor, the Contracting Officer shall consider the definition, description, and purpose of the factors together with considerations for evaluating them.

(iv) The structured approach was designed for arriving at profit objectives for other than nonprofit organizations. However, the Contracting Officer shall use the modified structured approach in paragraph (d)(1)(iv)(B) of this section to establish fee objectives for nonprofit organizations.

(A) For purposes of this section, nonprofit organizations are defined as those business entities organized and operated exclusively for charitable, scientific, or educational purposes, no part of the net earnings of which inure to the benefit of any private shareholder or individual, and which are exempt from Federal income taxation under Section 501(c)(3) of the Internal Revenue Code.

(B) For contracts with nonprofit organizations where fee is involved, the Contracting Officer shall subtract up to three percentage points from the total "profit" objective percentage. In determining the amount of this adjustment, the Contracting Officer shall consider the following factors:

(1) Tax position benefits.

(2) Granting of financing through advance payments.

(3) Other pertinent factors which may work to either the advantage or disadvantage of the contractor in its position as a nonprofit organization.

(2) *Contractor effort.* Contractor effort is a measure of how much the contractor is expected to contribute to the overall effort necessary to meet the contract performance requirement in an efficient manner. This factor, which is apart from the contractor's responsibility for contract performance, takes into account what resources are necessary and what steps the contractor must take to accomplish a conversion of ideas and material into the final service or product called for in the contract. This is a recognition that within a given performance output, or within a given sales dollar figure, necessary efforts on the part of individual contractors can vary widely in both value and quantity, and that the profit objective shall reflect the extent and nature of the contractor's contribution to total performance. A major consideration, particularly in connection with experimental or R & D work, is the difficulty or complexity of the work to be performed, and the unusual demands of the contract, such as whether the project involves a new approach unrelated to existing technology or equipment or only refinements to these items. The evaluation of this factor requires an analysis of the cost content of the proposed contract as follows:

(i) *Material acquisition* (subcontracted items, purchased parts, and other material). Analysis of these cost items shall include an evaluation of the managerial and technical effort necessary to obtain the required subcontracted items, purchased parts, material or services. The Contracting Officer shall determine whether the contractor will obtain the items or services by routine order from readily available sources or by detailed subcontracts for which the prime contractor must develop complex specifications. The Contracting Officer shall also consider the managerial and technical efforts necessary for the prime contractor to select subcontractors and to perform subcontract administration functions, which may be substantial. Normally, the lowest unadjusted weight for direct material is two percent. A weighting of less than two percent may be appropriate only in unusual circumstances when there is a minimal contribution by the contractor.

(ii) *Direct labor* (professional, service, manufacturing and other labor). Analysis of the various labor categories

of the cost content of the contract shall include evaluation of the comparative quality and quantity of professional and semiprofessional talents, manufacturing and service skills, and experience to be employed. In evaluating professional and semiprofessional labor for the purpose of assigning profit dollars, the Contracting Officer shall consider the amount of notable scientific talent or unusual or scarce talent needed in contrast to nonprofessional effort, including the contribution this talent will provide toward the achievement of contract objectives. Since nonprofessional labor is relatively plentiful and the contractor may easily obtain it, it is less critical to the successful performance of contract objectives. Therefore, the Contracting Officer cannot weight it nearly as high as professional or semiprofessional labor. The Contracting Officer shall evaluate service contract labor in a like manner by assigning higher weights to engineering or professional type skills required for contract performance and considering the variety of manufacturing and other categories of labor skills required and the contractor's personnel resources for meeting those requirements. For purposes of evaluation, the Contracting Officer may separately categorize, as appropriate, certain types of labor (e.g., quality control, receiving and inspection), that do not fall within the definition of professional, service or manufacturing labor; but shall apply the same evaluation considerations as outlined in this paragraph.

(iii) *Overhead and G & A expense.*

(A) Analysis of these overhead items of cost shall include the evaluation of the makeup of these expenses and how much they contribute to contract performance. To the extent practicable, analysis shall include a determination of the amount of labor within these overhead pools and how this labor would be treated if it were considered direct labor under the contract. The Contracting Officer shall give the allocable labor elements the same profit considerations that they would receive if they were treated as direct labor. The other elements of these overhead pools require analysis to determine whether they are routine expenses, such as utilities and maintenance, and hence given lesser profit consideration, or whether they are significant contributing elements. The composite of the individual determinations in relation to the elements of the overhead pools shall be the profit consideration given the pools as a whole. The procedure for assigning relative values to these overhead expenses differs from

the method used in assigning values of the direct labor. The upper and lower limits assignable to the direct labor are absolute. In the case of overhead expenses, individual expenses may be assigned values outside the range as long as the composite ratio is within the range.

(B) It is not necessary that the contractor's accounting system break down overhead expenses within the classifications of research overhead, other overhead pools, and general administrative expenses, unless dictated otherwise by Cost Accounting Standards (CAS). The contractor whose accounting system reflects only one overhead rate on all direct labor need not change its system, if CAS exempt, to correspond with these classifications. The Contracting Officer, in an evaluation of such a contractor's overhead rate, may break out the applicable sections of the composite rate which could be classified as research overhead, other overhead pools, and general and administrative expenses, and follow the appropriate evaluation technique.

(C) The Contracting Officer shall consider management problems that may surface in varying degrees and the management expertise exercised to solve them as an element of profit. For example, a contract for a new R & D program or an item which is on the cutting edge may cause more problems and require more managerial time and abilities of a higher order than a follow-on contract. If new contracts create more problems and require a higher profit weight, the Contracting Officer shall adjust follow-ons downward because many of the problems should have been solved. In any event, the evaluation shall consider the underlying managerial effort involved on a case-by-case basis.

(D) It may not be necessary for the Contracting Officer to make a separate profit evaluation of overhead expenses, in connection with each acquisition action for substantially the same project with the same contractor. Where the Contracting Officer has made an analysis of the profit weight to be assigned to the overhead pool, the weight assigned may apply to future acquisitions with the same contractor unless there is a change in the cost composition of the overhead pool or contract circumstances, or unless the factors discussed in paragraph (d)(2)(iii)(C) of this section are involved.

(iv) *Other costs.* Analysis of this factor shall include all other direct costs associated with contractor performance (e.g., travel and relocation, direct support, and consultants). Analysis of these items of cost shall include the

significance of the cost of contract performance, nature of the cost, and how much they contribute to contract performance. Normally, travel costs require minimal administrative effort by the contractor and, therefore, usually receive a weight no greater than one percent. Also, the contractor may designate individuals as "consultants," but in reality the contractor may obtain these individuals to supplement its workforce in the performance of routine duties required by contract. These costs would normally receive a minimum weight. However, there may be instances when contract performance may require the contractor to obtain the services of consultants having expertise in fields such as medicine or human services. In these instances, the contractor may expend greater managerial and technical effort to obtain these services and, consequently, the costs shall receive a much greater weight.

(3) Other factors:

(i) *Contract cost risk.* The contract type employed basically determines the degree of cost risk assumed by the contractor. For example, where a portion of the risk has been shifted to the Government through cost-reimbursement provisions, unusual contingency provisions, or other risk-reducing measures, the amount of profit shall be less than where the contractor assumes all the risk.

(A) In developing the prenegotiation profit objective, the Contracting Officer shall consider the type of contract anticipated and the contractor risk associated therewith, when selecting the position in the weight range for profit that is appropriate for the risk the contractor will bear. This factor is one of the most important in arriving at the prenegotiation profit objective.

Evaluation of this risk requires a determination of: The degree of cost responsibility assumed by the contractor; the reliability of the cost estimates in relation to the tasks assumed by the contractor; and the complexity of the tasks assumed by the contractor. This factor is specifically limited to the risk of contract costs. Risks associated with a contractor's reputation, a contractor's potential loss of a commercial market, or a contractor's loss of potential profits in other fields, are not within the scope of this factor.

(B) The first and basic determination of the degree of cost responsibility assumed by the contractor is related to the sharing of total risk of contract cost by the Government and the contractor through the selection of contract type. The extremes are a cost-plus-fixed-fee

contract requiring the contractor to use its best efforts to perform a task and a firm fixed-price contract for a service or a complex item. A cost-plus-fixed-fee contract would reflect a minimum assumption of cost responsibility, whereas a firm-fixed-price contract would reflect a complete assumption of cost responsibility. The determination of risk by contract type usually falls into the following percentage ranges:

	Percent
Cost-reimbursement type contracts .....	0-3
Fixed-price type contracts .....	2-7

(C) The second determination is that of the reliability of the cost estimates. Sound price negotiation requires well-defined contract objectives and reliable cost estimates. Prior experience assists the contractor in preparing reliable cost estimates on new acquisitions for similar efforts. An excessive cost estimate reduces the likelihood that the cost of performance will exceed the contract price, thereby reducing the contractor's assumption of contract cost risk.

(D) The third determination is that of the difficulty of the contractor's task. The contractor's task can be difficult or easy, regardless of the type of contract.

(E) Contractors are likely to assume greater cost risk only if Contracting Officers objectively analyze the risk associated with proposed contracts and are willing to compensate contractors for it. Generally, a cost-plus-fixed fee contract will not justify a reward for risk in excess of 0.5 percent, nor will a firm fixed-price contract justify a reward of less than the minimum in the structured approach. The reward for risk, by contract type, will usually fall into the following percentage ranges:

(1) Type of contract and percentage ranges for profit objectives based on structured approach for R & D and manufacturing contracts:

	Percent
Cost-plus-fixed-fee .....	0 to 0.5.
Cost-plus-incentive-fee: With cost incentive only.	1 to 2.
With multiple incentives .....	1.5 to 3.
Fixed-price-incentive: With cost incentive only.	2 to 4.
With multiple incentives .....	3 to 5.
Prospective price redetermination.	3 to 5.
Firm-fixed-price .....	5 to 7.

(2) Type of contract and percentage ranges for profit objectives based on the structured approach for service contracts:

	Percent
Cost-plus-fixed-fee .....	0 to 0.5.
Cost-plus-incentive-fee .....	1 to 2.
Fixed-price incentive .....	2 to 3.
Firm-fixed-price .....	3 to 4.

(F) These ranges may not be appropriate for all acquisitions. For instance, a fixed-price incentive contract with a low ceiling price and high incentive share may be tantamount to a firm fixed-price contract. In this situation, the Contracting Officer may determine that a basis exists for high confidence in the reasonableness of the estimate and that little opportunity exists for cost reduction without extraordinary efforts. On the other hand, a contract with a high ceiling and low incentive formula can be considered to contain cost-plus-incentive-fee contract features. In this situation, the Contracting Officer may determine that the Government is retaining much of the contract cost responsibility and that the risk the contractor assumes is minimal. Similarly, if a cost-plus-incentive-fee contract includes an unlimited downward (negative) fee adjustment on cost control, it could be comparable to a fixed-price-incentive contract. In such a pricing environment, the Contracting Officer may determine that the Government has transferred a greater amount of cost responsibility to the contractor than is typical under a normal cost-plus-incentive-fee contract.

(G) The contractor's subcontracting program may have a significant impact on the contractor's acceptance of risk. It could cause risk to increase or decrease in terms of both cost and performance. This consideration shall be a part of the Contracting Officer's overall evaluation in selecting a factor to apply to cost risk. The Contracting Officer may determine, for instance, that the prime contractor has effectively transferred real cost risk to a subcontractor and the contract cost risk evaluation may, as a result, be below the range which would otherwise apply for the contract type being proposed. However, without any substantial transfer of cost risk from the prime contractor to a subcontractor, the Contracting Officer shall not lower the contract cost risk evaluation merely because a substantial portion of the contract costs represents subcontracts.

(H) In making a contract cost risk evaluation for an acquisition that involves definitization of a letter contract, unpriced change orders, and unpriced orders under basic ordering agreements, the Contracting Officer shall consider the effect on total contract cost risk of partial performance before definitization. Under some

circumstances, the total amount of cost risk may have been effectively reduced. Under other circumstances it may be apparent that the contractor's cost risk remains substantially unchanged. To be equitable, the Contracting Officer shall make the determination of profit weight for all recognized costs, both incurred and yet to be expended, considering all attendant circumstances—not merely the portion of costs incurred or percentage of work completed prior to definitization.

(I) The Contracting Officer shall consider time-and-materials and labor-hour contracts to be cost-plus-fixed-fee contracts for the purpose of establishing profit weights in the evaluation of the contractor's assumption of contract cost risk, unless otherwise exempt from use of the structured approach under paragraph (b)(1)(ii) of this section.

(ii) *Investment.* HHS encourages its contractors to perform their contracts with the minimum of financial, facilities, or other assistance from the Government. As such, it is the purpose of this factor to encourage the contractor to acquire and use its own resources to the maximum extent possible. The evaluation of this factor shall include an analysis of the following:

(A) *Facilities* (including equipment). Evaluating how this factor contributes to the profit objective requires knowledge of the level of facilities utilization needed for contract performance, the source and financing of the required facilities, and the overall cost-effectiveness of the facilities offered. The Contracting Officer shall provide contractors with additional profit, if they furnish their own facilities and such contractor-furnished facilities contribute significantly to lower total contract costs. On the other hand, contractors that rely on the Government to provide or finance needed facilities shall receive a corresponding reduction in profit. Between these extremes, the Contracting Officer shall evaluate cases on their merits and make positive or negative adjustments in profit, as appropriate. When applicable, the contractor's computation of facilities capital cost of money under CAS 414 can help the Contracting Officer identify the level of facilities investment the contractor will employ in contract performance.

(B) *Payments.* In analyzing this factor, the Contracting Officer shall consider the frequency of payments by the Government to the contractor. The key to this weighting is to give proper consideration to the impact the contract will have on the contractor's cash flow. Generally, negative consideration applies to advance payments and

payments more frequent than monthly, with the Contracting Officer making a maximum reduction as the contractor's working capital approaches zero. The Contracting Officer shall generally give positive consideration for payments less frequent than monthly and for a capital turn-over rate on the contract less than the contractor's or the industry's normal capital turn-over rate.

(iii) *Performance* (cost control and other past accomplishments). The Contracting Officer shall evaluate the contractor's past performance in areas such as: quality of services or products, meeting performance schedules, efficiency in cost control (including need for and reasonableness of costs incurred), accuracy and reliability of previous cost estimates, degree of cooperation (both business and technical), compliance with previous contract requirements, and management of subcontract programs. Where a contractor has consistently achieved excellent results in these areas in comparison with other contractors in similar circumstances, this performance merits a proportionately greater opportunity for profit. Conversely, a poor record in this regard warrants less profit.

(iv) *Federal socioeconomic programs.* This factor, which may apply to special circumstances or particular acquisitions, relates to the extent of a contractor's successful participation in Government sponsored programs involving: Small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; women-owned small businesses; small disadvantaged businesses; sheltered workshops for the disabled; mentor-protégé; energy conservation, *etc.* The Contracting Officer shall give positive consideration for the contractor's policies and practices that support Federal socioeconomic programs and contribute to successful results. Conversely, the Contracting Officer shall view failure or unwillingness on the part of the contractor to support Federal socioeconomic programs as evidence of poor performance for the purpose of establishing a profit objective.

(v) *Special situations.*

(A) *Inventive and developmental contributions.* The Contracting Officer shall consider the extent and nature of contractor-initiated and contractor-financed independent development in formulating the profit objective, provided that the Contracting Officer has made a determination that the effort will benefit the contract. Examples of profit weighting factors include contribution of the independent development to health and human

service-related missions; the initiative demonstrated by the contractor in pursuing the independent development; the extent of the contractor's cost risk; and whether the independent development cost was recovered directly or indirectly from Government sources.

(B) *Unusual pricing agreements.* Occasionally, unusual contract pricing arrangements are made with the contractor wherein it agrees to cost ceilings (*e.g.*, a ceiling on overhead rates for conditions other than those discussed at *FAR 42.707*). In these circumstances, the Contracting Officer shall give the contractor favorable consideration in developing a profit objective.

(C) *Negative factors.* Special situations need not be limited to those which only increase profit levels. A negative consideration may be appropriate when the contractor is expected to obtain spin-off-benefits as a direct result of the contract (*e.g.*, products or services with commercial application).

(4) *Facilities capital cost of money.* When facilities capital cost of money (cost of capital committed to facilities) is included as an item of cost in the contractor's proposal, the Contracting Officer shall reduce the profit objective in an amount equal to the amount of facilities capital cost of money allowed in accordance with the Facilities Capital Cost-of-Money cost principle. If the contractor does not propose this cost, the Contracting Officer shall insert a provision in the contract that makes facilities capital cost of money an unallowable cost.

## Subpart 315.6—Unsolicited Proposals

### 315.605 Content of unsolicited proposals.

(d) *Certification by offeror.* To ensure against contacts between HHS personnel and prospective offerors that would exceed the limits of advance guidance set forth in *FAR 15.604* and potentially result in an unfair advantage to an offeror, the Contracting Officer shall: Furnish the following certification template to any prospective offeror of an unsolicited proposal; and require that the executed certification be included in any resultant unsolicited proposal:

#### Unsolicited Proposal

##### Certification by Offeror

This is to certify, to the best of my knowledge and belief, that—

- (a) This proposal has not been prepared under Government supervision;
- (b) The methods and approaches stated in the proposal were developed by this offeror;

(c) Any contact with Department of Health and Human Services (HHS) personnel has been within the limits of appropriate advance guidance set forth in *FAR 15.604*; and

(d) No prior commitments were received from HHS personnel regarding acceptance of this proposal.

Date: \_\_\_\_\_  
 Organization \_\_\_\_\_  
 Name \_\_\_\_\_  
 Title \_\_\_\_\_

(This certification shall be signed by a responsible management official of the proposing organization or by a person authorized to contractually obligate the organization.)

#### **315.606 Agency procedures.**

(a) The HCA is responsible for establishing procedures to comply with *FAR 15.606(a)*.

(b) The HCA or designee shall be the point of contact for coordinating the receipt and processing of unsolicited proposals.

#### **315.606-1 Receipt and initial review.**

(d) OPDIVs shall not refuse consideration of an unsolicited proposal because an organization initially submitted it as a grant application. However, OPDIVs shall not award contracts based on unsolicited proposals that have been rejected for grant awards due to lack of scientific merit.

#### **315.609 Limited use of data.**

An offeror shall use the legend, Use and Disclosure of Data, prescribed in *FAR 15.609(a)*, to restrict the use of data for evaluation purposes only. However, data contained within the unsolicited proposal may need to be disclosed as a result of a request submitted pursuant to the Freedom of Information Act. Because of this possibility, the Contracting Officer shall provide the following notice to all prospective offerors of unsolicited proposals:

“The Government will attempt to comply with the “Use and Disclosure of Data” legend. However, the Government may not be able to withhold a record (data, document, etc.) or deny access to a record requested by an individual (the public) when an obligation is imposed on the Government under the Freedom of Information Act, 5 U.S.C. 552, as amended. The Government determination to withhold or disclose a record will be based upon the particular circumstances surrounding the record and on whether the record is exempt from disclosure under the Freedom of Information Act. Per *FAR 15.609(e)*, the offeror should identify any records that it considers to be trade secrets, commercial or financial information, and privileged or confidential information.”

### **Subpart 315.70—Acquisition of Electronic Information Technology**

#### **315.7000 Section 508 accessibility standards.**

EIT products and services, including EIT deliverables such as electronic documents and reports, acquired using negotiated procedures shall comply with Section 508 of the Rehabilitation Act of 1973, as amended. Consistent with paragraph 4.3.1 of the HHS Section 508 policy—see Section 508 policy on HHS Office on Disability Web site, if products and services, including commercially available items, meet some but not all of the applicable Section 508 accessibility standards, and no commercially available products or services meet all of the applicable Section 508 accessibility standards, an OPDIV/STAFFDIV shall acquire the products and services that best meet the applicable Section 508 accessibility standards. Commercial nonavailability exception determinations for EIT products and services that do not meet some or all of the applicable Section 508 accessibility standards shall be processed in accordance with *339.203*.

### **PART 316—TYPES OF CONTRACTS**

#### **Subpart 316.3—Cost-reimbursement Contracts**

Sec.  
 316.307 Contract clauses.

#### **Subpart 316.5—Indefinite-Delivery Contracts**

316.505 Ordering.

#### **Subpart 316.6—Time-and-Materials, Labor-Hour, and Letter Contracts**

316.603 Letter contracts.  
 316.603-3 Limitations.  
 316.603-70 Procedure for requesting authority to issue a letter contract.  
 316.603-71 Approval for modifications to letter contracts.

#### **Subpart 316.7—Agreements**

316.770 Unauthorized types of agreements.  
 316.770-2 Memoranda of understanding.

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

#### **Subpart 316.3—Cost-reimbursement Contracts**

##### **316.307 Contract clauses.**

(a) If a contract for R & D is with a hospital (profit or nonprofit), the Contracting Officer shall modify the “Allowable Cost and Payment” clause at *FAR 52.216-7* by deleting from paragraph (a) the words “Subpart 31.2 of the Federal Acquisition Regulation (FAR)” and substituting “45 CFR Part 74 Appendix E.”

(j) The Contracting Officer shall insert the clause in *352.216-70*, Additional Cost Principles, in solicitations and

contracts when a cost-reimbursement contract is contemplated.

### **Subpart 316.5—Indefinite-Delivery Contracts**

#### **316.505 Ordering.**

(b)(5) The HHS task-order and delivery-order ombudsman is the Director, Strategic Acquisition Service, PSC. The task-order and delivery-order ombudsmen for each of the HHS contracting activities are as follows:

AHRQ: Director, Office of Performance Accountability, Resources and Technology  
 BARDA: Chief of Mission Support and Acquisition Policy  
 CDC: Chief Information Officer  
 CMS: Chief Operating Officer  
 FDA: Director, Office of Acquisitions and Grants Services  
 HRSA: Associate Administrator, Office of Operations  
 IHS: Director, Office of Management Services  
 NIH: Senior Scientific Advisor for Extramural Research, Office of Extramural Research (R & D) and Senior Advisor to the Director (Other than R & D)  
 PSC: Director, Strategic Acquisition Service  
 SAMHSA: Executive Officer

### **Subpart 316.6—Time-and-Materials, Labor-Hour, and Letter Contracts**

#### **316.603 Letter contracts.**

##### **316.603-3 Limitations.**

An official one level above the Contracting Officer shall make the written determination that no other contract type is suitable.

##### **316.603-70 Procedure for requesting authority to issue a letter contract.**

The Contracting Officer shall include the following information in a memorandum requesting approval to award a letter contract:

- (a) Name and address of proposed contractor.
- (b) Location where contract is to be performed.
- (c) Contract number, including modification number, if possible.
- (d) Brief description of work and services to be performed.
- (e) Proposed performance or delivery schedule.
- (f) Amount of letter contract.
- (g) Estimated total amount of definitized contract.
- (h) Type of definitive contract to be executed (fixed price, cost-reimbursement, etc.).
- (i) Statement of the necessity and advantage to the Government of the use of the proposed letter contract.
- (j) Statement of percentage of the estimated cost that the obligation of funds represents (in rare instances where the obligation represents 50

percent or more of the proposed estimated cost of the acquisition, the Contracting Officer shall include a justification for that obligation (e.g., the contractor requires a large initial outlay of funds for major subcontract awards or an extensive purchase of materials to meet an urgent delivery requirement)). In every case, documentation shall demonstrate that the amount to be obligated is not in excess of an amount reasonably required to perform the work.

(k) Period of effectiveness of a proposed letter contract. (If more than 180 days, the Contracting Officer shall provide a detailed justification).

(l) A statement of any substantive matters that need to be resolved.

#### **316.603-71 Approval for modifications to letter contracts.**

An official one level above the Contracting Officer shall approve all letter contract modifications. Contracting activities shall process requests for authority to issue letter contract modifications in the same manner as requests for authority to issue letter contracts. A request shall include the following:

(a) Name and address of the contractor.

(b) Description of work and services.

(c) Date original request was approved and name/title of approving official.

(d) Letter contract number and date issued.

(e) Detailed justification as to why the letter contract cannot currently be definitized.

(f) Detailed justification as to why the level of funding must be increased.

(g) Detailed justification as to why the period of effectiveness must be increased beyond 180 days, if applicable.

(h) If the funding of the letter contract is to be increased to more than 50 percent of the estimated cost of the acquisition, the Contracting Officer shall include the information required by 316.603-70(j).

#### **Subpart 316.7—Agreements**

##### **316.770 Unauthorized types of agreements.**

##### **316.770-2 Memorandum of understanding.**

Use of a "memorandum of understanding," which purports to modify mandatory FAR and HHSAR provisions to make them acceptable to a prospective contractor, is not authorized because it may address matters contrary to the language of the solicitation or prospective contract. A memorandum of understanding does not bind the Government under the

contract. The Contracting Officer shall make a change in a solicitation or contract only by amendment or modification, respectively. When a change to a prescribed contract clause is considered necessary, the Contracting Officer shall request a deviation.

#### **PART 317—SPECIAL CONTRACTING METHODS**

##### **Subpart 317.1—Multi-year Contracting**

Sec.

317.104 General.

317.105 Policy.

317.105-1 Uses.

317.107 Options.

317.108 Congressional notification.

##### **Subpart 317.2—Options**

317.204 Contracts.

317.207 Exercise of options.

##### **Subpart 317.5—Interagency Acquisitions Under the Economy Act**

317.503 Determination and findings requirements.

##### **Subpart 317.70—Multi-agency and Intra-agency contracts**

317.7000 Scope of subpart.

317.7001 Definitions.

317.7002 Potential multi-agency and intra-agency sources.

317.7003 Documentation for multi-agency contracts.

317.7004 Documentation for intra-agency contracts.

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

##### **Subpart 317.1—Multi-year Contracting**

##### **317.104 General.**

(b) The Senior Procurement Executive is the agency head for the purpose of FAR 17.104(b).

##### **317.105 Policy.**

##### **317.105-1 Uses.**

(a) Each HCA determination to use multi-year contracting, as defined in FAR 17.103, is limited to individual acquisitions where the cancellation ceiling obligated in the first year does not exceed 20 percent of the contract value over the full multi-year term or \$11.5 million, whichever is less. Cancellation ceiling provisions shall conform to the requirements of FAR 17.106-1(c). The determination is not delegable and shall address the issues in FAR 17.105-1(a) and the following:

(1) The amount of, and basis for, the proposed cancellation ceiling.

(2) Identification and assignment of a Contracting Officer holding a FAC-C Level III certification or, alternatively, one familiar with the application of this contracting method.

(3) Availability of appropriations to fund the obligation of total contract costs for the first year of performance

plus the estimated amount of the full cancellation ceiling.

(4) Reasonable expectation that, throughout the contemplated contract performance period, the OPDIV, through its annual budget request, will seek funding for the contract at the level necessary to avoid contract cancellation; and

(5) Program requirements are reasonably stable and the associated technical risks are not excessive—i.e., not of the nature or level to jeopardize contract completion or result in its cancellation.

Upon SPE request, the HCA shall provide a copy of each determination (other than those specified in 317.105-1(b) below).

(b) SPE approval is required for—

(1) Any individual determination to use multi-year contracting with a cancellation ceiling in excess of the limits in 317.105-1(a); and

(2) Any class determination (see FAR Subpart 1.7).

HCA determinations involving a cancellation ceiling in excess of the limits in 317.105-1(a) shall also include a compelling rationale why this approach is in the best interests of the Government and a draft congressional notification letter pursuant to FAR 17.108 and 317.108.

##### **317.107 Options.**

When used as part of a multi-year contract, options shall not be used to extend the performance of non-severable services beyond 5 years. Options may serve as a means to acquire related severable services and, upon being exercised, shall be funded from the then-current fiscal year's appropriation.

##### **317.108 Congressional notification.**

(a) The SPE is the agency head for the purposes of FAR 17.108(a). Upon SPE approval of the determination required by 317.105-1(b)(1), the SPE will finalize and sign the congressional notification letter and provide it to the appropriate House and Senate committees.

##### **Subpart 317.2—Options**

##### **317.204 Contracts.**

(e) The total of the basic and option periods shall not exceed 10 years in the case of services and the total of the basic and option quantities shall not exceed the requirement for 5 years in the case of supplies. These limitations do not apply to IT and R & D contracts. However, statutes applicable to various classes of contracts may place additional restrictions on the length of contracts.

**317.207 Exercise of options.**

(h) Before exercising an option for a subsequent performance period/ additional quantity under a multiple-year contract/order—*see 317.201–70(c)*, which involves the acquisition of EIT products and services, including EIT deliverables such as electronic documents and reports, subject to Section 508 of the Rehabilitation Act of 1973, as amended, the Contracting Officer shall ensure that the contractor has provided to the Contracting Officer and Project Officer a properly completed HHS Section 508 Annual Report—*see* Section 508 policy on HHS Office on Disability Web site. The Contracting Officer shall request that the contractor provide the report in sufficient time for its review and approval by the Contracting Officer, Project Officer, and the Section 508 Official or designee, prior to exercise of an option. The Contracting Officer shall ensure that the report and all related approvals are made a part of the official contract/order file.

**Subpart 317.5—Interagency Acquisitions Under the Economy Act****317.503 Determination and findings requirements.**

(a) In addition to the D & F contents specified in *FAR 17.503(a)(1) and (2)*, each Assisted Contracting D & F shall address—

(3) The servicing organization(s) contemplated (the assigned HHS contracting office shall be one of the servicing organizations contemplated);

(4) For each organization and alternative approach contemplated, the anticipated benefits to the OPDIV; the anticipated costs, including associated fees or other compensation; and the contract/order placement timeframe;

(5) The tradeoffs (cost, schedule, performance) among the approaches considered;

(6) The recommended multi-agency or intra-agency contracting approach; and

(7) The conclusion that the contract to be awarded by the selected servicing organization is the most advantageous alternative to the Government, notwithstanding fees and the increased risk associated with assisted contracting.

**Subpart 317.70—Multi-agency and Intra-agency Contracts****317.7000 Scope of subpart.**

(a) This subpart prescribes policies for HHS' use of multi-agency and intra-agency contracting under all authorities. It does not apply when HHS transfers funds to another agency under an

interagency agreement whose primary purpose is other than contracting on HHS' behalf.

(b) For multi-agency contracts under the authority of the Economy Act, *see FAR Subpart 17.5 and 317.503*.

(c) Multi-agency contracting authorities other than the Economy Act include but are not limited to the Clinger-Cohen Act [40 U.S.C. 11302(e)]; the Government Management Reform Act (Pub. L. 103–356); Title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 251, *et seq.*); and 40 U.S.C. 501, Services for Executive Agencies.

**317.7001 Definitions.**

As used in this subpart:

*Multi-agency contracting* describes a procedure in which a Federal agency needing supplies or services obtains them using another Federal agency's contract (direct ordering), the contracting assistance of another Federal agency (assisted contracting), or both. In some cases, more than one servicing organization may be involved in assisted contracting.

*Intra-agency contracting* describes a procedure in which an HHS OPDIV/STAFFDIV needing supplies or services obtains them by issuing an order under another HHS OPDIV/STAFFDIV's contract or agreement (*e.g.*, a BPA—direct ordering); or using the contracting assistance of another OPDIV/STAFFDIV (assisted contracting); or both.

*Assisted contracting* is a subset of multi-agency/intra-agency contracting in which a servicing contracting office other than the requesting organization's assigned contracting office contracts on behalf of the requesting organization.

*Direct ordering* is a subset of multi-/intra-agency contracting in which a contracting or ordering officer issues an order under another OPDIV's or Federal agency's indefinite delivery vehicle (*e.g.*, a GSA FSS schedule or a GWAC).

*Requesting organization* refers to the organization with the requirement for a multi- or intra-agency contract.

*Servicing organization* refers to an organization that assists a requesting organization by awarding a contract or order on its behalf. In the context of multi-agency contracting, the servicing organization and requesting organization must be in different Federal agencies. For intra-agency contracting, the servicing and requesting organizations must both be HHS organizations.

**317.7002 Potential multi-agency and intra-agency sources.**

(a) Prior to deciding to use multi-agency or intra-agency contracting, the

requesting organization must perform sufficient market research to consider the relative merits and costs of available contracts and contracting offices for meeting the requesting organization's need.

(b) Direct ordering conducted by HHS contracting officers using GSA vehicles, GWACs, and vehicles established under the Federal Strategic Sourcing Initiative does not require justification. HHS contracting officers should be cautious about using unfamiliar contract vehicles. When using vehicles other than those listed above, the Contracting Officer shall include in the contract file a D & F, which is prepared in consultation with the SBS, and which concludes that the chosen vehicle is the best way to obtain the required product or service.

(c) With the exception of assisted contracts and direct order acquisitions to be placed pursuant to the authority of the Economy Act, which always require preparation of a supporting D & F—*see FAR 17.503*, proposed assisted contracts approved as part of an annual or updated acquisition plan require no additional documentation or approvals.

(d) For proposed assisted contracts *not* approved as part of an annual or update acquisition plan, the requiring organization shall identify the potential servicing organization(s); summarize the services each source provides; and describe the compensation arrangement(s). The assigned contracting office shall be one of the alternatives considered. For multi-agency contract actions, this information shall be included in the Assisted Contracting D & F required in *317.7003(b)*.

**317.7003 Documentation for multi-agency contracts.**

(a) In the case of proposed direct ordering using vehicles other than those listed in *317.7002(b)*, the HHS contracting officer shall comply with the D & F requirement in *317.7003(b)*.

(b) If a proposed assisted contract, using a servicing organization outside HHS, was not approved during preparation and review of the annual acquisition plan, including updates, then the program/project office or other requiring activity shall prepare an Assisted Contracting D & F, similar to the D & F specified in *FAR 17.503*, but augmented with the information specified in *317.503*. The Project Officer or other requiring official shall be responsible for preparing and staffing this Assisted Contracting D & F.

(1) For assisted contracts greater than or equal to \$500,000 (including the value of the base contract and all



options and, for indefinite delivery vehicles, the value of the vehicle and all potential orders), the assigned HHS Contracting Officer shall review and approve or reject the Assisted Contracting D & F, annotated with the SBS' recommendation. The Contracting Officer's signature on the Assisted Contracting D&F signifies his/her concurrence that assisted contracting through the proposed servicing contracting office is in the best interest of the government. The Project Officer must retain a copy of the approved Assisted Contracting D & F.

(2) For assisted contracts less than \$500,000, the HCA may delegate authority to the Project Officer or other requiring official to approve the required Assisted Contracting D & F. The \$500,000 threshold includes the value of the base contract and all options and, for indefinite delivery vehicles, the value of the vehicle and all potential orders.

(3) During a declared (Presidential or HHS Secretarial) emergency, funding and requirements documentation may be transferred to a servicing organization without an Assisted Contracting D & F. The Project Officer shall document his/her file, explaining the exigent circumstances.

(c) Assisted contracts require supporting interagency agreements, as described in OFPP's memorandum, "Interagency Acquisitions," dated June 2008. Note that Part A of an interagency agreement can support multiple assisted contracts. Each interagency agreement shall address all the elements identified in OFPP's model interagency agreement (Appendix 2 of OFPP's "Interagency Acquisitions"). The level of detail in HHS interagency agreements should be commensurate with the dollar value and complexity of the assisted contract. HHS requesting organizations shall not forward funding or requirements documentation outside HHS without a properly executed interagency agreement; and servicing activities within HHS (e.g., PSC and the NIH Information Technology Acquisition and Assessment Center), shall not contract on behalf of non-HHS requesting organizations without properly executed interagency agreements.

#### **317.7004 Documentation for intra-agency contracts.**

(a) In the case of proposed direct ordering, using vehicles other than those listed in 317.7002(b), the HHS contracting officer shall comply with the D & F requirement in 317.7003(b).

(b) With the exception of assisted contracts and direct order acquisitions

to be placed pursuant to the authority of the Economy Act, which always require preparation of a supporting D & F—see FAR 17.503, proposed assisted contracts approved as part of an annual or updated acquisition plan require no additional documentation or approvals.

(c) For proposed assisted contracts *not* approved as part of an annual or updated acquisition plan, the requiring organization shall identify the potential servicing organization(s); summarize the services the source(s) provide(s); and describe the compensation arrangement(s). The assigned contracting office shall be one of the alternatives considered.

(d) Assisted intra-agency contracts may require supporting intra-agency agreements or other documentation as prescribed by OPDIV procedures.

### **SUBCHAPTER D—SOCIOECONOMIC PROGRAMS**

#### **PART 319—SMALL BUSINESS PROGRAMS**

##### **Subpart 319.2—Policies**

Sec.

319.201 General policy.

319.202–2 Locating small business sources.

319.270–1 Solicitation provision and contract clause.

##### **Subpart 319.5—Set-Asides for Small Business**

319.501 General.

319.506 Withdrawing or modifying set-asides.

##### **Subpart 319.7—Subcontracting with Small Business, Small Disadvantaged Business, and Women-Owned Small Business Concerns**

319.705 Responsibilities of the Contracting Officer under the subcontracting assistance program.

319.705–5 Awards involving subcontracting plans.

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

##### **Subpart 319.2—Policies**

###### **319.201 General policy.**

(d) The functional management responsibilities for HHS' small business program (*i.e.*, small businesses; veteran-owned small businesses; service-disabled, veteran-owned small businesses; HUBZone small businesses; small disadvantaged businesses; and women-owned small businesses) are delegated to the OSDBU Director. See the HHS Small Business Program manual for information on the HHS small business program, including SBS and Small Business Administration (SBA) Procurement Center Representative (PCR) acquisition review timeframes.

(e) (1) One or more qualified SBSs will implement the HHS small business program and shall be co-located within the following OPDIVs: AHRQ; BARDA; CDC; CMS; FDA; HRSA; IHS; NIH; PSC; and SAMHSA. The OSDBU Director shall exercise full management authority over SBSs.

(2) Within IHS, the primary SBS will be responsible for IHS' overall implementation of the HHS small business program; however, each IHS contracting office will have a small business technical advisor (SBTA) to carry out those functions and responsibilities to implement the small business program. The primary IHS SBS shall assist and provide guidance to respective SBTAs.

##### **319.202–2 Locating small business sources.**

(a) OPDIVs shall foster, to the extent practicable, maximum participation by small businesses in HHS acquisitions. Prior to issuing a solicitation, the Contracting Officer shall make every reasonable effort to find small business concerns that can compete for the proposed requirement—see FAR 19.202, 10.001(2)(v), and 10.002(b)(1)(vii).

(1) If it cannot be determined in advance (through market research under FAR Part 10, discussions between the Contracting Officer and the SBS, or other means—see FAR 15.201, whether a solicitation in excess of the simplified acquisition threshold can be set aside exclusively for small business participation [whether for small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; or 8(a) small business(es)], the Contracting Officer may publish a notice entitled "Small Business Sources Sought" in FedBizOpps. The purpose of a Small Business Sources Sought notice is to identify the availability and capability of qualified small business sources; and their size classification relative to the appropriate North American Industry Classification System (NAICS) code. This will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. However, to solicit technical, scientific, or business information for project planning purposes, an RFI may be used—see 315.201(e).

(2) When using a Small Business Sought notice, an OPDIV shall not request that potential sources provide more than the minimum information necessary—see FAR 10.001(b), to determine whether they have the apparent capability to perform a requirement and, therefore, whether they should be included in any future

competition. The notice and the information received shall not be used to determine how well respondents can perform a requirement, which can only be evaluated in response to a solicitation. Accordingly, the notice shall not be used to—

- (i) Obtain capability statements that are evaluated and determined acceptable or unacceptable;
- (ii) Require cost/price proposals or detailed technical solutions;
- (iii) Identify a prospective sole source;

or

- (iv) Exclude small business concerns.

(3) OPDIVs shall follow the standard HHS instructions for completing a "Small Business Sources Sought" notice." The template for the notice is available on the ASFR/OGAPA/DA Internet Web site. The Contracting Officer shall post the notice in FedBizOpps by selecting and completing a Sources Sought notice, accessible on the FedBizOpps "Notices" page at: <http://www.fedbizopps.gov>. Additional information may be included in the notice in accordance with OPDIV procedures. The Contracting Officer shall document, in the form of a memorandum to the file, the results of the review by technical personnel of information submitted in response to the notice, including whether each respondent appears to be capable of performing the requirement. The Contracting Officer shall attach a copy of the analysis provided by the technical personnel to the memorandum.

#### **319.270-1 Solicitation provision and contract clause.**

(a) The Contracting Officer shall insert the provision in *352.219-70*, Mentor-Protégé Program, in solicitations that include the clause in *FAR 52.219-9*, Small Business Subcontracting Plan. The provision requires that offerors provide the Contracting Officer a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU)-approved mentor-protégé agreement in response to a solicitation.

(b) The Contracting Officer shall insert the clause in *352.219-71*, Mentor-Protégé Program Reporting Requirements, in contracts that include the clause in *FAR 52.219-9*, Small Business Subcontracting Plan, and which are awarded to a contractor with an HHS OSDBU-approved mentor-protégé agreement.

#### **Subpart 319.5—Set-Asides for Small Business**

##### **319.501 General.**

(e) Subsequent to the Contracting Officer's recommendation on *Form HHS*

*653*, HHS Small Business Review Form, the SBS shall review each proposed acquisition strategy and either concur or not concur with the Contracting Officer's recommendation. The PCR shall also review the acquisition strategy and either concur or not concur with the Contracting Officer's recommendation. If the Contracting Officer disapproves the SBS's or the PCR's set-aside recommendation, the Contracting Officer shall document the reasons on *Form HHS 653* and place the form in the contract file. The Contracting Officer shall make the final determination as to whether the proposed acquisition will be set-aside or not.

#### **319.506 Withdrawing or modifying set-asides.**

(d) Immediately upon notice from the Contracting Officer, the SBS shall provide notification of all set-aside withdrawals to the OSDBU Director by both telephone and e-mail.

#### **Subpart 319.7—Subcontracting With Small Business, Small Disadvantaged Business, and Women-Owned Small Business Concerns**

##### **319.705 Responsibilities of the Contracting Officer under the subcontracting assistance program.**

##### **319.705-5 Awards involving subcontracting plans.**

(a) (3) The Contracting Officer shall provide the PCR a period of 1 to 5 working days to review the contract award package, depending upon the circumstances and complexity of the individual acquisition.

#### **PART 322—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS**

##### **Subpart 322.8—Equal Employment Opportunity**

Sec.  
322.810 Solicitation provisions and contract clauses.

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

##### **Subpart 322.8—Equal Employment Opportunity**

##### **322.810 Solicitation provisions and contract clauses.**

(h) The Contracting Officer shall insert the clause in *352.222-70*, Contractor Cooperation in Equal Employment Opportunity Investigations, in solicitations, contracts, and orders that include the clause in *FAR 52.222-26*, Equal Opportunity.

#### **PART 323—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE**

##### **Subpart 323.70—Safety and Health**

Sec.  
323.7000 Scope of subpart.  
323.7001 Policy.  
323.7002 Actions required.

##### **Subpart 323.71—Green Purchasing Requirements**

323.7100 Policy.

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

##### **Subpart 323.70—Safety and Health**

##### **323.7000 Scope of subpart.**

This subpart prescribes the use of a safety and health clause in contracts involving hazardous materials or operations, and provides procedures for administering safety and health provisions.

##### **323.7001 Policy.**

Various statutes and regulations (*e.g.*, the Walsh-Healy Act and *Service Contract Act*), require adherence to minimum safety and health standards by contractors engaged in potentially hazardous work. *FAR subpart 23.3* serves as the primary reference regarding hazardous materials. The Contracting Officer shall follow the guidance in this subpart when the guidance in the FAR is not sufficient or does not meet the safety and health situation for an acquisition.

##### **323.7002 Actions required.**

(a) *Contracting activities.* The Contracting Officer shall insert the clause in *352.223-70*, Safety and Health, or a clause substantially the same, in solicitations and contracts that involve hazardous materials or operations for the following types of requirements:

- (1) Services or products.
- (2) Research, development, or test projects.
- (3) Transportation of hazardous materials.

(4) Construction, including construction of facilities on the contractor's premises.

(b) *Safety officers.* OPDIV safety officers shall advise and assist initiators of acquisition requests and Contracting Officers in—

- (1) Determining whether safety and health provisions shall be part of a prospective contract;
- (2) Evaluating a prospective contractor's safety and health programs; and

(3) Conducting post-award reviews and surveillance to the extent deemed necessary.

(c) *Initiators*. Initiators of acquisition requests for items described in paragraph (a) of this section shall—

(1) During the preparation of an acquisition plan or other acquisition request documentation, and in the solicitation, ensure that hazardous materials and operations to be used in the performance of the contract are clearly identified; and

(2) During the period of performance—

(i) Apprise the Contracting Officer of any noncompliance with safety and health provisions identified in the contract; and

(ii) Cooperate with the safety officer in conducting review and surveillance activities.

### Subpart 323.71—Green Purchasing Requirements

#### 323.7100 Policy.

(a) The HHS guidelines and procedures for “green purchasing” may be found in the HHS Affirmative Procurement Plan (APP), “Purchasing Environmentally Preferable Products and Services at the U.S. Department of Health and Human Services.” The APP encompasses the acquisition and use of designated recycled content, and Energy Star®, Electronic Product Environmental Assessment Tool (EPEAT)-registered, energy-efficient, bio-based, and environmentally preferable products.

(1) ASFR/OGAPA/DA has overall responsibility for monitoring the OPDIVs’ implementation of HHS’ APP to ensure compliance with Executive Order 13423, “Strengthening Federal Environmental, Energy, and Transportation Management;” the White House Council on Environmental Quality’s Implementing Instructions for Executive Order 13423; Section 6002 of the Resource Conservation and Recovery Act of 1976; Section 104 of the Energy Policy Act of 2005; Section 9002 of the Farm Security and Rural Investment Act of 2002; Section 612 of the Clean Air Act of 1990; and FAR Part 23.

(2) The OPDIVs, through their designated APP Program Managers, are responsible for establishing the necessary local procedures and appropriate training requirements to ensure effective implementation of the HHS APP.

## PART 324—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

### Subpart 324.1—Protection of Individual Privacy

Sec.

324.000 Scope of subpart.

324.102 General.

324.103 Procedures.

### Subpart 324.2—Freedom of Information Act

324.203 Policy.

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

### Subpart 324.1—Protection of Individual Privacy

#### 324.000 Scope of subpart.

This part prescribes policies and procedures that apply requirements of the Privacy Act of 1974 (5 U.S.C. 552a) and *OMB Circular A-130, Revised, November 30, 2000*, to HHS contracts and cites the Freedom of Information Act (5 U.S.C. 552, as amended).

#### 324.102 General.

(a) It is HHS policy to protect the privacy of individuals to the maximum possible extent, while permitting the exchange of records required to fulfill HHS administrative and program responsibilities and its responsibilities for disclosing records to which the general public is entitled under the Freedom of Information Act (5 U.S.C. 552). The Privacy Act of 1974 and the HHS implementation under 45 CFR Part 5b apply “when an agency provides by a contract for the operation by or on behalf of the agency of a system of records to accomplish any agency function \* \* \*.” The key factor is whether an HHS function is involved. Therefore, the Privacy Act requirements apply to an HHS contract when, under the contract, the contractor must maintain or operate a system of records to accomplish an HHS function.

(e) The Project Officer, and, as necessary, the official designated as the OPDIV’s Privacy Act Coordinator and OGC-GLD, shall determine the applicability of the Privacy Act to each proposed acquisition. The Project Officer is required to include a statement in the AP or other acquisition request document indicating whether the Privacy Act is or is not applicable to a proposed acquisition.

(f) Whenever a Contracting Officer is informed that the Privacy Act is not applicable, but the resultant contract will involve the collection of individually identifiable personal data by the contractor, the Contracting Officer shall include provisions to protect the confidentiality of the records and the privacy of individuals identified in the records—see 324.70.

#### 324.103 Procedures.

(a) The Contracting Officer shall review all acquisition request documentation to determine whether the Privacy Act requirements are applicable. The Privacy Act requirements apply when a contract or order will require the contractor to design, develop, or operate any Privacy Act system of records on individuals to accomplish an agency function. When applicable, the Contracting Officer shall include the two Privacy Act clauses required by *FAR 24.104* in the solicitation and contract or order. In addition, the Contracting Officer shall include the two FAR Privacy Act clauses, and other pertinent information specified in this subpart, in any modification which results in the Privacy Act requirements becoming applicable to a contract or order.

(b)(1) The Contracting Officer shall identify in the SOW/PWS the system(s) of records to which the Privacy Act and the implementing regulations are applicable.

(2) The Contracting Officer shall include the clause specified in *352.224-70*, Privacy Act, in solicitations, contracts, and orders that involve Privacy Act requirements to notify the contractor that it and its employees are subject to criminal penalties for violations of the Privacy Act (5 U.S.C. 552a(i)) to the same extent as HHS employees. The clause also requires the contractor to ensure that each of its employees knows the prescribed rules of conduct and each contractor employee is aware that he/she is subject to criminal penalties for violations of the Privacy Act. These requirements also apply to all subcontracts awarded under the contract or order that require the design, development, or operation of a system of records. The Contracting Officer shall send the contractor a copy of 45 CFR Part 5b, which includes the rules of conduct and other Privacy Act requirements.

(c) The Contracting Officer shall specify in the contract SOW/PWS the disposition to be made of the system(s) of records upon completion of contract performance. The contract SOW/PWS may require the contractor to destroy the records, remove personal identifiers, or turn the records over to the Contracting Officer. If there is a legitimate need for a contractor to keep copies of the records after completion of a contract, the contractor must take measures, as approved by the Contracting Officer, to keep the records confidential and protect the individuals’ privacy.

(d) For any acquisition subject to Privacy Act requirements, the Project

Officer, prior to award, or the COTR, after award, shall prepare and have published in the **Federal Register** a "system notice," describing HHS' intent to establish a new system of records on individuals, to make modifications to an existing system, or to disclose information in regard to an existing system. The Project Officer shall attach a copy of the system notice to the acquisition plan or other acquisition request documentation. If a system notice is not attached, the Contracting Officer shall inquire about its status and shall obtain a copy from the Project Officer for inclusion in the contract file. If a system notice has not been published in the **Federal Register**, the Contracting Officer may proceed with the acquisition but shall not award the contract until the system notice is published and the Contracting Officer verifies its publication.

#### **Subpart 324.2—Freedom of Information Act**

##### **324.203 Policy.**

(a) The HHS regulation implementing the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, is set forth in 45 CFR Part 5.

(b) The Contracting Officer, upon receiving a FOIA request, shall follow HHS and OPDIV procedures. As necessary, the Contracting Officer shall coordinate all actions with the cognizant Freedom of Information (FOI) Officer and the OGC—GLD. Only the FOI Officer is authorized to release or deny release of records. The Contracting Officer shall be familiar with the entire FOIA regulation in 45 CFR Part 5.

#### **SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS**

### **PART 327—PATENTS, DATA, AND COPYRIGHTS**

#### **Subpart 327.4—Rights in Data and Copyrights**

Sec.  
327.404–70 Solicitation provision and contract clause.

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

#### **Subpart 327.4—Rights in Data and Copyrights**

##### **327.404–70 Solicitation provision and contract clause.**

The Contracting Officer shall insert the clause in 352.227–70, Publications and Publicity, in solicitations, contracts, and orders that involve requirements which could lead to the contractor's publishing the results of the award.

### **PART 328—BONDS AND INSURANCE**

#### **Subpart 328.3—Insurance**

Sec.  
328.301 Policy.  
328.311 Solicitation provision and contract clause on liability insurance under cost-reimbursement contracts.  
328.311–2 Agency solicitation provisions and contract clauses.

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

#### **Subpart 328.3—Insurance**

##### **328.301 Policy.**

It is HHS policy to limit the Government's reimbursement, of its contractors' liability to third persons for claims not covered by insurance in cost-reimbursement contracts, to the Limitation of Funds or Limitation of Cost clause of the contract. In addition, the amount of the Government's reimbursement cannot exceed the final judgments or settlements approved in writing by the Government.

##### **328.311 Solicitation provision and contract clause on liability insurance under cost-reimbursement contracts.**

##### **328.311–2 Agency solicitation provisions and contract clauses.**

The Contracting Officer shall insert the clause in 352.228–7, Insurance—Liability to Third Persons, in lieu of the clause in FAR 52.228–7, Insurance—Liability to Third Persons, in solicitations and contracts when a cost-reimbursement contract is contemplated. The Contracting Officer shall insert Alternate I or II based on the conditions specified therein. This is an authorized FAR deviation.

### **PART 330—COST ACCOUNTING STANDARDS**

#### **Subpart 330.2—CAS Program Requirements**

Sec.  
330.201 Contract requirements.  
330.201–5 Waiver.

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

#### **Subpart 330.2—CAS Program Requirements**

##### **330.201 Contract requirements.**

##### **330.201–5 Waiver.**

(a) OPDIVs shall forward waiver requests through appropriate acquisition channels, including the HCA, to the Associate DAS for Acquisition (non-delegable) for review. Associate DAS for Acquisition shall exercise the waiver authority under FAR 30.201–5(a)(2).

### **PART 331—CONTRACT COST PRINCIPLES AND PROCEDURES**

#### **Subpart 331.1—Applicability**

Sec.  
331.101–70 Salary rate limitation.  
331.102–70 Pricing of adjustments.

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

#### **Subpart 331.1—Applicability**

##### **331.101–70 Salary rate limitation.**

(a) Beginning in fiscal year 1990, Congress has stipulated in HHS appropriations acts and continuing resolutions that, under applicable NIH, SAMHSA, and AHRQ contracts, appropriated funds cannot be used to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level I.

(b) The Contracting Officer shall insert the clause in 352.231–70, Salary Rate Limitation, in NIH, SAMHSA, and AHRQ solicitations and contracts that exceed the simplified acquisition threshold when a cost-reimbursement, fixed-price level-of-effort, time-and-materials, or labor-hour contract is contemplated, including modifications of contracts of those types for projects that support extramural program activities. For purposes of this clause, for NIH: Projects that support extramural program activities are basic and applied research projects; and for SAMHSA and AHRQ: Projects that support extramural program activities are mission-related projects, exclusive of contracts for general support services.

##### **331.102–70 Pricing of adjustments.**

The Contracting Officer shall insert the clause in 352.231–71, Pricing of Adjustments, in solicitations and contracts when a fixed-price contract is contemplated.

### **PART 332—CONTRACT FINANCING**

#### **Subpart 332.4—Advance Payments for Non-Commercial Items**

Sec.  
332.402 General.  
332.403 Applicability.  
332.407 Interest.  
332.409 Contracting Officer action.  
332.409–1 Recommendation for approval.

#### **Subpart 332.5—Progress Payments Based on Cost**

332.501 General.  
332.501–2 Unusual progress payments.

#### **Subpart 332.7—Contract Funding**

332.703–70 Funding contracts during a continuing resolution.  
332.704 Limitation of cost or funds.

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

**Subpart 332.4—Advance Payments for Non-Commercial Items****332.402 General.**

(e) The HCA (non-delegable) shall determine whether an advance payment is in the public interest in accordance with *FAR 32.402(c)(1)(iii)(A)*.

**332.403 Applicability.**

All R&D contracts with educational institutions located in the United States shall provide for financing by use of advance payments, in reasonable amounts, unless otherwise prohibited by law.

**332.407 Interest.**

(d) The HCA (non-delegable) shall make the determinations in *FAR 32.407(d)*. The HCA may also approve interest-free advance payments for educational institutions and other nonprofit organizations, whether public or private, performing work under nonprofit contracts (without fee) involving health services, educational programs, or social service programs, such as the following:

- (1) Community health representative services for an Indian Tribe.
- (2) Narcotic addict rehabilitative services.
- (3) Comprehensive health care services for Model Neighborhood programs.
- (4) Planning and development of health maintenance organizations.
- (5) Dissemination of information derived from educational research.
- (6) Surveys or demonstrations in the field of education.
- (7) Producing or distributing educational media for disabled persons including captioned films for the hearing impaired.
- (8) Operation of language or area centers.
- (9) Biomedical research and support services.
- (10) Research surveys or demonstrations involving the training and placement of health personnel and health professionals, and dissemination of related information.
- (11) Surveys or demonstrations in the field of social service.

**332.409 Contracting Officer action.****332.409-1 Recommendation for approval.**

The Contracting Officer shall transmit the information in *FAR 32.409-1* (or *FAR 32.409-2*) to the HCA by memorandum.

**Subpart 332.5—Progress Payments Based on Cost****332.501 General.****332.501-2 Unusual progress payments.**

(a)(3) The HCA (non-delegable) shall approve an unusual progress payment.

**Subpart 332.7—Contract Funding****332.703-70 Funding contracts during a continuing resolution.**

(a) *Continuing resolutions.* A continuing resolution (CR) is a legislative measure enacted to keep existing Federal programs functioning, generally at minimal levels, after the expiration of prior fiscal year budget authority and until passage of regular appropriation acts by Congress.

(b) *Operating guidance.* Because the terms of CRs may vary, for each CR, specific operating guidance will be issued by the Office of the Assistant Secretary for Resources and Technology (ASRT). This guidance will—

- (1) Establish the availability of funds for existing and new projects or activities (consistent with the language of the CR);
  - (2) Identify any specific limits or constraints imposed; and
  - (3) Establish the authorized level and timing of obligations permitted.
- (c) Contracting activities, in concert with program, budget and finance personnel, must carefully assess contract funding decisions to—
- (1) Ensure compliance with HHS guidance regarding the specific terms of a CR;
  - (2) Maintain essential operations and activities; and
  - (3) Guard against violations of the Anti-Deficiency Act—see *FAR 32.702*.

**332.704 Limitation of cost or funds.**

See subpart 342.71, “Administrative Actions for Cost Overruns,” for procedures for handling anticipated cost overruns.

**PART 333—PROTESTS, DISPUTES, AND APPEALS****Subpart 333.1—Protests**

Sec.

- 333.102 General.  
333.103 Protests to the agency.  
333.104 Protests to GAO.

**Subpart 333.2—Disputes and Appeals**

- 333.203 Applicability.  
333.209 Suspected fraudulent claims.  
333.211 Contracting Officer’s decision.  
333.212 Contracting Officer’s duties upon appeal.  
333.212-70 Formats.  
333.213 Obligation to continue performance.  
333.215-70 Contract clauses.

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

**Subpart 333.1—Protests****333.102 General.**

(g)(1) The OGC–GLD serves as the liaison for protests lodged with the Government Accountability Office (GAO); is designated as the office responsible for all protests within HHS; and serves as the notification point with GAO for all protests.

(2) Each contracting activity shall designate a protest control officer to serve as an advisor to the Contracting Officer and to monitor protests from the time of initial notification until the protest has been resolved. Contracting activities shall forward a copy of each appointment and termination of appointment of protest control officers through appropriate acquisition channels, including the HCA, to ASFR/OGAPA/DA and the Deputy Associate General Counsel, OGC–GLD.

**333.103 Protests to the agency.**

(f)(1) The Contracting Officer is authorized to make the determination, using the criteria in *FAR 33.104(b)*, to award a contract notwithstanding the protest after obtaining the concurrence of the contracting activity’s protest control officer and the OGC–GLD. If a protest has been lodged with the Secretary, is addressed to the Secretary, or requests referral to the Secretary, the Contracting Officer shall also obtain approval from Associate DAS for Acquisition and OGC–GLD before making the award.

(2) The Contracting Officer shall require written confirmation of any oral protest. To be considered timely, the protester must file a written confirmation in accordance with the applicable provisions in *FAR 33.102(d)(2) and (e)*. In the following cases, the Contracting Officer shall forward written protests received before award through appropriate acquisition channels, including the HCA, to OGC–GLD for processing:

- (i) The protester requests referral to the Secretary of HHS.
  - (ii) The protest is known to have been lodged with GAO or the Secretary or is addressed to either.
  - (iii) The Contracting Officer entertains some doubt as to the proper action regarding the protest or believes it to be in the best interest of the Government that the Secretary or GAO consider the protest. Otherwise, the Contracting Officer may answer protests addressed to the Contracting Officer with the concurrence of the contracting activity’s protest control officer and OGC–GLD.
- The Contracting Officer shall submit files concerning these protests in

duplicate, or as otherwise specified by OGC–GLD, within 5 calendar days after protest receipt; mark the files “IMMEDIATE ACTION—PROTEST BEFORE AWARD;” and include any documents relevant to issues raised in the protest.

(3) The Contracting Officer shall treat protests received after award as indicated in *FAR 33.103(f)(3)*.

### 333.104 Protests to GAO.

(a) *General procedures.*

(3)(ii) OGC–GLD shall process protests filed with GAO, whether pre- or post- award. The Contracting Officer shall prepare protest files as follows: assemble them in a secure binder, fastened at the left side with a fastener that will permit the full page to be read; include a numerical document index, with the first two positions reserved for the Contracting Officer’s Statement of Facts and Circumstances and the second for OGC–GLD’s Memorandum of Law, that is paginated and, as necessary for sizable files, divided into two or more volumes; and the cover of the report shall identify it as the protest file and include the solicitation number and the GAO Bid Protest file number—*i.e.*, “B-number.” In addition, the Contracting Officer shall fold drawings and place them in an envelope in the binder and the solicitation/contract shall constitute a separate exhibit, if it is voluminous in size. The Contracting Officer shall distribute protest files as follows: four copies to OGC–GLD and one copy to the contracting activity’s protest control officer. In addition to the items listed in *FAR 33.104(a)(3)(ii)(A) through (G)*, the protest file shall include the following documents:

(H) The current status of award. (*Note:* When award has been made, this shall include whether performance has commenced, shipment or delivery has been made, or a stop work order has been issued.)

(I) A copy of any mutual agreement to suspend work on a no-cost basis, when appropriate—*see FAR 33.104(c)(4)*.

(J) Copies of the notice of protest given offerors and other parties when the notice is appropriate—*see FAR 33.104(a)(2)*.

(K) A copy of the negotiation memorandum, when applicable.

(L) The name and telephone number of the person in the contracting office who may be contacted for information relevant to the protest.

(M) A copy of the competitive range determination.

(N) The acquisition plan, source selection plan, and the source selection decision document.

(O) The Contracting Officer’s statement of facts and circumstances, including numbered findings of fact prepared with complete documentation, and all the facts and rationale, both favorable and unfavorable, to the Contracting Officer’s position.

(4) OGC–GLD shall make the necessary distributions referenced in *FAR 33.104(a)(4)*.

(5) Unless an alternative arrangement is reached with OGC–GLD, the Contracting Officer shall furnish one copy of the protest file containing the documentation specified in paragraph (a)(3)(ii) of this section (with the exception of the Contracting Officer statement of facts and circumstances) and *FAR 33.104(a)(3)(ii)(A) through (G)* to OGC–GLD within 5 calendar days from receipt of the protest. In addition, the Contracting Officer shall also accommodate any other OGC–GLD requests for documents which may be needed prior to the aforementioned 5-day time period. The Contracting Officer shall submit the Contracting Officer’s statement of facts and circumstances and the additional copies of documentation within 14 calendar days from receipt of the protest. Since the statute allows only a short time period in which to respond to protests lodged with GAO, the Contracting Officer shall handle each protest on a priority basis. OGC–GLD shall submit copies of the protest file to GAO, the protestor, and any intervenors in accordance with *FAR 33.104(a)(4)(i)*.

(6) Since OGC–GLD will furnish the protest file to GAO, the protestor, and any intervenors, comments on the file from the protestor and any intervenors will be sent to OGC–GLD.

(7) OGC–GLD shall serve as the GAO point of contact for protests lodged with GAO.

(b) *Protests before award.*

(1) To make an award notwithstanding a protest, the Contracting Officer shall prepare a finding using the criteria in *FAR 33.104(b)(1)*, have it executed by the HCA (non-delegable), and forward it, along with a written request for approval to make the award (addressed to the Associate DAS for Acquisition through OGC–GLD). Should OGC–GLD concur, it shall forward the request to the Associate DAS for Acquisition for final approval. The written request for approval shall contain all relevant documentation as attachments to the request, so that the information may be considered by Associate DAS for Acquisition.

(2) If the request to make an award notwithstanding the protest is approved by the Associate DAS for Acquisition,

OGC–GLD shall notify GAO. Whether the request is approved or not, OGC–GLD shall telephonically notify the contracting activity’s protest control officer of the Associate DAS for Acquisition decision, and the contracting activity’s protest control officer shall immediately notify the Contracting Officer. Should the Associate DAS for Acquisition approve the request, ASFR/OGAPA/DA shall send a copy of that written approval to the contracting activity’s protest control officer.

(c) *Protests after award.*

(2) If the Contracting Officer believes performance should be allowed to continue notwithstanding a protest, the Contracting Officer shall prepare a written finding using the criteria in *FAR 33.104(c)(2)*. The HCA (non-delegable) shall execute the written finding, which the contracting office shall forward pursuant to the procedures described in paragraph (b)(1) of this section. The notification procedures stated in paragraph (b)(2) of this section shall apply to protests after award.

(d) *Findings and notice.* The Contracting Officer shall prepare the written notice required by *FAR 33.104(d)* and provide a copy to OGC–GLD. OGC–GLD shall provide copies to GAO, the protestor, and any intervenors.

(g) *Notice to GAO.* *FAR 33.104(g)* requires the agency to notify GAO, if the agency has not followed any of GAO’s recommendations (other than costs) within 60 days after its decision. By the end of the 60-day period, the Contracting Officer shall notify OGC–GLD of the status of implementing the recommendations and reasons for any non-compliance. OGC–GLD shall serve as the designated official to comply with the requirements of *FAR 33.104(g)*.

(i) *Express option.* When GAO invokes the express option, the Contracting Officer shall prepare the complete protest file as described in paragraph (a)(3) of this section, to include the item in paragraph (a)(3)(i), and deliver it (hand-carry, if necessary) to OGC–GLD in time to meet the submittal date GAO established. OGC–GLD shall notify the Contracting Officer of the submittal date after GAO has finalized its requirements. If the Contracting Officer is not notified about a changed schedule, the timelines for a regular bid protest outlined in *FAR 33.104(a)(3)(i)* shall apply.

## Subpart 333.2—Disputes and Appeals

### 333.203 Applicability.

(c) The Secretary has designated the Civilian Board of Contract Appeals (CBCA) as the authorized “Board” to

hear and determine disputes for the Department.

**333.209 Suspected fraudulent claims.**

The Contracting Officer shall submit any instance of a contractor's suspected fraudulent claim to the OIG for investigation.

**333.211 Contracting Officer's decision.**

(a)(2) The Contracting Officer shall refer a proposed final decision to OGC-GLD, for advice as to the legal sufficiency and format before sending the final decision to the contractor. The Contracting Officer shall provide OGC-GLD with the pertinent documents with the submission of each proposed final decision.

(4)(v) When using the paragraph in *FAR 33.211 (a)(4)(v)*, the Contracting Officer shall insert the words "Civilian" before each mention of the term "Board of Contract Appeals."

(h) At any time within the period of appeal, the Contracting Officer may modify or withdraw the final decision. If a contractor has appealed the final decision to the CBCA, the Contracting Officer shall forward the recommended action to OGC-GLD with a supplement to the contract file that supports the recommended correction or amendment.

**333.212 Contracting Officer's duties upon appeal.**

(a) The rules set forth in the "Rules of the Civilian Board of Contract Appeals," or the rules established by the U.S. Court of Federal Claims, as appropriate, shall govern appeals.

(b) The OGC-GLD is designated as the Government Trial Attorney to represent the Government in the defense of appeals before the CBCA. OGC-GLD shall provide the decision by CBCA to the appropriate Contracting Officer for compliance in accordance with the CBCA's decision.

(c) If an appeal is filed with the CBCA, the Contracting Officer shall assemble a file, within 30 days of receipt of an appeal or notification that an appeal has been filed, that consists of all documents pertinent to the appeal, including the following:

(1) The decision and findings of fact from which the appeal is taken.

(2) The contract, including specifications and pertinent modifications, plans and drawings.

(3) All correspondence between the parties pertinent to the appeal, including the letter or letters of claim in response to which the decision was issued.

(4) Transcripts of any testimony taken during the course of proceedings, and

affidavits or statements of any witness on the matter in dispute made prior to the filing of the notice of appeal with the CBCA.

(5) Any additional information considered pertinent. The Contracting Officer shall furnish the appeal file to the Government Trial Attorney for review and approval. After approval, the Contracting Officer shall prepare four copies of the file—*i.e.*, one for the CBCA, one for the appellant, one for the Government Trial Attorney, and one for the contracting office.

(d) At all times after the filing of an appeal, the Contracting Officer shall render whatever assistance is requested by the Government Trial Attorney. When an appeal is set for hearing, the Contracting Officer shall provide Government witnesses and specified physical and documentary evidence to the Trial Attorney. The Trial Attorney shall ensure the presence of all witnesses and documentary evidence at both the prehearing conference and hearing.

(e) If a contractor, which has filed an appeal with the CBCA, elects to accept fully the decision from which the appeal was taken, or any modification to it, and gives written notification of acceptance to the Government Trial Attorney or the concerned Contracting Officer, the Government Trial Attorney shall notify the CBCA of the disposition of the dispute in accordance with Rule 27 of the CBCA.

(f) If the contractor has elected to appeal to the U.S. Court of Federal Claims, the U.S. Department of Justice will represent HHS. However, the Contracting Officer shall coordinate all actions through OGC-GLD.

**333.212-70 Formats.**

(a) Contracting activities shall use the following format in transmitting appeal files to CBCA:

Your reference:

(Docket No.)

(insert name)

Clerk of the Board, Civilian Board of

Contract Appeals

1800 F. Street, Washington, DC 20405

(for regular mail delivery)

1800 M Street, 6th floor, Washington,

DC 20036 [for overnight and physical

(hand-carry) delivery]

Dear (insert name):

Transmitted herewith are documents relative to the appeal under Contract No. \_\_\_\_\_ with the \_\_\_\_\_ (insert name of contractor) in accordance with the procedures under Rule 4. The Government Trial Attorney for this case is \_\_\_\_\_ (insert General Law Division, Office of

General Counsel, Department of Health and Human Services, 330 Independence Avenue, SW., Washington, DC 20201).

The request for payment of charges resulting from the processing of this appeal shall be addressed to:

\_\_\_\_\_ (insert name and address of cognizant finance office.)

Sincerely yours,

Contracting Officer

Enclosures

(b) Contracting activities shall use the following format in notifying the appellant that the appeal file was submitted to CBCA:

\_\_\_\_\_ (insert contractor name and address)

Dear \_\_\_\_\_: (insert name)

An appeal file has been compiled relative to the appeal under Contract No. \_\_\_\_\_ (insert number), and has been submitted to the Civilian Board of Contract Appeals (CBCA). The enclosed duplicate of the appeal file is identical to that submitted to CBCA, except for contract documents which you already have been provided. You may furnish or suggest any additional information deemed pertinent to the appeal to CBCA according to their rules.

The CBCA will provide you with further information concerning this appeal.

Sincerely yours,

Contracting Officer

Enclosure

**333.213 Obligation to continue performance.**

(a) The Contracting Officer shall use the Disputes clause at *FAR 52.233-1* without the use of Alternate I. However, if the Contracting Officer determines that the Government's interest would be better served by use of paragraph (i) in Alternate I, the HCA or CCO shall approve its use.

**333.215-70 Contract clauses.**

(a) The Contracting Officer shall insert the clause in *352.233-70*, Choice of Law (Overseas), in solicitations and contracts when performance will be outside the United States, its possessions, and Puerto Rico, except as otherwise provided in a government-to-government agreement.

(b) The Contracting Officer shall insert the clause in *352.233-71*, Litigation and Claims, in solicitations and contracts when a cost-reimbursement, time-and-materials, or labor-hour contract is contemplated



(other than a contract for a commercial item.)

## SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING

### PART 334—MAJOR SYSTEM ACQUISITION

#### Subpart 334.2—Earned Value Management System

Sec.

- 334.200 Definitions.
- 334.201 Policy.
- 334.202 Integrated Baseline Reviews (IBRs).
- 334.203 Solicitation provisions and contract clauses.
- 334.203–70 HHS solicitation provisions and contract clauses.

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

#### Subpart 334.2—Earned Value Management System

##### 334.200 Definitions.

As used in this subpart, the following definitions shall apply:

*Full EVMS* means tracking and reporting of both the cost and schedule aspects of a contract using the principles and guidelines described in ANSI/EIA Standard-748, Earned Value Management Systems (using the version of the Standard that is in effect at the time of the solicitation).

*Partial EVMS* means tracking and reporting of only the schedule aspects of a contract using the principles and guidelines described in ANSI/EIA Standard-748, Earned Value Management Systems (using the version of the Standard that is in effect at the time of the solicitation).

##### 334.201 Policy.

(a) For acquisitions for development designated as major in accordance with both OMB Circular A–11 and HHS policy on major acquisitions; for acquisitions that involve substantial development, modification or enhancement; or for acquisitions that involve significant upgrade of operational or steady state systems or programs, use of an Earned Value Management System (EVMS) is required as follows:

(1) For individual cost-reimbursement or fixed-price-incentive contracts (with incentive based on cost) valued at \$10 million to \$25 million, including options, full EVMS (as defined in 334.200) is required and the contractor's EVMS shall comply with the guidelines in ANSI/EIA Standard-748.

(2) For individual firm-fixed-price, term form (level-of-effort) of any type, time-and-materials, or labor-hour contracts valued at \$10 million to \$25 million, including options, partial EVMS (as defined in 334.200) is

required and the contractor's EVMS shall comply with the guidelines in ANSI/EIA Standard-748.

(3) For individual cost-reimbursement or fixed-price-incentive contracts (with incentive based on cost) valued at more than \$25 million, including options, full EVMS (as defined in 334.200) is required and the contractor's EVMS must be formally validated and accepted by the Government—*i.e.*, the contractor's Cognizant Federal Agency (CFA), as defined in *FAR 2.101* and described in *FAR 42.003*.

(4) For individual firm-fixed-price, term form (level-of-effort) of any type, time-and-materials, or labor-hour contracts valued at more than \$25 million, including options, partial EVMS (as defined in 334.200) is required and the contractor's EVMS must be formally validated and accepted by the Government—*i.e.*, the contractor's CFA.

(5) For individual contracts of any type valued at less than \$10 million, including options, full or partial EVM application, as appropriate to the contract type involved, is optional. The recommendation to use EVM should be based upon a risk analysis by the Program Manager/Project Officer. A decision to use EVM at this level requires the prior approval of the cognizant HCA.

(b) EVM is not required, but may be applied with prior written approval of the HCA, on contracts of any dollar amount meeting either of the following criteria:

(1) The acquisition is for non-developmental support services (*e.g.*, program office support, Independent Verification & Validation services), steady state operations, basic and applied research, and routine services (*e.g.*, building maintenance, help-desk services, landscaping services).

(2) The contract is for a commercial item(s) under *FAR Part 12*.

(c) When full EVM is required on a prime contract, it applies to subcontracts issued there under if those subcontracts have a value and are of a type and subject matter that would have required the use of full EVM had they been prime contracts. However, if the prime contract requires the use of only partial EVM, any subcontracts to which EVM is made applicable, because of dollar value, contract type or subject matter, shall require only partial EVM.

(d) When offerors are required to provide an EVMS plan as part of their proposals, the Contracting Officer shall request the assistance of the Project Officer (and/or an appropriate HHS-designated third party) in determining

the adequacy of such proposed EVMS plans.

(e) The selection or use of a particular contract type, if done only or primarily to avoid the application of full EVM to the acquisition is prohibited.

##### 334.202 Integrated Baseline Reviews (IBRs).

(a) An IBR normally should be conducted as a post-award activity. A pre-award IBR may be conducted only if—

(1) The AP contains documentation that demonstrates the need and rationale for a pre-award IBR, including an assessment of the impact on the source selection schedule and the expected benefits;

(2) The use of a pre-award IBR is approved in writing by the HCA prior to the issuance of the solicitation;

(3) The source selection plan specifically addresses how the results of a pre-award IBR will be used during source selection, including any weight to be given to it in source evaluation, and that same or similar rationale is clearly set forth in the solicitation; and,

(4) Specific arrangements are made, and budget authority is provided, to compensate all offerors who prepare for or participate in a pre-award IBR; and the solicitation informs prospective offerors of the means for and conditions of such compensation.

##### 334.203 Solicitation provisions and contract clauses.

The FAR EVMS solicitation provisions and contract clause shall not be used in HHS contracts. *See 334.203–70* for the HHS solicitation provisions and contract clauses.

##### 334.203–70 HHS solicitation provisions and contract clauses.

As provided in 334.201(a) and 334.202, the Contracting Officer shall insert the following:

(a) The provision in 352.234–1, Notice of Earned Value Management System—Pre-Award IBR, in solicitations that will require the contractor to use an EVMS, whether full or partial, when the Government requires an IBR prior to award.

(b) The provision in 352.234–2, Notice of Earned Value Management System—Post-Award IBR, in solicitations that will require the contractor to use an EVMS, whether full or partial, when the Government requires an IBR after contract award.

(c) The clause in 352.234–3, Full Earned Value Management System, in solicitations and contracts, valued at, or greater than, \$25 million, when a cost-reimbursement or fixed-price-incentive contract (where the incentive is based

on cost) is contemplated, and which require a contractor to use full EVMS. The Contracting Officer shall use the clause with its Alternate I when the contract value is equal to or greater than \$10 million, but less than \$25 million.

(d) The clause in 352.234-4, Partial Earned Value Management System, in solicitations and contracts, valued at, or greater than, \$25 million, when a firm-fixed-price, time-and-materials, labor-hour, or term-form cost-plus-fixed-fee contract is contemplated, and which require a contractor to use partial EVMS. The Contracting Officer shall use the clause with its Alternate I when the contract value, is equal to or greater than \$10 million, but less than \$25 million.

## **PART 335—RESEARCH AND DEVELOPMENT CONTRACTING**

Sec.

335.070 Cost sharing.

335.070-1 Policy.

335.070-2 Amount of cost sharing.

335.070-3 Method of cost sharing.

335.070-4 Contract award.

335.071 Special determinations and findings affecting research and development contracting.

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

### **335.070 Cost-sharing.**

#### **335.070-1 Policy.**

(a) Contracting activities shall encourage performing organizations to contribute to the cost of performing R & D, through the use of cost-sharing contracts, where there is a probability that the contractor will receive present or future benefits from participation, such as increased technical know-how, training for employees, acquisition of equipment, and use of background knowledge in future contracts. Cost-sharing is intended to serve the mutual interests of the Government and the performing organization by helping to ensure efficient utilization of the resources available for the conduct of R & D projects and by promoting sound planning and prudent fiscal policies of the performing organization. The Contracting Officer shall use a cost-sharing contract, unless the Contracting Officer determines that a request for cost-sharing would not be appropriate because of the following circumstances:

(1) The particular R & D objective or scope of effort for the project is specified by the Government rather than proposed by the performing organization. This would usually include any formal Government solicitation for a specific project.

(2) The R & D effort has only minor relevance to the non-Federal activities

of the performing organization, and the organization is proposing to undertake the R & D primarily as a service to the Government.

(3) The organization has little or no non-Federal sources or funds from which to make a cost contribution. Organizations which are predominantly engaged in R & D and have little or no production or other service activities may not be in a favorable position to make a cost contribution. Accordingly, the Contracting Officer shall normally not request cost-sharing, if cost-sharing would require the Government to provide funds through some other means (such as fees) to enable the organization to cost-share.

(b) The Contracting Officer has the responsibility for negotiating cost-sharing. Each R & D contract file shall indicate whether the Contracting Officer considered cost-sharing appropriate for that particular contract and in what amount. If cost sharing was not appropriate, the file must include a statement and factual basis for that decision (e.g., "Because the contractor will derive no benefits from this award that can be applied to its commercial activities, cost-sharing is not considered appropriate.") The Contracting Officer shall coordinate with the Project Officer before documenting this decision.

(c) If the Contracting Officer considers cost-sharing appropriate for an R & D contract and the contractor refuses to accept this type of contract, the Contracting Officer may make an award without cost-sharing, if the Contracting Officer concludes that payment of the full cost of the R & D effort is necessary to obtain the services of that particular contractor.

#### **335.070-2 Amount of cost sharing.**

When cost-sharing is appropriate, the Contracting Officer shall use the following guidelines to determine the amount of cost participation by the contractor:

(a) The amount of cost participation depends on the extent to which the R & D effort or results are likely to enhance the performing organization's capability, expertise, or competitive position, and the value of this enhancement to the performing organization. Therefore, contractor cost participation could reasonably range from as little as one percent or less of the total project cost to more than 50 percent of the total project cost. Ultimately, cost-sharing is a negotiable item. As such, the amount of cost-sharing shall be proportional to the anticipated value of the contractor's gain.

(b) If the performing organization will not acquire title to, or the right to use,

inventions, patents, or technical information resulting from the R & D project, it is normally appropriate to obtain less cost-sharing than in cases in which the performer acquires these rights.

(c) A fee or profit is not normally paid to the performing organization, if the organization is to contribute to the cost of the R & D effort, but the amount of cost-sharing may be reduced to reflect the fact that the organization is foregoing its normal fee or profit in the research. However, if the R & D is expected to be of only minor value to the performing organization, and if a statute does not require cost-sharing, it may be appropriate for the performer to make a contribution in the form of a reduced fee or profit rather than sharing costs of the project.

(d) The organization's participation may be considered over the total term of the project, so that a relatively high contribution in one year may be offset by a relatively low contribution in another.

(e) A relatively low degree of cost-sharing may be appropriate, if an area of R & D requires special stimulus in the national interest.

#### **335.070-3 Method of cost sharing.**

Cost-sharing on individual contracts may be accomplished either by a contribution of part or all of one or more elements of allowable cost of the work being performed or by a fixed amount or stated percentage of the total allowable costs of the project. Contractors shall not charge costs contributed to the Government under any other instrument (e.g., grant or contract), including allocations to other instruments as part of any independent R & D program.

#### **335.070-4 Contract award.**

Consistent with HHS' objectives of competition and support of the small business program, Contracting Officers shall not award contracts solely on the basis of an organization's ability or willingness to cost-share. Contracting Officers shall make awards primarily on the contractor's competence and only after adequate competition has been obtained among large and small business organizations, whenever possible. An offeror's willingness to share costs is not a technical evaluation consideration, but a business consideration, which is secondary to selecting the best qualified source.

#### **335.071 Special determinations and findings affecting research and development contracting.**

OPDIV heads shall sign individual and class D & Fs for—

(a) Acquisition or construction of equipment or facilities on property not owned by the United States pursuant to 42 U.S.C. 241(a)(7); and

(b) Use of an indemnification provision in an R & D contract pursuant to 42 U.S.C. 241(a)(7).

## PART 337—SERVICE CONTRACTING—GENERAL

### Subpart 337.1—Service Contracts—General

Sec.

337.103–70 Solicitation provisions and contract clauses.

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

### Subpart 337.1—Service Contracts—General

#### 337.103–70 Solicitation provisions and contract clauses.

(a) The Contracting Officer shall insert the clause in *352.237–70*, Pro-Children Act, in solicitations, contracts, and orders that involve (a) kindergarten, elementary, or secondary education or library services or (b) health or daycare services that are provided to children under the age of 18 on a routine or regular basis pursuant to the Pro-Children Act of 1994.

(b) The Contracting Officer shall insert the clause in *352.237–71*, Crime Control Act—Reporting of Child Abuse, in solicitations, contracts, and orders that require performance on Federal land or in a Federally operated (or contracted) facility and involve the professions/activities performed by persons specified in the Crime Control Act of 1990, including, but not limited to, physicians, nurses, dentists, health care practitioners, optometrists, psychologists, emergency medical technicians, alcohol or drug treatment personnel, child care workers and administrators, emergency medical technicians and ambulance drivers.

(c) The Contracting Officer shall insert the clause in *352.237–72*, Crime Control Act—Requirement for Background Checks, in solicitations, contracts, and orders that involve providing child care services to children under the age of 18, including social services, health and mental health care, child- (day) care, education (whether or not directly involved in teaching), and rehabilitative programs covered under the Crime Control Act of 1990 (Act).

## PART 339—ACQUISITION OF INFORMATION TECHNOLOGY

### Subpart 339.1—General

Sec.

339.101 Policy.

### Subpart 339.2—Electronic and Information Technology

339.201 Clarification.

339.201–70 Required provision and contract clause.

339.203 Approval of exceptions.

### Subpart 339.70—Use of General Services Administration Blanket Purchase Agreements for Independent Risk Analysis Services

339.7000 Policy.

339.7001 Request for approval to make an award to other than a GSA BPA holder.

339.7002 Notice of intended award.

### Subpart 339.71—Information Security Management

339.7100 Definitions.

339.7101 Policy.

339.7102 Applicability.

339.7103 Solicitation and contract clause.

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

### Subpart 339.1—General

#### 339.101 Policy.

(d)(1) The Contracting Officer shall insert the clause in *352.239–70*, Standard for Security Configurations, in solicitations, contracts, and orders that involve the operation or acquisition of an information technology system (for definition of the latter term, see <http://www.hhs.gov/ocio/policy>.)

An HHS information security policy waiver, the template for which is available at: [http://intranet.hhs.gov/infosec/policies\\_memos.html](http://intranet.hhs.gov/infosec/policies_memos.html), must be approved in order to deviate from HHS OCIO Standard 2009–0001.001S, HHS Standard for Security Configurations Language in HHS Contracts, dated January 30, 2009. A copy of the approved waiver shall be forwarded to the Contracting Officer who, in turn, shall request a comparable deviation for the clause in *352.239–70*.

(2) The Contracting Officer shall insert the clause in *352.239–71*, Standard for Encryption Language, in solicitations, contracts, and orders that involve the acquisition or lease of, or the requirement to use, desktop or laptop computers, mobile devices, or portable media to store or process HHS sensitive information that the Project Officer categorizes as moderate or high under Federal Information Processing Standard (FIPS) 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004. An HHS information security policy waiver, the template for which is available at: [http://intranet.hhs.gov/infosec/policies\\_memos.html](http://intranet.hhs.gov/infosec/policies_memos.html), must be approved in order to deviate from HHS OCIO Standard 2009–0002.001S, HHS Standard for Encryption Language in HHS Contracts, dated January 30, 2009.

A copy of the approved waiver shall be forwarded to the Contracting Officer who, in turn, shall request a comparable deviation for the clause in *352.239–71*.

### Subpart 339.2—Electronic and Information Technology

#### 339.201 Clarification.

*FAR Subpart 39.2, Electronic and Information Technology*, requires Federal agencies to ensure that, when acquiring EIT, Federal employees with disabilities and members of the public with disabilities have access to and use of information and data that is comparable to individuals without disabilities. This EIT access requirement does not apply to a contractor's internal workplaces. EIT that is neither used nor accessed by Federal employees or members of the public is not subject to the Access Board accessibility standards. Contractors in their professional capacity are not members of the public for purposes of Section 508.

#### 339.201–70 Required provision and contract clause.

(a) The Contracting Officer shall insert the provision in *352.239–73(a)*, Electronic and Information Technology Accessibility, in solicitations valued at more than the micro-purchase threshold that involve the development, acquisition, maintenance, or use of EIT products and services subject to Section 508 of the Rehabilitation Act of 1973, as amended, including EIT deliverables such as electronic documents and reports. (**Note:** Exceptions to this requirement can be found in *FAR 39.204*.) After approval of the Section 508 Official or designee, the Contracting Officer may waive the requirement for offerors to provide an HHS Section 508 Product Assessment Template, if Section 508 EIT conformance can be determined conclusively through other less formal methods. The Contracting Officer shall document in the award file any waiver for submission of the Product Assessment Template. The approval of a waiver by the Section 508 Official does not, however, eliminate the requirement for product assessment against Section 508 accessibility standards.

(b) The Contracting Officer shall insert the clause in *352.239–73(b)*, Electronic and Information Technology Accessibility, in contracts and orders that involve the development, acquisition, maintenance, or use of EIT products and services, including EIT deliverables such as electronic documents and reports, subject to Section 508 of the Rehabilitation Act of

1973, as amended, unless the EIT products and services are incidental to the project. (**Note:** Other exceptions to this requirement can be found at *FAR 39.204*.)

(c) When acquiring EIT products and services subject to Section 508 of the Rehabilitation Act of 1973, as amended, in the following circumstances, the Contracting Officer shall insert the paragraph in *352.239-73(c)*, Schedule for Contractor Submission of Section 508 Annual Report, which requires a contractor to provide an HHS Section 508 Annual Report, at the end of the clause in *352.239-73(b)* and cite the schedule for report submission, where indicated:

(1) New multiple-year contracts.

(2) Existing multiple-year contracts, with a performance period of 1 year or more remaining as of January 16, 2008 (the effective date of HHS' interim acquisition guidance).

(3) New multiple-year task and delivery orders exceeding \$100,000 awarded under IDIQ or FSS contracts.

(4) Existing multiple-year task and delivery orders exceeding \$100,000 awarded under IDIQ or FSS contracts, with a task/delivery order performance period of 1 year or more remaining as of January 16, 2008.

(5) New multiple-year BPA orders that exceed \$100,000.

(6) Existing multiple-year BPA orders with a performance period of 1 year or more remaining as of January 16, 2008.

(7) New multiple-year contracts with option periods/quantities.

(8) Existing multiple-year contracts with option periods/quantities remaining as of January 16, 2008.

(d) Before adding funds to a multiple-year contract or order—*see 339.201-70(c)*, that involves the acquisition of EIT products and services, including EIT deliverables such as electronic documents and reports, subject to Section 508 of the Rehabilitation Act of 1973, as amended, the Contracting Officer shall ensure that the contractor has provided to the Contracting Officer and COTR a properly completed HHS Section 508 Annual Report—*see Section 508 policy on HHS Office on Disability Web site*. The Contracting Officer shall request that the contractor provide the report in sufficient time for its review and approval by the Contracting Officer, COTR, and the Section 508 Official or designee, prior to funding performance beyond the currently funded contract performance period. The Contracting Officer shall ensure that the report and all related approvals are made a part of the official contract/order file. The Section 508 Official or designee shall monitor the Annual Reports, direct

corrective measures to improve their submission and quality, and report improvement actions taken to the HHS Office on Disability.

### **339.203 Approval of exceptions.**

(a) Procedures to document exception and determination requests are set forth in the OPDIV/STAFFDIV Section 508 Implementation Plans required by paragraph 4.1 of the HHS Section 508 policy.

(b) In the development of an AP or other acquisition request document, the Contracting Officer shall ensure that all Section 508 commercial non-availability or undue burden exception determination requests for applicable EIT requirements are: (1) Documented and certified in accordance with the requirements of paragraph 4.3, Section 508 Compliance Exceptions, of the HHS Section 508 policy; (2) signed by the Project Officer; (3) approved by the OPDIV Section 508 Official or designee; and (4) included in the AP or other acquisition request document provided by the Project Officer to the contracting office.

(c) In instances where a technical evaluation has been performed, and no organization's proposed products or services meet some or all of Section 508 accessibility standards, in order to proceed with the acquisition, the Contracting Officer shall provide an exception determination request along with the technical evaluation panel's assessment of the Section 508 evaluation factor to the designated Section 508 Official or designee for review and approval/disapproval. *See 315.304* regarding obtaining approval of technical evaluation panel assessments by the Section 508 Official or designee. The Contracting Officer shall include the Section 508 Official's or designee's approval/disapproval of the exception determination request in the official contract file and reference it, as appropriate, in all source selection documents. For further information, *see paragraphs 4.3, Section 508 Compliance Exceptions, and paragraph 11, Appendix A, of HHS Section 508 policy—see Section 508 policy on HHS Office on Disability Web site*.

### **Subpart 339.70—Use of General Services Administration Blanket Purchase Agreements for Independent Risk Analysis Services**

#### **339.7000 Policy.**

GSA has established government-wide BPAs for independent risk analysis services, including verification and validation of in-house risk assessments. For information on

ordering procedures, *see* the attachment to OMB memorandum (M-08-10), Use of Commercial Independent Risk Analysis Services Blanket Purchase Agreements (BPA), dated February 4, 2008, available on the OMB Web site. HHS policy is for contracting activities to use the GSA BPA sources to the maximum practicable extent.

#### **339.7001 Request for approval to make an award to other than a GSA BPA holder.**

The Contracting Officer, in conjunction with the OPDIV/STAFFDIV Chief Information Security Officer (CISO), may determine, as part of conducting market research for independent risk analysis services expected to exceed the micro-purchase threshold, that obtaining the required services from a source other than a GSA BPA holder will result in the best value to the Government. In that event, the Contracting Officer shall prepare a request for approval at least 15 business days prior to the planned date of the contract or order award and forward it through the HCA and the OPDIV/STAFFDIV CISO for concurrence, to the SPE. The SPE shall coordinate the processing of the request with the CAO and the HHS CIO. The request for approval shall briefly describe the services required, indicate the intended source's pricing and other terms and conditions, and provide the rationale for award to the intended source rather than the GSA BPA holders. The request may include additional supporting rationale to document the best value decision, as appropriate.

#### **339.7002 Notice of intended award.**

The CAO, or designee, in conjunction with the HHS CIO, will review the Contracting Officer's request for approval to make an award to other than a GSA BPA holder for independent risk analysis services and either approve or disapprove the request in writing. If the CAO, or designee, approves the request, upon approval, the CAO, or designee, shall send a notice of intended award to the designated GSA BPA Contracting Officer, with a copy to OMB's E-Government and Information Technology Administrator, at least 10 business days prior to the date of the proposed award explaining how it provides the best value to the Government. In the event of unusual and compelling urgency, the CAO, or designee, shall provide the notice of intended award to GSA as soon as practicable.

### Subpart 339.71—Information Security Management

#### 339.7100 Definitions.

As used in this subpart, the following definitions shall apply:

*Adequate security* means, in accordance with OMB Circular A–130, Management of Federal Information Resources, Appendix 3 (Security of Federal Automated Information Resources), security commensurate with the risk and magnitude of harm resulting from the loss, misuse, or unauthorized access to or modification of information.

*Federal information* means, in accordance with OMB Circular A–130, Management of Federal Information Resources, Appendix 3 (Security of Federal Automated Information Resources), information created, collected, processed, disseminated, or disposed of by or for the Federal Government.

*Federal information system* means an information system used or operated by an executive agency, by a contractor of an executive agency, or by another organization on behalf of an executive agency.

*Information* means, in accordance with OMB Circular A–130, Management of Federal Information Resources, Appendix 3 (Security of Federal Automated Information Resources), any communication or representation of knowledge such as facts, data, or opinions in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms.

*Information infrastructure* means the underlying framework that information systems and assets rely on in processing, transmitting, receiving, or storing information electronically.

*Information security* means protecting information and information systems from unauthorized access, use, disclosure, disruption, modification or destruction in order to provide—

(1) *Integrity*, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

(2) *Confidentiality*, which means preserving authorized restrictions on access and disclosure, including means of protecting personal privacy and proprietary information;

(3) *Availability*, which means ensuring timely and reliable access to and use of information; and

(4) *Privacy*, which means regulating the appropriate collection, maintenance, use, and dissemination of personal information by Federal executive branch

agencies. It essentially prohibits disclosure without consent.

*Information system* means a discrete set of information resources organized for the collection, processing, maintenance, transmission, and dissemination of information, in accordance with defined procedures, whether automated or manual.

*Information technology* includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources.

#### 339.7101 Policy.

HHS is responsible for implementing an information security program to ensure that its information systems and associated facilities, as well as those of its contractors, provide a level of security commensurate with the risk and magnitude of harm that could result from the loss, misuse, disclosure, or modification of the information contained in those systems. Each system's level of security shall protect the integrity, confidentiality, and availability of the information and comply with all security and privacy-related laws and regulations.

#### 339.7102 Applicability.

Contracting Officers are responsible for ensuring that all information technology acquisitions comply with the Federal Information Security Management Act (FISMA), the HHS–OCIO Information Systems Security and Privacy Policy, and FISMA-related FAR and HHSAR requirements. This policy does not apply to national security systems as defined in FISMA.

#### 339.7103 Solicitation and contract clause.

The Contracting Officer shall insert the clause in 352.239–72, Security Requirements for Federal Information Technology Resources, in solicitations and contracts that involve contractor access to Federal information or Federal information systems.

### SUBCHAPTER G—CONTRACT MANAGEMENT

### PART 342—CONTRACT ADMINISTRATION

#### Subpart 342.3—Contract Administration Office Functions

Sec.

342.302 Contract administration functions.

#### Subpart 342.7—Indirect Cost Rates

342.705 Final indirect cost rates.

#### Subpart 342.70—Contract Monitoring

342.7000 Purpose.

342.7001 Contract monitoring responsibilities.

342.7002 Procedures to be followed when a contractor fails to perform.

342.7003 Withholding of contract payments.

342.7003–1 Solicitation provisions and contract clauses.

342.7003–2 Procedures to be followed when withholding payments.

#### Subpart 342.71—Administrative Actions for Cost Overruns

342.7100 Scope of subpart.

342.7101 Contract administration.

342.7101–1 General.

342.7101–2 Procedures.

342.7102 Contract modifications.

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

#### Subpart 342.3—Contract Administration Office Functions

#### 342.302 Contract administration functions.

(c)

(1) In multiple-year contracts or orders, the OPDIV's Section 508 Official or designee, as well as the Contracting Officer and COTR, shall review and approve all Section 508 Annual Reports before the Contracting Officer makes final payment or any option is exercised under any applicable contract/order. In contracts/orders of 1 year or less in duration, the aforementioned officials shall review and approve the Section 508 conformance certification before final payment is made. The Contracting Officer also shall ensure that the report and all related approvals are made a part of the official contract/order file.

(2) The Contracting Officer shall insert the clause in 352.242–70, Key Personnel, in solicitations and contracts when the Contracting Officer will designate contractor key personnel. See FAR 35.015 for additional information regarding key personnel when contracting for R & D.

(3) The Contracting Officer shall insert the clause in 352.242–71, Tobacco-free Facilities, in solicitations, contracts, and orders when some or all of the contractor's performance (including construction services), will take place on HHS-owned or controlled properties. The clause shall not be included if performance requires only that contractor staff attend occasional meetings on HHS properties. In that case, contractor employees are considered "visitors." Further, for any proposed or existing construction contract or order, the Contracting Officer shall coordinate any exceptions to the policy, raised by an incumbent or potential contractor based on union or collective bargaining agreements, with the designated OPDIV tobacco-free

policy contact point for final disposition.

(4) The Contracting Officer shall insert the clause in 352.242–72, Native American Graves Protection and Repatriation Act, in solicitations, contracts, and orders that require performance on Tribal lands or are for construction on Federal or Tribal lands.

#### Subpart 342.7—Indirect Cost Rates

##### 342.705 Final indirect cost rates.

(a) The Division of Cost Allocation, PSC, shall establish indirect cost rates, research patient care rates, and, as necessary, fringe benefit, computer, and other special costing rates for use in contracts awarded to State and local governments, colleges and universities, hospitals, and other nonprofit organizations.

(b) The Division of Financial Advisory Services, NIH, shall establish indirect cost rates, fringe benefit rates, and similar rates for use in contracts awarded to commercial organizations.

#### Subpart 342.70—Contract Monitoring

##### 342.7000 Purpose.

Contract monitoring is an essential element of contract administration that the Contracting Officer and the COTR perform jointly. This subpart describes HHS' operating concepts.

##### 342.7001 Contract monitoring responsibilities.

(a) The contract establishes the obligations of both the Government and the contractor. The Contracting Officer is the only person authorized to modify the contract and shall confirm all modifications in writing.

(b) The Contracting Officer shall ensure the contractor's compliance with all the terms and conditions of the contract. The Contracting Officer shall inform the contractor by letter (if not already stipulated in the contract) of the authorities and responsibilities of the Government personnel involved with the contract.

(c) The Contracting Officer shall use program, technical, and other personnel for assistance and advice in monitoring the contractor's performance and in other areas of post-award administration. The Contracting Officer shall ensure that these individuals understand and carry out their assigned responsibilities. The individual roles and corresponding responsibilities typically involve, but are not limited to, the following:

(1) The role of program and technical personnel in monitoring the contract is to assist and advise the Contracting Officer, and act as the COTR when so

designated by the Contracting Officer. COTR activities include—

(i) Providing technical monitoring during contract performance and advising the Contracting Officer relating to delivery, acceptance, or rejection of deliverables in accordance with the terms of the contract;

(ii) Assessing contractor performance;

(iii) Recommending necessary changes to the schedule of work and period of performance to accomplish the objectives of the contract (The COTR shall provide the Contracting Officer a written request along with an appropriate justification and a funding document, if additional funds are needed.);

(iv) Reviewing invoices/vouchers and recommending approval/disapproval by the Contracting Officer, including providing comments regarding anything unusual discovered in the review (*Note:* If a contract contains the Salary Rate Limitation clause specified in 352.231–70, the Contracting Officer, in conjunction with the COTR, shall monitor the contractor's invoices to ensure that the contractor is billing salaries, including those of subcontractors, at rates no higher than the Federal Executive Schedule salary rate limitation in effect on the date(s) the expense(s) was/were incurred.);

(v) Reviewing and recommending approval or disapproval of subcontractors, overtime, travel, and key personnel changes; and

(vi) Participating, as necessary, in various phases of the contract closeout process.

(2) The roles of the contract administrator, auditor, cost analyst, and property administrator are to assist or advise the Contracting Officer in post-award administration. Such activities include—

(i) Evaluating contractor systems and procedures, including accounting policies and procedures, purchasing policies and practices, property accounting and control, wage and salary plans and rate structures, personnel policies and practices, *etc.*;

(ii) Processing disputes under the Disputes clause and any resultant appeals;

(iii) Modifying or terminating the contract; and

(iv) Determining the allowability of: costs charged in incentive or cost-reimbursement type contracts, and progress payments under fixed-price contracts. This is important for awards to new organizations or those with financial weaknesses.

(d) The Contracting Officer shall ensure that contractor performance and contract monitoring conform with

contract terms and conditions. If performance is not satisfactory or if problems are anticipated, the Contracting Officer shall take immediate action to protect the Government's rights under the contract. The Contracting Officer shall notify appropriate officials of problems that cannot be resolved within contract limitations and whenever the contractor is not meeting contract or program objectives. The notification shall include a statement of corrective actions that the Contracting Officer is taking.

##### 342.7002 Procedures to be followed when a contractor fails to perform.

(a) The Contracting Officer shall initiate immediate action to protect the Government's rights whenever the contractor fails to comply with either the delivery or reporting terms of the contract. Compliance with the reporting terms includes those reports the contractor is required to submit directly to the payment office. The payment office shall notify the Contracting Officer promptly when the contractor does not submit such a report on time.

(b) When the contract contains a termination for default clause, the contractor's failure to submit any report, perform services, or deliver work when required by the contract is considered a default in performance. The Contracting Officer shall immediately issue a formal 10-day cure notice pursuant to FAR 49.607. The notice shall include a statement to the effect that payments will be withheld if the default is not cured within the time period specified in the notice or if the default is not determined to be excusable.

(1) If the default is cured or is determined to be excusable, the Contracting Officer shall not initiate the withholding action.

(2) If the default is not determined to be excusable or a response is not received within the allotted time, the Contracting Officer shall initiate withholding action on all contract payments and shall determine whether termination for default or other action would be in the best interest of the Government.

(c) When the contract does not contain a termination for default clause, the Contracting Officer shall consider a contractor's failure to submit any required report, perform services, or deliver work when required by the contract a failure to perform. The Contracting Officer shall immediately issue a written notice to the contractor that: specifies the failure, and provides a 10-day period (or longer period if the Contracting Officer deems it necessary) within which the contractor shall either

cure the failure or provide reasons for an excusable delay. The notice shall include a statement to the effect that payments will be withheld, if the default is not cured within the time period specified in the notice or if the default is not determined to be excusable.

(1) If the contractor cures the failure or the Contracting Officer determines it to be excusable, the Contracting Officer shall not initiate the withholding action.

(2) If the Contracting Officer does not determine the failure excusable or the contractor does not provide a response within the allotted time, the Contracting Officer shall initiate withholding action on all contract payments and shall determine whether termination for convenience or other action would be in the best interest of the Government.

(d) The Contracting Officer shall consult *FAR subpart 49.4* for further guidance before taking any of the actions described in this section.

#### **342.7003 Withholding of contract payments.**

##### **342.7003-1 Solicitation provisions and contract clauses.**

(a) The Contracting Officer shall insert the clause in *352.242-73*, Withholding of Contract Payments, and the clause in *FAR 52.249-14*, Excusable Delays, in solicitations and contracts when a cost-reimbursement, time-and-materials, or labor-hour contract is contemplated.

(b) The Contracting Officer shall insert the clause in *352.242-74*, Final Decisions on Audit Findings, in solicitations and contracts when a cost-reimbursement contract is contemplated, except for those contracts with:

(1) A foreign government or agency of that government; or

(2) An international organization or a subsidiary body of that organization that the HCA determines would not be appropriate.

##### **342.7003-2 Procedures to be followed when withholding payments.**

(a) When appropriate, the Contracting Officer shall withhold any contract payment when a required report is overdue or the contractor fails to perform or deliver required work or services. When making the determination to withhold contract payments in accordance with the Withholding of Contract Payments clause, the Contracting Officer shall immediately notify the servicing finance office in writing of the determination to withhold payments. The notice of suspension shall contain all information necessary for the finance office to identify the contract—*i.e.*, contract

number, task/delivery order number, and contractor name and address.

(b) The Contracting Officer shall immediately notify the contractor in writing that payments have been suspended until the default or failure is cured.

(c) When the contractor cures the default or failure, the Contracting Officer shall immediately notify, in writing, all recipients of the notice of withholding that the withholding is to be lifted and contract payments are to be resumed.

(d) When taking any actions regarding the withholding of payments, the Contracting Officer shall not waive any of the Government's rights when corresponding with the contractor.

#### **Subpart 342.71—Administrative Actions for Cost Overruns**

##### **342.7100 Scope of subpart.**

This subpart sets forth the procedures to follow when a cost overrun is anticipated. A cost overrun occurs when the allowable actual cost of performing a cost-reimbursement type contract exceeds the total estimated cost specified in the contract.

##### **342.7101 Contract administration.**

###### **342.7101-1 General.**

Upon receipt of information that a contractor's accumulated cost and projected expenditures will exceed the limit of funds obligated by the contract, the Contracting Officer shall coordinate immediately with the appropriate program office to determine whether the contract should be modified or terminated. If the Contracting Officer receives information from a source other than the contractor that a cost overrun is anticipated, the Contracting Officer shall verify the information with the contractor and remind the contractor of the notification requirements of the Limitation of Cost clause.

###### **342.7101-2 Procedures.**

(a) Upon notification that a cost overrun is anticipated, the Contracting Officer shall inform the contractor to submit a request for additional funds, which shall include the following:

(1) Name and address of contractor.

(2) Contract number and expiration date.

(3) Contract item(s) and amount(s) creating overrun.

(4) The elements of cost which changed from the original estimate—*i.e.*, labor, material, travel, and overhead, to be furnished in the following format:

(i) Original estimate.

(ii) Costs incurred to date.

(iii) Estimated cost to completion.

(iv) Revised estimate.

(v) Amount of adjustment.

(5) The factors responsible for the increase (*e.g.*, error in estimate, changed conditions).

(6) The latest date by which funds must be available for commitment to avoid contract slippage, work stoppage, or other program impairment.

(b) When the contractor submits a notice of a projected overrun, the Contracting Officer shall—

(1) Immediately advise the appropriate program office and furnish the office a copy of the notice and any other data received;

(2) Request audit or cost advisory services, and technical support, as necessary, for evaluation of information and data received; and

(3) Maintain continuous communications with the program office to obtain: a timely written decision and justification to continue the contract with additional funds (including verification of funds availability); or a timely written decision and request to terminate the contract.

(c) After receiving the decision by the program office, the Contracting Officer shall promptly notify the contractor in writing of the following:

(1) The specified amount of additional funds allotted to the contract.

(2) Work shall be discontinued when the allotted funds are exhausted, and any work performed after that date is at the contractor's risk.

(3) The Government is considering whether to allot additional funds to the contract and will notify the contractor as soon as possible, but that any work performed after the currently allotted funds are exhausted is at the contractor's risk. (Timely, formal notification of the Government's intention is essential to preclude loss of contractual rights in the event of dispute, termination, or litigation.)

(d) If the program office permits, the Contracting Officer shall refrain from issuing any contractual documents that require new work or an extension of time, pending resolution of the projected overrun.

###### **342.7102 Contract modifications.**

(a) Modifications to contracts containing the Limitation of Cost clause shall include either—

(1) A provision which: Increases the estimated or ceiling amount in the Limitation of Cost clause of the contract; and states that such clause will thereafter apply to the increased amount; or

(2) A provision stating that the estimated or ceiling amount in the



Limitation of Cost clause is not changed by the modification.

(b) The Contracting Officer shall not change a fixed-fee in a contract when funding a cost overrun. The Contracting Officer shall make changes in fixed-fee only to reflect changes in the SOW/PWS that justify an increase or decrease in fee.

## SUBCHAPTER H—CLAUSES AND FORMS

### PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

#### Subpart 352.1—Instructions for Using Provisions and Clauses

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352.101–70 Application of provisions and clauses.

#### Subpart 352.2—Texts of Provisions and Clauses

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352.202–1 Definitions.

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352.219–71 Mentor-protégé program reporting requirements.

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352.224–70 Privacy Act.

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352.231–70 Salary rate limitation.

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352.233–70 Choice of law (overseas).

352.233–71 Litigation and claims.

352.234–1 Notice of earned value management system—pre-award Integrated Baseline Review.

352.234–2 Notice of earned value management system—post-award Integrated Baseline Review.

352.234–3 Full earned value management system.

352.234–4 Partial earned value management system.

352.237–70 Pro-Children Act.

352.237–71 Crime Control Act—reporting of child abuse.

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352.239–70 Standard for security configurations.

352.239–71 Standard for encryption language.

352.239–72 Security requirements for Federal information technology resources.

352.239–73 Electronic information and technology accessibility.

352.242–70 Key personnel.

352.242–71 Tobacco-free facilities.

352.242–72 Native American Graves Protections and Repatriation Act.

352.242–73 Withholding of contract payments.

352.242–74 Final decisions on audit findings.

352.270–1 Accessibility of meetings, conferences, and seminars to persons with disabilities.

352.270–2 Indian preference.

352.270–3 Indian preference program.

352.270–4 Protection of human subjects.

352.270–5 Care of laboratory animals.

352.270–6 Restriction on use of human subjects.

352.270–7 Conference sponsorship request and conference materials disclaimer.

352.270–8 Prostitution and related activities.

352.270–9 Non-discrimination for conscience.

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

#### Subpart 352.1—Instructions for Using Provisions and Clauses

##### 352.100 Scope of subpart.

This subpart provides guidance for applying HHS provisions and clauses in solicitations, contracts, and orders.

##### 352.101–70 Application of provisions and clauses.

(a) Unless otherwise qualified (*e.g.*, by the type of contract contemplated, the nature of the requirement, or dollar amount) in a prescription for a solicitation provision or contract clause specified in Part 352 or elsewhere in the HHSAR, the term “contract” means—

(1) An award, including modifications thereunder, that exceeds the simplified acquisition threshold, including a task order or delivery order, whether placed under a GSA FSS contract, an IDIQ contract, a GWAC, or a BPA, and a purchase order placed under the authority of *FAR subpart 13.5*); and

(2) A bilateral award—*i.e.*, when both the Contracting Officer and the contractor sign the award document, that exceeds the micro-purchase threshold but which does not exceed the simplified acquisition threshold.

(b) When the term “order” is specified in a prescription for a solicitation provision or order clause, it means an order that exceeds the micro-purchase threshold but which does not exceed the simplified acquisition threshold, except those bilateral awards specified in (a)(2) above.

(c) If a clause is included in the master instrument (*e.g.*, in an IDIQ contract or a BPA), it is not necessary to also include the clause in a task order or delivery order thereunder.

(d) When a dollar amount or dollar threshold is specified (*e.g.*, \$25 million or simplified acquisition threshold), the dollar amount of the award (contract or order) includes any options thereunder.

## Subpart 352.2—Texts of Provisions and Clauses

### 352.201–70 Paperwork Reduction Act.

As prescribed in *301.106(b)*, the Contracting Officer shall insert the following clause:

#### Paperwork Reduction Act (January 2006)

(a) This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the *Paperwork Reduction Act of 1995* (44 U.S.C. 3501 *et seq.*) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer's Technical Representative shall be guided by the provisions of 5 CFR Part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall not expend any funds or begin any data collection until OMB Clearance is received. Once OMB Clearance is received from the Contracting Officer's Technical Representative, the Contracting Officer shall provide the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor shall allow at least 120 days for OMB clearance. The Contracting Officer will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor in accordance with the Excusable Delays or Default clause of this contract.

(End of clause)

### 352.202–1 Definitions.

As prescribed in *FAR 2.201*, the Contracting Officer shall insert the clause in *FAR 52.202–1*, Definitions, as revised by *302.201*:

#### Definitions (January 2006)

(a) In accordance with *52.202–1(a)(1)*, substitute the following as paragraph (a):

“(a) The term “Secretary” or “Head of the Agency” (also called “Agency Head”) means the Secretary, Deputy Secretary, or any Assistant Secretary, Administrator or Commissioner of the Department of Health and Human Services; and the term “his/her duly authorized representative” means any person, persons, or board authorized to act for the Secretary.”

(b) In accordance with *52.202–1(a)(1)*, add the following paragraph (h):

“(h) The term “Contracting Officer's Technical Representative” means the person

who monitors the technical aspects of contract performance. The Contracting Officer's Technical Representative is not authorized to issue any instructions or directions which cause any increase or decrease in the Statement of Work/Performance Work Statement/Specifications which would result in the increase or decrease in the price of this contract, or changes in the delivery schedule or period of performance of this contract. If applicable, the Contracting Officer's Technical Representative is not authorized to receive or act upon any notification or revised cost estimate provided by the Contractor in accordance with the Limitation of Cost or Limitation of Funds clauses of this contract."

### 352.203-70 Anti-lobbying.

As prescribed in 303.808-70, the Contracting Officer shall insert the following clause:

#### Anti-Lobbying (January 2006)

Pursuant to the current HHS annual appropriations act, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for (i) publicity or propaganda purposes; (ii) the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself; or (iii) payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

(End of clause)

### 352.215-1 Instructions to offerors—competitive acquisition.

As prescribed in 315.209, the Contracting Officer shall insert the following paragraph (e) in the provision in FAR 52.215-1, Instructions to Offerors—Competitive Acquisition:

(e) *Restriction on disclosure and use of data.*

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the

Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g., data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS' FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)."

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with nonconforming statement(s).

### 352.215-70 Late proposals and revisions.

As prescribed in 315.208, the Contracting Officer shall insert the following provision:

#### Late Proposals and Revisions (January 2006)

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, the Government may consider a proposal received after the date specified for receipt if it appears to offer the best value to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

### 352.216-70 Additional cost principles.

As prescribed in 316.307(j), the Contracting Officer shall insert the following clause:

#### Additional Cost Principles (January 2006)

(a) Bid and proposal (B & P) costs.

(1) B & P costs are the immediate costs of preparing bids, proposals, and applications for potential Federal and non-Federal contracts, grants, and agreements, including

the development of scientific, cost, and other data needed to support the bids, proposals, and applications.

(2) B & P costs of the current accounting period are allowable as indirect costs.

(3) B & P costs of past accounting periods are unallowable in the current period. However, if the organization's established practice is to treat these costs by some other method, they may be accepted if they are found to be reasonable and equitable.

(4) B & P costs do not include independent research and development (IR & D) costs covered by the following paragraph, or pre-award costs covered by paragraph 36 of Attachment B to OMB Circular A-122.

(b) IR & D costs.

(1) IR & D is research and development conducted by an organization which is not sponsored by Federal or non-Federal contracts, grants, or other agreements.

(2) IR & D shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development.

(3) The cost of IR & D, including its proportionate share of indirect costs, is unallowable.

(End of clause)

### 352.219-70 Mentor-protégé program.

As prescribed in 319.270-1(a), the Contracting Officer shall insert the following provision:

#### Mentor-Protégé Program (October 2009)

(a) Large business prime contractors serving as mentors in the HHS Mentor-Protégé program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU)-approved mentor protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>. The mentor firm and protégé firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a \$10,000 subcontract awarded to a protégé firm and provision of \$5,000 of developmental assistance as \$15,000 of developmental assistance.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

(b) The program consists of—

(1) *Mentor firms*—large businesses that: (i) demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and (ii) have a Mentor-Protégé agreement approved by HHS' OSDBU;

(2) *Protégé firms*—firms that: (i) seek developmental assistance; (ii) qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses,

small disadvantaged businesses, or woman-owned businesses; and (iii) have a Mentor-Protégé agreement approved by HHS' OSDBU; and

(3) *Mentor-Protégé agreements*—joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

### **352.219-71 Mentor-protégé program reporting requirements.**

As prescribed in *319.270-1(b)*, the Contracting Officer shall insert the following clause:

#### **Mentor-Protégé Program Reporting Requirements (October 2009)**

The Contractor shall comply with all reporting requirements specified in its Mentor-Protégé agreement approved by HHS' OSDBU.

(End of clause)

### **352.222-70 Contractor cooperation in equal employment opportunity investigations.**

As prescribed in *322.810(h)*, the Contracting Officer shall insert the following clause:

#### **Contractor Cooperation in Equal Employment Opportunity Investigations (October 2009)**

(a) In addition to complying with the clause in FAR 52.222-26, Equal Opportunity, the Contractor shall, in good faith, cooperate with the Department of Health and Human Services (Agency) in investigations of Equal Employment Opportunity (EEO) complaints processed pursuant to 29 CFR Part 1614. For purposes of this clause, the following definitions apply:

(1) "Complaint" means a formal or informal complaint that has been lodged with Agency management, Agency EEO officials, the Equal Employment Opportunity Commission (EEOC), or a court of competent jurisdiction.

(2) "Contractor employee" means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees, who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor's or subcontractor's organization, the Contractor shall provide the Agency with that employee's last known mailing address, e-mail address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

(3) "Good faith cooperation" cited in paragraph (a) includes, but is not limited to, making Contractor employees available for: (i) Formal and informal interviews by EEO counselors or other Agency officials processing EEO complaints; (ii) formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees; (iii) reviewing and signing

appropriate affidavits or declarations summarizing statements provided by such Contractor employees during the course of EEO investigations; (iv) producing documents requested by EEO counselors, EEO investigators, Agency employees, or the EEOC in connection with a pending EEO complaint; and (v) preparing for and providing testimony in hearings before the EEOC and U.S. District Court.

(b) The Contractor shall include the provisions of this clause in all subcontract solicitations and subcontracts awarded at any tier under this contract.

(c) Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause may be grounds for the Contracting Officer to terminate this contract for default.

(End of clause)

### **352.223-70 Safety and health.**

As prescribed in *323.7002*, the Contracting Officer shall insert the following clause:

#### **Safety and Health (January 2006)**

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

(1) In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

(i) 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR Part 1910. These regulations are available at <http://www.osha.gov>.

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 *et seq.*). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at <http://www.cdc.gov/OD/ohs/biosfty/bmbl4/bmbl4toc.htm>.

(ii) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW., Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This

publication is available at <http://www.nap.edu/catalog/4911.html>.

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the Contracting Officer's Technical Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable "Changes" clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

### **352.224-70 Privacy Act.**

As prescribed in *324.103(b)(2)*, the Contracting Officer shall insert the following clause:

#### **Privacy Act (January 2006)**

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the

individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

### 352.227-70 Publications and publicity.

As prescribed in 327.404-70, the Contracting Officer shall insert the following clause:

#### Publications and Publicity (January 2006)

(a) Unless otherwise specified in this contract, the Government encourages the Contractor to publish the results of its work under this contract. A copy of each article the Contractor submits for publication shall be promptly sent to the Contracting Officer's Technical Representative. The Contractor shall also inform the Contracting Officer's Technical Representative when the article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized by the Contracting Officer's Technical Representative, the Contractor shall not display the HHS logo on any publications.

(End of clause)

### 352.228-7 Insurance—liability to third persons.

As prescribed in 328.311-2, the Contracting Officer shall insert the following clause and either Alternate I or II, as appropriate:

#### Insurance—Liability to Third Persons (Dec. 1991)

(a)(1) Except as provided in paragraph (a)(2) immediately following, or in paragraph (h) of this clause [if the clause has a paragraph (h)], the Contractor shall provide and maintain workers' compensation, employer's liability, comprehensive general liability (bodily injury), comprehensive automobile liability (bodily injury and property damage) insurance, and such other insurance as the Contracting Officer may require under this contract.

(2) The Contractor may, with the approval of the Contracting Officer, maintain a self-insurance program; provided that, with respect to workers' compensation, the Contractor is qualified pursuant to statutory authority.

(3) All insurance required by this paragraph shall be in form and amount and

for those periods as the Contracting Officer may require or approve and with insurers approved by the Contracting Officer.

(b) The Contractor agrees to submit for the Contracting Officer's approval, to the extent and in the manner required by the Contracting Officer, any other insurance that is maintained by the Contractor in connection with performance of this contract and for which the Contractor seeks reimbursement.

(c) Except as provided in paragraph (h) of this clause [if the clause has a paragraph (h)], the Contractor shall be reimbursed—

(1) For that portion of the reasonable cost of insurance allocable to this contract, and required or approved under this clause; and

(2) For certain liabilities (and expenses incidental to such liabilities) to third persons not compensated by insurance or otherwise within the funds available under the Limitation of Cost or the Limitation of Funds clause of this contract. These liabilities must arise out of the performance of this contract, whether or not caused by the negligence of the Contractor or the Contractor's agents, servants, or employees, and must be represented by final judgments or settlements approved in writing by the Government. These liabilities are for—

(i) Loss of or damage to property (other than property owned, occupied, or used by the Contractor, rented to the Contractor, or in the care, custody, or control of the Contractor); or

(ii) Death or bodily injury.

(d) The Government's liability under paragraph (c) of this clause is limited to the amounts reflected in final judgments, or settlements approved in writing by the Government, but in no event to exceed the funds available under the Limitation of Cost or Limitation of Funds clause of this contract. Nothing in this contract shall be construed as implying that, at a later date, the Government will request, or the Congress will appropriate, funds sufficient to meet any deficiencies.

(e) The Government shall not reimburse the Contractor for liabilities (and expenses incidental to such liabilities)—

(1) For which the Contractor is otherwise responsible under the express terms of any clause specified in the Schedule or elsewhere in the contract;

(2) For which the Contractor has failed to insure or to maintain insurance as required by the Contracting Officer; or

(3) That result from willful misconduct or lack of good faith on the part of the Contractor's directors, officers, managers, superintendents, or other representatives who have supervision or direction of —

(i) All or substantially all of the Contractor's business;

(ii) All or substantially all of the Contractor's operations at any one plant or separate location in which this contract is being performed; or

(iii) A separate and complete major industrial operation in connection with the performance of this contract.

(f) The provisions of paragraph (e) of this clause shall not restrict the right of the Contractor to be reimbursed for the cost of insurance maintained by the Contractor in

connection with the performance of this contract, other than insurance required in accordance with this clause; provided, that such cost is allowable under the Allowable Cost and Payment clause of this contract.

(g) If any suit or action is filed or any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, and the risk of which is then uninsured or is insured for less than the amount claimed, the Contractor shall—

(1) Immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received;

(2) Authorize Government representatives to collaborate with counsel for the insurance carrier in settling or defending the claim when the amount of the liability claimed exceeds the amount of coverage; and

(3) Authorize Government representatives to settle or defend the claim and to represent the Contractor in or to take charge of any litigation, if required by the Government, when the liability is not insured or covered by the bond. The Contractor may, at its own expense, be associated with the Government representatives in any such claim or litigation.

(End of clause)

*Alternate I (APR 1984).* If the successful offeror represents in its offer that it is partially immune from tort liability as a State agency, the Contracting Officer shall add the following paragraph (h) to the basic clause:

(h) Notwithstanding paragraphs (a) and (c) of this clause—

(1) The Government does not assume any liability to third persons, nor will the Government reimburse the Contractor for its liability to third persons, with respect to loss due to death, bodily injury, or damage to property resulting in any way from the performance of this contract or any subcontract under this contract; and

(2) The Contractor need not provide or maintain insurance coverage as required by paragraph (a) of this clause; provided, that the Contractor may obtain any insurance coverage deemed necessary, subject to approval by the Contracting Officer as to form, amount, and duration. The Contractor shall be reimbursed for the cost of such insurance and, to the extent provided in paragraph (c) of this clause, for liabilities to third persons for which the Contractor has obtained insurance coverage as provided in this paragraph, but for which such coverage is insufficient in amount.

(End of clause)

*Alternate II (APR 1984).* If the successful offeror represents in its offer that it is totally immune from tort liability as a State agency, the Contracting Officer shall substitute the following paragraphs (a) and (b) for paragraphs (a) and (b) of the basic clause:

(a) The Government does not assume any liability to third persons, nor will the Government reimburse the Contractor for its

liability to third persons, with respect to loss due to death, bodily injury, or damage to property resulting in any way from the performance of this contract or any subcontract under this contract.

(b) If any suit or action is filed, or if any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, the Contractor shall immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received by the Contractor. The Contractor shall, if Government requires, authorize Government representatives to settle or defend the claim and to represent the Contractor in or take charge of any litigation. The Contractor may, at its own expense, be associated with the Government representatives in any such claims or litigation.

(End of clause)

**352.231-70 Salary rate limitation.**

As prescribed in 331.101-70, the Contracting Officer shall insert the following clause:

**Salary Rate Limitation (October 2009)**

(a) Pursuant to the current and applicable prior HHS appropriations acts, the Contractor

shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level I in effect on the date an expense is incurred.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary" in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

**Note:** The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.

(c) The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year contract or order, it may be subject to unilateral modification by the

Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract or order funding.

(d) See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

(End of clause)

**352.231-71 Pricing of adjustments.**

As prescribed in 331.102-70, the Contracting Officer shall insert the following clause:

**Pricing of Adjustments (January 2001)**

When costs are a factor in determination of a contract price adjustment pursuant to the "Changes" clause or any provision of this contract, the applicable cost principles and procedures set forth below shall form the basis for determining such costs:

Principles	Types of organizations
(a) Subpart 31.2 of the Federal Acquisition Regulation .....	Commercial.
(b) Subpart 31.3 of the Federal Acquisition Regulation .....	Educational.
(c) Subpart 31.6 of the Federal Acquisition Regulation .....	State, local, and Federally recognized Indian Tribal governments.
(d) 45 CFR Part 74 Appendix E .....	Hospitals (performing research and development contracts only).
(e) Subpart 31.7 of the Federal Acquisition Regulation .....	Other nonprofit organizations.

(End of clause)

**352.233-70 Choice of law (overseas).**

As prescribed in 333.215-70(a), the Contracting Officer shall insert the following clause:

**Choice of Law (Overseas) (October 2009)**

This contract shall be construed in accordance with the substantive laws of the United States of America. By the execution of this contract, the Contractor expressly agrees to waive any rights to invoke the jurisdiction of local national courts where this contract is performed and agrees to accept the exclusive jurisdiction of the Civilian Board of Contract Appeals and the United States Court of Federal Claims for hearing and determination of any and all disputes that may arise under the Disputes clause of this contract.

(End of clause)

**352.233-71 Litigation and claims.**

As prescribed in 333.215-70(b), the Contracting Officer shall insert the following clause:

**Litigation and Claims (January 2006)**

(a) The Contractor shall provide written notification immediately to the Contracting Officer of any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the

performance of this contract, including, but not limited to the performance of any subcontract hereunder; and any claim against the Contractor the cost and expense of which is allowable under the clause entitled "Allowable Cost and Payment."

(b) Except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent papers received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the Contracting Officer's approval, settle any such action or claim. If required by the Contracting Officer, the Contractor shall effect an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and authorize representatives of the Government to settle or defend any such action or claim and to represent the Contractor in, or to take charge of, any action.

(c) If the Government undertakes a settlement or defense of an action or claim, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the

expense of defending any action or for any costs resulting from the loss thereof to the extent that the Contractor would have been compensated by insurance which was required by law or regulation or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence. In any event, unless otherwise expressly provided in this contract, the Government shall not reimburse or indemnify the Contractor for any liability loss, cost, or expense, which the Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

**352.234-1 Notice of earned value management system—pre-award Integrated Baseline Review.**

As prescribed in 334.203-70(a), the Contracting Officer shall insert the following provision:

**Notice of Earned Value Management System—Pre-Award Integrated Baseline Review (October 2008)**

The offeror shall provide documentation that its proposed Earned Value Management System (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of solicitation).

(a) If the offeror proposes to use a system that currently does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the guidelines.

(1) The plan shall—

(i) Describe the EVMS the offeror intends to use in performance of the contract;

(ii) Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;

(iii) Describe the management system and its application in terms of the EVMS guidelines;

(iv) Describe the proposed procedure for application of the EVMS requirements to subcontractors;

(v) Provide documentation describing the process and results, including Government participation if applicable, of any third-party evaluation or self-evaluation of the system's compliance with the EVMS guidelines; and

(vi) Provide a schedule of events leading up to formal validation and Government acceptance of the offeror's EVMS, if the value of the offeror's proposal, including options, is \$25 million or more.

(2) The offeror shall provide information and assistance, as required by the Contracting Officer, to support review of the plan.

(3) The Contracting Officer will review the offeror's EVMS implementation plan prior to contract award.

(4) The offeror's EVMS plan must provide milestones indicating when the offeror anticipates that the EVMS will be compliant with the ANSI/EIS Standard-748 guidelines.

(b) The offeror shall identify in its offer the subcontractors, or subcontracted effort if subcontractors have not been identified, to which the requirements of EVMS will be applied. Prior to contract award, the offeror and HHS shall agree on the subcontractors, or subcontracted effort, subject to the EVMS requirement.

(c) HHS will conduct an Integrated Baseline Review (IBR) prior to contract award. The offeror shall be compensated as set forth elsewhere in this solicitation for its preparation for and participation in the IBR. (End of provision)

### **352.234-2 Notice of earned value management system—post-award Integrated Baseline Review.**

As prescribed in 334.203-70(b), the Contracting Officer shall insert the following provision:

#### **Notice of Earned Value Management System—Post-Award Integrated Baseline Review (October 2008)**

(a) The offeror shall provide documentation that its proposed Earned Value Management System (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (current version in effect at time of solicitation).

(b) If the offeror proposes to use a system that currently does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the guidelines.

(1) The plan shall—

(i) Describe the EVMS the offeror intends to use in performance of the contract;

(ii) Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;

(iii) Describe the management system and its application in terms of the EVMS guidelines;

(iv) Describe the proposed procedure for application of the EVMS requirements to subcontractors;

(v) Provide documentation describing the process and results, including Government participation if applicable, of any third-party evaluation or self-evaluation of the system's compliance with the EVMS guidelines; and

(vi) Provide a schedule of events leading up to formal validation and Government acceptance of the offeror's EVMS, if the value of the offeror's proposal, including options, is \$25 million or more.

(2) The offeror shall provide information and assistance, as required by the Contracting Officer, to support review of the plan.

(3) The Contracting Officer will review the offeror's EVMS implementation plan prior to contract award.

(4) The offeror's EVMS plan must provide milestones indicating when the offeror anticipates that the EVM system will be compliant with the ANSI/EIA Standard-748 guidelines.

(c) The offeror shall identify in its offer the subcontractors, or subcontracted effort if subcontractors have not been identified, to which the requirements of EVMS will be applied. Prior to contract award, the offeror and HHS shall agree on the subcontractors, or subcontracted effort, subject to the EVMS requirement.

(d) HHS will conduct an Integrated Baseline Review after contract award.

(End of provision)

### **352.234-3 Full earned value management system.**

As prescribed in 334.203-70(c), the Contracting Officer shall insert the following clause:

#### **Full Earned Value Management System (October 2008)**

(a) The Contractor shall use an Earned Value Management System (EVMS) that has been validated and accepted by the Cognizant Federal Agency (CFA) as being compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been validated and accepted by the CFA at the time of award, *see* paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVM system has not been validated and accepted by the CFA as complying with EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall—

(1) Apply the current system to the contract; and

(2) Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) HHS requires the Contractor to obtain validation and acceptance of its EVM system by the CFA during the base period of performance of this contract. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action, which may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

(d) HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than 90 days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.

(e) Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (*Insert list of applicable subcontractors.*)

(End of clause)

#### **(Alternate I) (October 2008)**

As prescribed in 334.203-70(c), the Contracting Officer shall substitute the following paragraphs (a), (b), and (c) for paragraphs (a), (b), and (c) of the basic clause and delete paragraph (e) of the basic clause:

(a) The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS is not compliant at the time of award, *see* paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVM system is not in compliance with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall—

(1) Apply the current system to the contract; and

(2) Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) HHS will not formally validate or accept the Contractor's EVMS with respect to this contract. The use of the Contractor's EVMS for this contract does not imply HHS acceptance of the Contractor's EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

#### **352.234-4 Partial earned value management system.**

As prescribed in 334.203-70(d), the Contracting Officer shall insert the following clause:

##### **Partial Earned Value Management System (October 2008)**

(a) The Contractor shall use an Earned Value Management System (EVMS) that has been validated and accepted by the Cognizant Federal Agency (CFA) as being compliant with the schedule-related guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been validated and accepted by the CFA at the time of award, *see* paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVM system has not been validated and accepted by the CFA as complying with the schedule-related EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall—

(1) Apply the current system to the contract; and

(2) Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) HHS requires the Contractor to obtain validation and acceptance of the schedule-related portions of its EVM system by the CFA during the base period of performance of this contract. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action, which may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

(d) HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be

conducted by HHS as early as practicable, but no later than 90 days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.

(e) Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (*Insert list of applicable subcontractors.*)

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(End of clause)

##### **(Alternate I) (October 2008)**

As prescribed in 334.203-70(d), the Contracting Officer shall substitute the following paragraphs (a), (b), and (c) for paragraphs (a), (b), and (c) of the basic clause and delete paragraph (e) of the basic clause:

(a) The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the schedule-related guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS is not compliant at the time of award, *see* paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's schedule-related EVM system is not in compliance with the schedule-related EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), or the Contractor does not have an existing schedule control system that is compliant with such guidelines, the Contractor shall—

(1) Apply the current system to the contract; and

(2) Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) HHS will not formally validate or accept the Contractor's schedule-related EVMS with respect to this contract. The use of the Contractor's EVMS for this contract does not imply HHS acceptance of the Contractor's EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review

to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

#### **352.237-70 Pro-Children Act.**

As prescribed in 337.103-70(a), the Contracting Officer shall insert the following clause:

##### **Pro-Children Act (January 2006)**

(a) Public Law 103-227, Title X, Part C, also known as the *Pro-Children Act of 1994* (Act), 20 U.S.C. 7183, imposes restrictions on smoking in facilities where certain Federally funded children's services are provided. The Act prohibits smoking within any indoor facility (or portion thereof), whether owned, leased, or contracted for, that is used for the routine or regular provision of (i) kindergarten, elementary, or secondary education or library services or (ii) health or day care services that are provided to children under the age of 18. The statutory prohibition also applies to indoor facilities that are constructed, operated, or maintained with Federal funds.

(b) By acceptance of this contract or order, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all subcontracts awarded under this contract for the specified children's services. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understand, and comply with the provisions of the Act. Failure to comply with the Act may result in the imposition of a civil monetary penalty in an amount not to exceed \$1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity. Each day a violation continues constitutes a separate violation.

(End of clause)

#### **352.237-71 Crime Control Act—reporting of child abuse.**

As prescribed in 337.103-70(b), the Contracting Officer shall insert the following clause:

##### **Crime Control Act of 1990—Reporting of Child Abuse (January 2006)**

(a) *Public Law 101-647, also known as the Crime Control Act of 1990 (Act)*, imposes responsibilities on certain individuals who, while engaged in a professional capacity or activity, as defined in the Act, on Federal land or in a Federally-operated (or contracted) facility, learn of facts that give the individual reason to suspect that a child has suffered an incident of child abuse.

(b) The Act designates "covered professionals" as those persons engaged in professions and activities in eight different categories including, but not limited to, physicians, dentists, medical residents or interns, hospital personnel and administrators, nurses, health care practitioners, chiropractors, osteopaths,



pharmacists, optometrists, podiatrists, emergency medical technicians, ambulance drivers, alcohol or drug treatment personnel, psychologists, psychiatrists, mental health professionals, child care workers and administrators, and commercial film and photo processors. The Act defines the term "child abuse" as the physical or mental injury, sexual abuse or exploitation, or negligent treatment of a child.

(c) Accordingly, any person engaged in a covered profession or activity under an HHS contract or subcontract, regardless of the purpose of the contract or subcontract, shall immediately report a suspected child abuse incident in accordance with the provisions of the Act. If a child is suspected of being harmed, the appropriate State Child Abuse Hotline, local child protective services (CPS), or law enforcement agency shall be contacted. For more information about where and how to file a report, the Childhelp USA, National Child Abuse Hotline (1-800-4-A-CHILD) shall be called. Any covered professional failing to make a timely report of such incident shall be guilty of a Class B misdemeanor.

(d) By acceptance of this contract or order, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all applicable subcontracts awarded under this contract. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understand, and comply with the provisions of the Act.

(End of clause)

### 352.237-72 Crime Control Act—requirement for background checks.

As prescribed in 337.103-70(c), the Contracting Officer shall insert the following clause:

#### Crime Control Act of 1990—Requirement for Background Checks (January 2006)

(a) *Public Law 101-647, also known as the Crime Control Act of 1990 (Act)*, requires that all individuals involved with the provision of child care services to children under the age of 18 undergo a criminal background check. "Child care services" include, but are not limited to, social services, health and mental health care, child (day) care, education (whether or not directly involved in teaching), and rehabilitative programs. Any conviction for a sex crime, an offense involving a child victim, or a drug felony, may be grounds for denying employment or for dismissal of an employee providing any of the services listed above.

(b) The Contracting Officer will provide the necessary information to the Contractor regarding the process for obtaining the background check. The Contractor may hire a staff person provisionally prior to the completion of a background check, if at all times prior to the receipt of the background check during which children are in the care of the newly-hired person, the person is within the sight and under the supervision of a previously investigated staff person.

(c) By acceptance of this contract or order, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all applicable subcontracts awarded under

this contract. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understand, and comply with the provisions of the Act.

(End of clause)

### 352.239-70 Standard for security configurations.

As prescribed in 339.101(d)(1), the Contracting Officer shall insert the following clause:

#### Standard for Security Configurations (October 2009)

(a) The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (*see* <http://nvd.nist.gov/fdcc/index.cfm>) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

**Note:** FDCC is applicable to all computing systems using Windows XP™ and Windows Vista™, including desktops and laptops—regardless of function—but not including servers.

(b) The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:

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**Note:** The Contracting Officer shall specify applicable security configuration requirements in solicitations and contracts based on information provided by the Project Officer, who shall consult with the OPDIV/STAFFDIV Chief Information Security Officer.

(c) The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings—*see* <http://nvd.nist.gov/validation.cfm>. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products meet the latest FDCC major version and subsequent major versions.

(d) The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.

(e) The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.

(f) The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (*see* <http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf>), Homeland Security Presidential

Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, *Personal Identity Verification*.

(g) The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

(End of clause)

### 352.239-71 Standard for encryption language.

As prescribed in 339.101(d)(2), the Contracting Officer shall insert the following clause:

#### Standard for Encryption Language (October 2009)

(a) The Contractor shall use Federal Information Processing Standard (FIPS) 140-2-compliant encryption (Security Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (**Note:** The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004.)

(b) The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (*see* <http://csrc.nist.gov/cryptval/>) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.

(c) The Contractor shall use the Key Management Key (*see* FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (*see* <http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf>). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.

(d) The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).

(e) The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

(f) The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

(End of clause)

**352.239-72 Security requirements for Federal information technology resources.**

As prescribed in 339.7103, the Contracting Officer shall insert the following clause:

**Security Requirements for Federal Information Technology Resources (October 2009)**

(a) *Applicability.* This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.

(b) *Contractor responsibilities.* The Contractor is responsible for the following:

(1) Protecting Federal information and Federal information systems in order to ensure their—

(i) *Integrity*, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

(ii) *Confidentiality*, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(iii) *Availability*, which means ensuring timely and reliable access to and use of information.

(2) Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.

(3) Adopting, and implementing, at a minimum, the policies, procedures, controls, and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

(c) *Contractor security deliverables.* In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:

(1) *IT Security Plan (IT-SP)—due within 30 days after contract award.* The IT-SP shall be consistent with, and further detail the

approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

(i) The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:

(A) Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automated Information Resources.

(B) National Institute of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Federal Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

(C) HHS-OCIO Information Systems Security and Privacy Policy.

(ii) After resolution of any comments provided by the Government on the draft IT-SP, the Contracting Officer shall accept the IT-SP and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. On an annual basis, the Contractor shall provide to the Contracting Officer verification that the IT-SP remains valid.

(2) *IT Risk Assessment (IT-RA)—due within 30 days after contract award.* The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.

(3) *FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)—due within 30 days after contract award.* The FIPS 199 Assessment shall be consistent with the cited NIST

standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.

(4) *IT Security Certification and Accreditation (IT-SC&A)—due within 3 months after contract award.* The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems—see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security Certification and Accreditation of Federal Information Systems; and NIST SP 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provide it to the Contracting Officer for review, comment, and acceptance.

(i) After resolution of any comments provided by the Government on the draft IT-SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.

(ii) The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:

(A) Annual testing of the system contingency plan; and

(B) The performance of security control testing and evaluation.

(d) *Personal identity verification.* The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Technical Representative (COTR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.

(e) *Contractor and subcontractor employee training.* The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COTR evidencing that Contractor employees have completed the required training.

(f) *Government access for IT inspection.* The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT

inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

(g) *Subcontracts.* The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that—

(1) Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or

(2) Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.

(h) *Contractor employment notice.* The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.

(i) *Document information.* The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.

(j) *Contractor responsibilities upon physical completion of the contract.* The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.

(k) *Failure to comply.* Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of clause)

### **352.239-73 Electronic information and technology accessibility.**

(a) As prescribed in 339.201-70(a), the Contracting Officer shall insert the following provision:

#### **Electronic and Information Technology Accessibility (October 2009)**

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR Part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit—

(1) Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and

(2) Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data

by members of the public who are not individuals with disabilities.

(b) Accordingly, any vendor submitting a proposal/quotation/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility standards. Information about Section 508 is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

(c) The Section 508 accessibility standards applicable to this solicitation are identified in the Statement of Work/Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 accessibility standard. Instructions for preparing the HHS Section 508 Evaluation Template may be found under Section 508 policy on the HHS Office on Disability Web site (<http://www.hhs.gov/od>).

(d) Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 accessibility standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government—*i.e.*, after award of a contract/order, that products or services delivered do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor and at its expense.

(End of provision)

(b) As prescribed in 339.201-70(b), the Contracting Officer shall insert the following clause:

#### **Electronic and Information Technology Accessibility (October 2009)**

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the

Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

(b) The Section 508 accessibility standards applicable to this contract/order are identified in the Statement of Work/Specification/Performance Work Statement. The Contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding \$100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

(c) In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Office on Disability Web site (<http://www.hhs.gov/od>).

(c) As prescribed in 339.201-70(c), the Contracting Officer shall add the following paragraph to the end of clause 352.239-73(b):

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

#### **Schedule for Contractor Submission of Section 508 Annual Report**

(To be completed by the Contracting Officer at time of contract/order award.)

**352.242-70 Key personnel.**

As prescribed in 342.302(c)(2), the Contracting Officer shall insert the following clause:

**Key Personnel (January 2006)**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

(End of clause)

**352.242-71 Tobacco-free facilities.**

As prescribed in 342.302(c)(3), the Contracting Officer shall insert the following clause:

**Tobacco-free Facilities (January 2006)**

In accordance with Department of Health and Human Services (HHS) policy, the Contractor and its staff are prohibited from using tobacco products of any kind (e.g., cigarettes, cigars, pipes, and smokeless tobacco) while on any HHS property, including use in personal or company vehicles operated by Contractor employees while on an HHS property. This policy also applies to all subcontracts awarded under the contract or order. The term "HHS properties" includes all properties owned, controlled and/or leased by HHS when totally occupied by HHS, including all indoor and outdoor areas of such properties. Where HHS only partially occupies such properties, it includes all HHS-occupied interior space. Where HHS leases space in a multi-occupant building or complex, the tobacco-free HHS policy will apply to the maximum area permitted by both law and current lease agreements. The Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understand, and comply with this policy.

(End of clause)

**352.242-72 Native American Graves Protection and Repatriation Act.**

As prescribed in 342.302(c)(4), the Contracting Officer shall insert the following clause:

**Native American Graves Protection and Repatriation Act (January 2006)**

(a) Public Law 101-601, dated November 16, 1990, also known as the *Native American Graves Protection and Repatriation Act* (Act), imposes certain responsibilities on individuals and organizations when they discover Native American cultural items

(including human remains) on Federal or Tribal lands.

(b) In the event the Contractor discovers Native American cultural items (including human remains, associated funerary objects, unassociated funerary objects, sacred objects and cultural patrimony), as defined in the Act during contract performance, the Contractor shall—

(i) Immediately cease activity in the area of the discovery;

(ii) Notify the Contracting Officer of the discovery; and

(iii) Make a reasonable effort to protect the items discovered before resuming such activity. Upon receipt of the Contractor's discovery notice, the Contracting Officer will notify the appropriate authorities as required by the Act.

(c) Unless otherwise specified by the Contracting Officer, the Contractor may resume activity in the area on the 31st calendar day following the date that the appropriate authorities certify receipt of the discovery notice. The Contracting Officer shall provide to the Contractor the date that the appropriate authorities certify receipt of the discovery notice and the date on which the Contractor may resume activities.

(End of clause)

**352.242-73 Withholding of contract payments.**

As prescribed in 342.7003-1(a), the Contracting Officer shall insert the following clause:

**Withholding of Contract Payments (January 2006)**

Notwithstanding any other payment provisions of this contract, failure of the Contractor to submit required reports when due or failure to perform or deliver required work, supplies, or services, may result in the withholding of payments under this contract unless such failure arises out of causes beyond the control, and without the fault or negligence of the Contractor as defined by the clause entitled "Excusable Delays" or "Default," as applicable. The Government will immediately notify the Contractor of its intention to withhold payment of any invoice or voucher submitted.

(End of clause)

**352.242-74 Final decisions on audit findings.**

As prescribed in 342.7003-1(b), the Contracting Officer shall insert the following clause:

**Final Decisions on Audit Findings (April 1984)**

For the purpose of issuing final decisions under the Disputes clause of this contract concerning monetary audit findings, the Contracting Officer is the individual authorized to make such decisions.

(End of clause)

**352.270-1 Accessibility of meetings, conferences, and seminars to persons with disabilities.**

As prescribed in 370.102, the Contracting Officer shall insert the following clause:

**Accessibility of Meetings, Conferences, and Seminars to Persons With Disabilities (January 2001)**

The Contractor agrees as follows:

(a) *Planning.* The Contractor shall develop a plan to assure that any meeting, conference, or seminar held pursuant to this contract will meet or exceed the minimum accessibility standards set forth in 28 CFR 36.101-36.500 and Appendix A: ADA Accessibility Guidelines (ADAAG). The Contractor shall submit the plan to the Contracting Officer's Technical Representative for approval prior to initiating action. (The Contractor may submit a consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars in lieu of separate plans.)

(b) *Facilities.* Any facility the Contractor intends to utilize for meetings, conferences, or seminars in performance of this contract shall be in compliance with 28 CFR 36.101-36.500 and Appendix A. The Contractor shall determine, by an on-site inspection, that the facility meets these requirements. (1) *Parking.* Parking shall be in compliance with 28 CFR 36.101-36.500 and Appendix A.

(2) *Entrances.* Entrances shall be in compliance with 28 CFR 36.101-36.500 and Appendix A.

(3) *Meeting Rooms.* Meeting rooms, including seating arrangements, shall be in compliance with 28 CFR 36.101-36.500 and Appendix A. In addition, stages, speaker platforms, etc. which are to be used by persons in wheelchairs must be accessible by ramps or lifts. When used, the ramp may not necessarily be independently negotiable if space does not permit. However, the Contracting Officer's Technical Representative must approve any slope over 1:12, and the Contractor must provide assistance to negotiate access to the stage or platform.

(4) *Restrooms.* Restrooms shall be in compliance with 28 CFR 36.101-36.500 and Appendix A.

(5) *Eating Facilities.* Eating facilities in the meeting facility must also comply with 28 CFR 36.101-36.500 and Appendix A.

(6) *Overnight Facilities.* If overnight accommodations are required, the facility providing the overnight accommodations shall also comply with 28 CFR 36.101-36.500 and Appendix A.

(7) *Water Fountains.* Water fountains shall comply with 28 CFR 36.101-36.500 and Appendix A.

(8) *Telephones.* Public telephones shall comply with 28 CFR 36.101-36.500 and Appendix A.

(c) Provisions of Services for Attendees with Sensory Impairments.

(1) The Contractor, in planning the meeting, conference, or seminar, shall include in all announcements and other materials pertaining to the meeting, conference, or seminar a notice indicating that services will be made available to persons with sensory impairments attending the meeting, if requested within five (5) days of the date of the meeting, conference, or seminar. The announcement(s) and other material(s) shall indicate that persons with sensory impairments may contact a specific person(s), at a specific address and phone

number(s), to make their service requirements known. The phone number(s) shall include a telecommunication device for the deaf (TDD).

(2) The Contractor shall provide, at no additional cost to the individual, those services required by persons with sensory impairments to ensure their complete participation in the meeting, conference, or seminar.

(3) At a minimum, when requested in advance, the Contractor shall provide the following services:

(i) For persons with hearing impairments, qualified interpreters. Also, the meeting rooms shall be adequately illuminated so signing by interpreters can be easily seen.

(ii) For persons with vision impairments, readers and/or cassette materials, as necessary, to enable full participation. Also, meeting rooms shall be adequately illuminated.

(iii) Agenda and other conference material(s) shall be translated into a usable form for persons with sensory impairments. Readers, Braille translations, large print text, and/or tape recordings are all acceptable. These materials shall be available to individuals with sensory impairments upon their arrival.

(4) The Contractor shall make a reasonable effort to ascertain the number of individuals with sensory impairments who plan to attend the meeting, conference, or seminar. However, if the Contractor can determine that there will be no person with sensory impairment in attendance, the provision of those services under paragraph (c) of this clause for the non-represented group, or groups, is not required.

(End of clause)

### 352.270-2 Indian preference.

As prescribed in 370.202(a), the Contracting Officer shall insert the following clause:

#### Indian Preference (April 1984)

(a) The Contractor agrees to give preference in employment opportunities under this contract to Indians who can perform required work, regardless of age (subject to existing laws and regulations), sex, religion, or Tribal affiliation. To the extent feasible and consistent with the efficient performance of this contract, the Contractor further agrees to give preference in employment and training opportunities under this contract to Indians who are not fully qualified to perform regardless of age (subject to existing laws and regulations), sex, religion, or Tribal affiliation. The Contractor also agrees to give preference to Indian organizations and Indian-owned economic enterprises in the awarding of any subcontracts to the extent feasible and consistent with the efficient performance of this contract. The Contractor shall maintain statistical records as are necessary to indicate compliance with this paragraph.

(b) In connection with the Indian employment preference requirements of this clause, the Contractor shall provide opportunities for training incident to such employment. Such training shall include on-the-job, classroom or apprenticeship training

which is designed to increase the vocational effectiveness of an Indian employee.

(c) If the Contractor is unable to fill its employment and training opportunities after giving full consideration to Indians as required by this clause, the Contractor may satisfy those needs by selecting persons other than Indians in accordance with the clause of this contract entitled "Equal Opportunity."

(d) If no Indian organizations or Indian-owned economic enterprises are available under reasonable terms and conditions, including price, for awarding of subcontracts in connection with the work performed under this contract, the Contractor agrees to comply with the provisions of this contract involving utilization of small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; women-owned small businesses; or small disadvantaged businesses.

(e) As used in this clause,

(1) "Indian" means a person who is a member of an Indian Tribe. If the Contractor has reason to doubt that a person seeking employment preference is an Indian, the Contractor shall grant the preference but shall require the individual to provide evidence within 30 days from the Tribe concerned that the person is a member of the Tribe.

(2) "Indian Tribe" means an Indian Tribe, pueblo, band, nation, or other organized group or community, including Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601) which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(3) "Indian organization" means the governing body of any Indian Tribe or entity established or recognized by such governing body in accordance with the Indian Financing Act of 1974 (88 Stat. 77; 25 U.S.C. 1451).

(4) "Indian-owned economic enterprise" means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and that ownership shall encompass active operation and control of the enterprise.

(f) The Contractor agrees to include the provisions of this clause, including this paragraph (f) of this clause, in each subcontract awarded at any tier under this contract.

(g) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may impose any other sanctions authorized by law or by other provisions of the contract.

(End of clause)

### 352.270-3 Indian preference program.

As prescribed in 370.202(b), the Contracting Officer shall insert the following clause:

#### Indian Preference Program (January 2006)

(a) In addition to the requirements of the clause of this contract entitled "Indian

Preference," the Contractor agrees to establish and conduct an Indian preference program which will expand opportunities for Indians to receive preference for employment and training in connection with the work to be performed under this contract, and which will expand the opportunities for Indian organizations and Indian-owned economic enterprises to receive a preference in the awarding of subcontracts. In this connection, the Contractor shall perform the following:

(1) Designate a liaison officer who will maintain liaison with the Government and the Tribe(s) on Indian preference matters; supervise compliance with the provisions of this clause; and administer the Contractor's Indian preference program.

(2) Advise its recruitment sources in writing and include a statement in all advertisements for employment that Indian applicants will be given preference in employment and training incident to such employment.

(3) Not more than 20 calendar days after award of the contract, post a written notice in the Tribal office of any reservations on which or near where the work under this contract is to be performed that sets forth the Contractor's employment needs and related training opportunities. The notice shall include the approximate numbers and types of employees needed; the approximate dates of employment; the experience or special skills required for employment, if any; training opportunities available; and other pertinent information necessary to advise prospective employees of any other employment requirements. The Contractor shall also request the Tribe(s) on or near whose reservation(s) the work is to be performed to provide assistance to the Contractor in filling its employment needs and training opportunities. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to contact in regard to the posting of notices and requests for Tribal assistance.

(4) Establish and conduct a subcontracting program which gives preference to Indian organizations and Indian-owned economic enterprises as subcontractors and suppliers under this contract. The Contractor shall give public notice of existing subcontracting opportunities and, to the extent feasible and consistent with the efficient performance of this contract, shall solicit bids or proposals only from Indian organizations or Indian-owned economic enterprises. The Contractor shall request assistance and information on Indian firms qualified as suppliers or subcontractors from the Tribe(s) on or near whose reservation(s) the work under the contract is to be performed. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to be contacted in regard to the request for assistance and information. Public notices and solicitations for existing subcontracting opportunities shall provide an equitable opportunity for Indian firms to submit bids or proposals by including—

(i) A clear description of the supplies or services required, including quantities, specifications, and delivery schedules which facilitate the participation of Indian firms;

(ii) A statement indicating that preference will be given to Indian organizations and Indian-owned economic enterprises in accordance with section 7(b) of Public Law 93-638 [88 Stat. 2205; 25 U.S.C. 450e(b)];

(iii) Definitions for the terms "Indian organization" and "Indian-owned economic enterprise" as prescribed under the "Indian Preference" clause of this contract;

(iv) A statement to be completed by the bidder or offeror that it is an Indian organization or Indian-owned economic enterprise; and

(v) A closing date for receipt of bids or proposals which provides sufficient time for preparation and submission of a bid or proposal. If after soliciting bids or proposals from Indian organizations and Indian-owned economic enterprises, no responsive bid or acceptable proposal is received, the Contractor shall comply with the requirements of paragraph (d) of the "Indian Preference" clause of this contract. If one or more responsible bids or acceptable proposals are received, award shall be made to the low responsible bidder or acceptable offeror if the price is determined to be reasonable. If the low responsive bid or acceptable proposal is determined to be unreasonable as to price, the Contractor shall attempt to negotiate a reasonable price and award a subcontract. If a reasonable price cannot be agreed upon, the Contractor shall comply with the requirements of paragraph (d) of the "Indian Preference" clause of this contract.

(5) Maintain written records under this contract which indicate—

(i) The numbers of Indians seeking employment for each employment position available under this contract;

(ii) The number and types of positions filled by Indians and non-Indians;

(iii) The total number of Indians employed under this contract;

(iv) For those positions where there are both Indian and non-Indian applicants, and a non-Indian is selected for employment, the reason(s) why the Indian applicant was not selected;

(v) Actions taken to give preference to Indian organizations and Indian-owned economic enterprises for subcontracting opportunities which exist under this contract;

(vi) Reasons why preference was not given to Indian firms as subcontractors or suppliers for each requirement where it was determined by the Contractor that such preference would not be consistent with the efficient performance of the contract; and

(vii) The number of Indian organizations and Indian-owned economic enterprises contacted, and the number receiving subcontract awards under this contract.

(6) Submit to the Contracting Officer for approval a quarterly report which summarizes the Contractor's Indian preference program and indicates the number and types of available positions filled by Indians and non-Indians, and the dollar amounts of all subcontracts awarded to Indian organizations and Indian-owned economic enterprises, and to all other firms.

(7) Maintain records pursuant to this clause and keep them available for review by

the Government for one year after final payment under this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulation.

(b) For purposes of this clause, the following definitions of terms shall apply:

(1) The terms "Indian," "Indian Tribe," "Indian Organization," and "Indian-owned economic enterprise" are defined in the clause of this contract entitled "Indian Preference."

(2) "Indian reservation" includes Indian reservations, public domain Indian Allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the *Alaska Native Claims Settlement Act* (85 Stat. 688; 43 U.S.C. 1601 *et seq.*)

(3) "On or near an Indian Reservation" means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably be expected to commute to and from in the course of a work day.

(c) Nothing in the requirements of this clause shall be interpreted to preclude Indian Tribes from independently developing and enforcing their own Indian preference requirements. Such requirements must not conflict with any Federal statutory or regulatory requirement dealing with the award and administration of contracts.

(d) The Contractor agrees to include the provisions of this clause, including this paragraph (d), in each subcontract awarded at any tier under this contract and to notify the Contracting Officer of such subcontracts.

(e) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may impose any other sanctions authorized by law or by other provisions of the contract.

(End of clause)

#### **352.270-4 Protection of human subjects.**

(a) As prescribed in *370.303(a)*, the Contracting Officer shall insert the following provision:

##### **Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (January 2006)**

(a) Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by HHS.

(b) The regulations define a human subject as 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. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or

recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Government's Project Officer will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, the Project Officer will consult with OHRP.

(e) In accordance with 45 CFR Part 46, offerors being considered for award shall file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall ensure that: the rights and welfare of the human subjects involved are adequately protected; the risks to the subjects are reasonable in relation to both the potential benefits, if any, to the subjects and the importance of the knowledge to be gained; and informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site (at <http://www.hhs.gov/ohrp/>).

(f) Offerors may consult with OHRP for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

(b) As prescribed in *370.304(a)*, the Contracting Officer shall insert the following clause:

##### **Protection of Human Subjects (January 2006)**

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all

work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Human Subject Assurances. (End of clause)

#### **352.270-5 Care of laboratory animals.**

(a) As prescribed in *370.403(a)*, the Contracting Officer shall insert the following provision:

##### **Notice to Offerors of Requirement for Compliance With the Public Health Service Policy on Humane Care and Use of Laboratory Animals (January 2006)**

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, applicant organizations must establish an Institutional Animal Care & Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. Applicant organizations are required to provide verification of IACUC approval prior to release of an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the

Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Assurance and verification of IACUC approval are required. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: [olaw@od.nih.gov](mailto:olaw@od.nih.gov); Phone: 301-496-7163). (End of provision)

(b) As prescribed in *370.404*, the Contracting Officer shall insert the following clause:

##### **Care of Live Vertebrate Animals (October 2009)**

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (*see* 7 U.S.C. 2131 *et seq.* and 9 CFR Subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Assurances.

**Note:** The Contractor may request registration of its facility and a current listing

of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: [ace@aphis.usda.gov](mailto:ace@aphis.usda.gov); Web site: ([http://www.aphis.usda.gov/animal\\_welfare](http://www.aphis.usda.gov/animal_welfare))).

(End of clause)

#### **352.270-6 Restriction on use of human subjects.**

As prescribed in *370-304(b)*, the Contracting Officer shall insert the following clause:

##### **Restriction on Use of Human Subjects (January 2006)**

Pursuant to 45 CFR part 46, *Protection of Human Research Subjects*, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) designated under the Contractor's Federal-wide assurance of compliance. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors. (End of clause)

#### **352.270-7 Conference sponsorship request and conference materials disclaimer.**

As prescribed in *370.602*, the Contracting Officer shall insert the following clause:

##### **Conference Sponsorship Request and Conference Materials Disclaimer (October 2009)**

(a) If HHS is not the sole provider of funding under this conference contract, then prior to the Contractor claiming HHS conference sponsorship, the Contractor shall submit a written request (including rationale) to the Contracting Officer for permission to claim such HHS sponsorship.

(b) Whether or not HHS is the conference sponsor, the Contractor shall include the following statement on conference materials, including promotional materials, agendas, and Web sites:

"This conference was funded, in whole or in part, through a contract (insert contract number) with the Department of Health and Human Services (HHS) (insert name of OPDIV/STAFFDIV). The views expressed in written conference materials and by speakers and moderators at this conference, do not necessarily reflect the official policies of HHS, nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

(c) Unless authorized by the Contracting Officer's Technical Representative, the Contractor shall not display the HHS logo on any conference materials.

(End of clause)



**352.270-8 Prostitution and related activities.**

As prescribed in 370.701, the Contracting Officer shall insert the following clause:

**Prostitution and Related Activities (October 2009)**

(a) The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing and contribute to the phenomenon of trafficking in persons.

(b) Neither the Contractor nor any subcontractor(s) shall use Government funds provided under this contract to promote or advocate the legalization or practice of prostitution or sex trafficking. (**Note:** The term "contract" includes "order" wherever it appears in this clause.) The Contractor shall not construe anything in the preceding sentence to preclude providing individuals with palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(c) The Government does not require the Contractor to endorse or utilize a multisectoral approach to combating HIV/AIDS, or endorse, utilize, or participate in a prevention method or treatment program to which it has a religious or moral objection. Any information the Contractor provides about the use of condoms as part of projects or activities that are funded in connection with this contract shall be medically accurate and shall include the public health benefits and failure rates of such use.

(d) In addition, the Contractor shall have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any "exempt organizations" (*i.e.*, the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency), or to any contractors that are awarded "specified types of commercial contracts" as set forth below.

(e) The following definitions apply for purposes of this clause:

(1) "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.

(2) "Prostitution" means procuring or providing any commercial sex act.

(3) "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act [22 U.S.C. 7102(9)].

(4) "Specified types of commercial contracts" means contracts awarded for commercial items and services as defined in Federal Acquisition Regulation (FAR) 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding. Notwithstanding the preceding definition of "specified types of commercial contracts," contracts for the purposes specified in paragraphs (e)(4)(i) through (iii) of this clause, that are awarded to implement HIV/AIDS programs, require that the Contractor have a policy explicitly opposing prostitution and sex trafficking—

(i) Supplies or services provided directly to the final populations receiving such supplies or services in host countries;

(ii) Technical assistance and training furnished directly to host country individuals or entities for the provision of supplies or services to the final populations receiving such supplies and services; or

(iii) The types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in paragraphs (e)(4)(i) and (ii) of this clause, or making decisions or functioning in a recipient's chain of command (*e.g.*, providing managerial or supervisory services; approving financial transactions, personnel actions, *etc.*).

(f) The Contractor must have and maintain "objective integrity and independence" from any organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking. HHS will consider the Contractor to have objective integrity and independence from such an organization if the—

(1) Organization is a legally separate entity;

(2) Organization receives no transfer of Leadership Act funds, and Leadership Act funds do not subsidize activities inconsistent with a policy opposing prostitution and sex trafficking; and

(3) Contractor is physically and financially separate from the organization. Mere bookkeeping separation of Leadership Act funds from other funds is not sufficient. HHS will determine, on a case-by-case basis, and based on the totality of the facts, whether sufficient physical and financial separation exists. The presence or absence of any one factor below will not be determinative.

Factors relevant to this determination shall include, but not be limited to, the following:

(i) The existence of separate personnel, management, and governance.

(ii) The existence of separate accounts, accounting records, and timekeeping records.

(iii) The degree of separation from facilities, equipment, and supplies used by the organization to conduct activities inconsistent with a policy opposing prostitution and sex trafficking, and the extent of such activities by the organization.

(iv) The extent to which—

(A) Signs and other forms of identification that distinguish the Contractor from the organization are present, and

(B) Signs and materials that could be associated with the organization or activities inconsistent with a policy opposing prostitution and sex trafficking are absent.

(v) The extent to which the U.S. Government, HHS, and the project name are protected from public association with an organization and its activities that are inconsistent with a policy opposing prostitution and sex trafficking in materials, such as publications, conferences, and press or public statements.

(g) The Contractor shall include, as express terms and conditions, the applicable provisions of this clause in all subcontract solicitations and subcontracts awarded under this contract. The Contractor agrees that HHS may, at any reasonable time, inspect the documents and materials the Contractor

maintains or prepares in the usual course of its operations that relate to the Contractor's compliance with this clause.

(h) As a prerequisite to award and payment of any Government funds under this contract, the Contractor shall certify compliance with this clause for the performance period funded by the contract. The Contractor shall provide the three following compliance certifications in a written statement addressed to the Contracting Officer:

(1) Organizational Integrity Certification:

"I certify that (*insert Contractor's name*), which will be the recipient of Government funds made available through this contract, has objective integrity and independence from any organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking."

(2) Subcontractor Compliance Certification:

"I certify that (*insert Contractor's name*) will include the Organizational Integrity certification in any subcontract awarded under this contract and will require such subcontractor to provide the same certification that the Contractor provided."

(3) Acknowledgment Certification:

"I certify that (*insert Contractor's name*) acknowledges that these certifications are a prerequisite to receipt of Government funds in connection with this contract, and that any violation of these certifications by the Contractor or subcontractor(s) at any level shall be grounds for termination of the contract by HHS in accordance with the Federal Acquisition Regulation, Part 49, as well as any other remedies provided by law."

**Note:** In the case of existing contracts, the Contracting Officer shall add the certification requirements whenever the contract is modified to extend the period of performance or add funds, including any options that may be exercised. In so doing, the Contracting Officer shall delete in paragraph (h) the language "As a prerequisite to award and payment of any Government funds under this contract," and replace it with: "As a prerequisite to continuation of this contract and payment of any Government funds under it,".

(i) A person(s) authorized to bind the Contractor and any subcontractor(s) shall execute the certifications. The Contractor shall provide its certifications to the Contracting Officer. A subcontractor(s) shall provide its certifications to the Contractor. The Contracting Officer may request that the Contractor provide any subcontractor certifications. In addition, the Contractor and any subcontractors shall provide *renewed* certifications for any modification that extends the contract period of performance or adds funds to the contract, including any options that may be exercised.

(j) This clause does not affect the applicability of the FAR clause at 52.222-50 entitled, "Combating Trafficking in Persons."

(End of clause)

**352.270-9 Non-discrimination for conscience.**

As prescribed in 370.702, the Contracting Officer shall insert the following provision:

**Non-discrimination for Conscience (October 2009)**

(a) Section 301(d) of the *United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, as amended*, provides that an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961, under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, or under any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care—

(1) Shall not be required, as a condition of receiving such assistance, to—

(i) Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(ii) Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.

(2) Shall not be discriminated against under the provisions of law in subparagraph (a) for refusing to meet any requirement described in paragraph (a)(1) in this solicitation.

(b) Accordingly, an offeror who believes this solicitation contains work requirements that would require it to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS, or to endorse, utilize, make referral to, become integrated with, or otherwise participate in a program or activity to which it has a religious or moral objection, shall identify those work requirements it has excluded in its technical proposal.

(c) The Government acknowledges that an offeror has specific rights, as cited in paragraph (b) of this provision, to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right to not make an award to an offeror whose proposal does not comply with the salient work requirements of the solicitation. Any exercise of that Government right will be made by the Head of the Contracting Activity.

(End of provision)

**PART 353—FORMS****Subpart 353.3—Illustrations of Forms**

Sec.

353.370–674 Form HHS 674, Structured Approach Profit/Fee Objective.

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

**Subpart 353.3—Illustrations of Forms**

**353.370–674 Form HHS 674, Structured Approach Profit/Fee Objective.**

This form is available from local cost advisory personnel or PSC.

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

**SUBCHAPTERS I THROUGH L [RESERVED]****PARTS 354 THROUGH 369 [RESERVED]****SUBCHAPTER M—HHS SUPPLEMENTATIONS****PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION****Subpart 370.1—Accessibility of Meetings, Conferences, and Seminars to Persons With Disabilities**

Sec.

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370.102 Responsibilities.

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370.400 Scope of subpart.

370.401 Policy.

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370.403 Notice to offerors.

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**Subpart 370.5—Acquisitions Under the Buy Indian Act**

370.500 Scope of subpart.

370.501 Policy.

370.502 Definitions.

370.503 Requirements.

370.504 Competition.

370.505 Responsibility determinations.

**Subpart 370.6—Conference Funding and Sponsorship**

370.600 Policy.

370.601 Funding and sponsorship.

370.602 Contract clause.

**Subpart 370.7—Acquisitions under the Leadership Act**

370.700 Scope of subpart.

370.701 Contract clause.

370.702 Solicitation provision.

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

**Subpart 370.1—Accessibility of Meetings, Conferences, and Seminars to Persons With Disabilities**

**370.101 Policy.**

(a) It is HHS policy that all meetings, conferences, and seminars be accessible to persons with disabilities. For the purpose of this policy, accessibility is

defined as both physical access to meeting, conference, and seminar sites, and aids and services to enable individuals with sensory disabilities to fully participate in meetings, conferences, and seminars.

(b) In regard to acquisition, the policy is applicable to all contracts where the SOW/PWS requires the contractor to conduct meetings, conferences, or seminars that are open to the public or involve HHS personnel, but not to ad hoc meetings that may be necessary or incidental to contract performance.

**370.102 Responsibilities.**

(a) The Contracting Officer shall insert the clause in 352.270–1, Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities, in solicitations, contracts, and orders when the SOW/PWS requires the contractor to conduct meetings, conferences, or seminars in accordance with 370.101(b).

(b) The COTR shall obtain, review, and approve the contractor's plan, which is to be submitted in response to paragraph (a) of the contract clause in 352.270–1. A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars is acceptable. The COTR, prior to approving the plan, shall consult with the OPDIV or other designated organization responsible for monitoring compliance with the Architectural Barriers Act of 1968 and the Americans with Disabilities Act of 1990, to ensure that the contractor's plan meets the accessibility requirements of the contract clause. The COTR shall request the responsible organization to review, and determine the adequacy of, the contractor's plan, and respond to the COTR, in writing, within 10 working days of receiving the request from the COTR.

**Subpart 370.2—Indian Preference in Employment, Training, and Subcontracting Opportunities****370.201 Statutory requirements.**

Section 7(b) of the Indian Self-Determination and Education Assistance Act, Public Law 93–638, 88 Stat. 2205, 25 U.S.C. 450e(b), requires:

“Any contract, subcontract, grant, or subgrant pursuant to this Act, the Act of April 16, 1934 (48 Stat. 596), as amended, or any other Act authorizing Federal contracts with or grants to Indian organizations or for the benefit of Indians, shall require that to the greatest extent feasible:

(1) Preferences and opportunities for training and employment in connection with the administration of such

contracts or grants shall be given to Indians; and

(2) Preference in the award of subcontracts and subgrants in connection with the administration of such contracts or grants shall be given to Indian organizations and to Indian-owned economic enterprises as defined in section 3 of the Indian Financing Act of 1974 (88 Stat. 77)."

### 370.202 Applicability.

The Indian Preference clause set forth in 352.270-2 and the Indian Preference Program clause set forth in 352.270-3 implement section 7(b) of Public Law 93-638 for all HHS activities.

Contracting activities shall use the clauses as follows, except that solicitations issued and contracts awarded pursuant to Title I of Public Law 93-638 (25 U.S.C. 450 *et seq.*) are exempted:

(a) The Contracting Officer shall insert the clause in 352.270-2, Indian Preference, in solicitations, contracts, and orders when—

(1) The award is (or will be) made pursuant to an act specifically authorizing such awards with Indian organizations; or

(2) The work to be performed is specifically for the benefit of Indians and is in addition to any incidental benefits which might otherwise accrue to the general public.

(b) The Contracting Officer shall insert the clause in 352.270-3, Indian Preference Program, in solicitations, contracts, and orders when—

(1) The dollar amount of the acquisition is expected to equal or exceed \$50,000 for nonconstruction work or \$100,000 for construction work;

(2) The Indian Preference clause is included in the solicitation, contract, or order; and

(3) The Contracting Officer makes the determination, prior to solicitation, that performance will take place in whole or in substantial part on or near an Indian reservation(s). In addition, the Contracting Officer may insert the Indian Preference Program clause in solicitations, contracts, and orders below the \$50,000 or \$100,000 level for nonconstruction or construction contracts, respectively, but which meet the requirements of paragraphs (b)(2) and (3) of this section 370.202, and, in the opinion of the Contracting Officer, offer substantial opportunities for Indian employment, training, and subcontracting.

### 370.203 Definitions.

For purposes of this Subpart 370.2, the following definitions shall apply:

(a) *Indian* means a person who is a member of an Indian Tribe. If the

contractor has reason to doubt that a person seeking employment preference is an Indian, the contractor shall grant the preference but shall require the individual to provide evidence within 30 days from the Tribe concerned that the person is a member of the Tribe.

(b) *Indian Tribe* means an Indian Tribe, pueblo, band, nation, or other organized group or community, including any Alaska Native Village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(c) *Indian organization* means the governing body of any Indian Tribe, or entity established or recognized by such governing body, in accordance with the Indian Financing Act of 1974 (88 Stat. 77, 25 U.S.C. 1451).

(d) *Indian-owned economic enterprise* means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and the ownership shall encompass active operation and control of the enterprise.

(e) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601 *et seq.*)

(f) *On or near an Indian Reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably be expected to commute to and from in the course of a work day.

### 370.204 Compliance enforcement.

(a) The contracting activity shall conduct periodic reviews to ensure contractor compliance with the requirements of the clauses in 352.270-2 and 352.270-3. The Indian Tribe(s) concerned may assist in the conduct of these reviews.

(b) The Contracting Officer shall promptly investigate and resolve complaints of noncompliance with the requirements of the clauses in 352.270-2 and 352.270-3 that are filed in writing with the contracting activity.

### 370.205 Tribal preference requirements.

(a) When the contractor will perform work under a contract on an Indian

reservation, the Contracting Officer may supplement the clause in 352.270-3 by adding specific Indian preference requirements of the Tribe on whose reservation the work is to be performed. The contracting activity and the Tribe shall jointly develop supplemental requirements for the contract.

Supplemental preference requirements shall represent a further implementation of the requirements of section 7(b) of Public Law 93-638 and require the approval of the affected program director and OGC-GLD, or a regional attorney, before the Contracting Officer adds them to a solicitation and resultant contract. Any supplemental preference requirements the Contracting Officer adds to the clause in 352.270-3 shall also be part of the solicitation and clearly identified, to ensure uniform understanding of the additional requirements by all prospective bidders or offerors.

(b) Nothing in this part shall preclude tribes from independently developing and enforcing their own Tribal preference requirements. Such independently developed Tribal preference requirements shall not, except as provided in paragraph (a) of this section, become a requirement in contracts covered under this 370.2, and shall not conflict with any Federal statutory or regulatory requirement concerning the award and administration of contracts.

## Subpart 370.3—Acquisitions Involving Human Subjects

### 370.300 Scope of subpart.

This subpart applies to all R & D activities involving human subjects conducted under contract—*see* 45 CFR 46.102(d) and (f).

### 370.301 Policy.

It is HHS policy that the Contracting Officer shall not award a contract involving human subjects until a prospective contractor has provided acceptable assurance that the activity will be subject to initial and continuing review by an appropriate Institutional Review Board (IRB) as described in HHS regulations at 45 CFR 46.103. The Contracting Officer shall require an applicable Federal-wide assurance (FWA), approved by the HHS Office for Human Research Protections (OHRP), of each contractor, subcontractor, or cooperating institution having responsibility for human subjects involved in performance of a contract. OHRP is responsible for negotiating assurances covering all HHS-supported or HHS-conducted activities involving human subjects. OHRP shall provide

guidance to Contracting Officers regarding non-award or termination of a contract due to inadequate assurance or breach of assurance for protection of human subjects.

#### **370.302 Types of assurances.**

(a) If an institution does not currently hold an FWA, it should submit one. An FWA listed in OHRP's current "List of Registered Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) and Approved Assurances" is acceptable for the purposes of this policy.

(b) The OHRP Web site includes links to instructions and the forms for submitting both a domestic and international FWA at: [http://www.hhs.gov/ohrp/assurances/assurances\\_index.html](http://www.hhs.gov/ohrp/assurances/assurances_index.html). To expedite approval of a FWA, as well as any update/renewal, the institution shall use the OHRP Electronic Submission System. Once the institution "submits" an electronic file to OHRP, the institution must fax or mail (but not both) a copy of the signature page to initiate the review process. The institution shall mail the FWA to the OHRP, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852, or fax it to OHRP at 240-453-8202 (but not both).

#### **370.303 Notice to offerors.**

(a) The Contracting Officer shall insert the provision in *352.270-4(a)*, Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects, in solicitations that involve human subjects.

(b) Institutions having an OHRP-approved FWA shall certify IRB approval of submitted proposals in the manner required by instructions for completion of the contract proposal; by completion of an OMB Form No. 0990-0263, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule); or by letter indicating the institution's OHRP-assigned FWA number, the date of IRB review and approval, and the type of review (convened or expedited). The date of IRB approval must not be more than 12 months prior to the deadline for proposal submission.

(c) The Contracting Officer generally will not request FWAs for contractors, subcontractors, or cooperating institutions prior to determination that a contract proposal has been selected for negotiation. When a contractor submits an FWA, it provides certification for the initial contract period. No additional documentation is required. If the

contract provides for additional years to complete the project, the contractor shall certify the noncompetitive renewal proposal in the manner described in the preceding paragraph.

#### **370.304 Contract clauses.**

(a) The Contracting Officer shall insert the clause in *352.270-4(b)*, Protection of Human Subjects, in solicitations, contracts, and orders that involve human subjects.

(b) The Contracting Officer shall insert the clause in *352.270-6*, Restriction on Use of Human Subjects, in contracts and orders if the contractor has an approved Federal-wide assurance of compliance in place, but cannot certify prior to award that the research has been reviewed and approved by the IRB designated under the contractor's Federal-wide assurance of compliance, because definite plans for involvement of human subjects are not set forth in the proposal (e.g., projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds). Under these conditions, the Contracting Officer may make the award without the requisite certification, as long as the Contracting Officer includes appropriate conditions in the contract or order.

### **Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals**

#### **370.400 Scope of subpart.**

This subpart applies to all R & D, research training, and biological testing activities involving live vertebrate animals conducted under contract (*see Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), Rev. 1986, Repr. 1996*).

#### **370.401 Policy.**

(a) It is HHS policy that contracting activities shall not award a contract involving live vertebrate animals until the contractor has given acceptable assurance that the work under the contract will be subject to initial and continuing review by an appropriate Institutional Animal Care and Use Committee (IACUC) as described in the PHS Policy at IV.B.6. and 7. The Contracting Officer shall require an applicable Full Animal Welfare Assurance or Inter-institutional Agreement/Assurance, approved by the Office of Laboratory Animal Welfare (OLAW), NIH, of each contractor, subcontractor, or cooperating institution having responsibility for animal care and use involved in performance of the contract—*see PHS Policy II., IV.A., and V.B.*

(b) The OLAW, NIH, is responsible for negotiating assurances covering all HHS/PHS-supported or HHS/PHS-conducted activities involving the care and use of live vertebrate animals. OLAW shall provide guidance to Contracting Officers regarding adequate animal care, and use, approval, disapproval, restriction, or withdrawal of approval of assurances—*see PHS Policy V.A.*

#### **370.402 Assurances.**

(a) Assurances may be one of two following types:

(1) *Full Animal Welfare Assurance (AWA)*. An AWA describes the institution's complete program for the care and use of animals, including but not limited to the facilities, occupational health, training, veterinary care, IACUC procedures and lines of authority and responsibility. An AWA listed in OLAW's list of institutions which have an approved full AWA is acceptable for purposes of this policy.

(2) *Inter-institutional Agreement/Assurance (IAA)*. An IAA describes the arrangements between an offeror and usually a subcontractor where animal activities will occur. An IAA is limited to the specific award or single project.

(b) The Contracting Officer shall forward copies of proposals selected for negotiation and requiring an assurance to the Assurance Branch, Office of Laboratory Animal Welfare, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible to secure the necessary assurances.

(c) A contractor providing animal care services at an assured entity, such as a Government-owned, contractor-operated (GOCO) site, does not need a separate assurance. GOCO site assurances normally cover such contractor services.

#### **370.403 Notice to offerors.**

(a) The Contracting Officer shall insert the provision in *352.270-5(a)*, Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, in solicitations that involve vertebrate animals.

(b) Offerors having a full AWA on file with OLAW shall submit IACUC approval of the use of animals in the manner required by instructions for completion of the contract proposal, but prior to the technical review of the proposal. The date of IACUC approval must not be more than 36 months prior to the deadline for proposal submission.

(c) It is not necessary for non-assured offerors to submit assurances or IACUC approval with proposals. OLAW shall contact contractors, subcontractors and

cooperating institutions to negotiate necessary assurances and verify IACUC approvals when requested by the Contracting Officer.

#### **370.404 Contract clause.**

The Contracting Officer shall insert the clause in 352.270-5(b), Care of Live Vertebrate Animals, in solicitations, contracts, and orders that involve vertebrate animals.

### **Subpart 370.5—Acquisitions Under the Buy Indian Act**

#### **370.500 Scope of subpart.**

This subpart sets forth the policy on preferential acquisition from Indians under the negotiation authority of the Buy Indian Act. This subpart applies only to acquisitions made by or on behalf of IHS.

#### **370.501 Policy.**

(a) The IHS shall utilize the negotiation authority of the Buy Indian Act to give preference to Indians whenever the use of that authority is authorized and is practicable. The Buy Indian Act, 25 U.S.C. 47, prescribes the application of the advertising requirements of section 3709 of the Revised Statutes to the acquisition of Indian supplies. As specified in 25 U.S.C. 47, the Buy Indian Act provides that, so far as may be practicable, Indian labor shall be employed, and purchases of the products (including, but not limited to printing, notwithstanding any other law) of Indian industry may be made in open market in the discretion of the Secretary of the Interior.

(b) Due to the transfer of authority from the Department of the Interior to HHS, the Secretary of HHS is authorized to use the Buy Indian Act in the acquisition of products of Indian industry, in connection with the maintenance and operation of hospital and health facilities for Indians, and for the conservation of the health of Indians. This authority has been delegated exclusively to IHS and is not available for use by any other HHS component (unless that component is making an acquisition on behalf of IHS). However, the Buy Indian Act itself does not exempt IHS from meeting the statutorily mandated small business goals.

(c) Subsequent legislation, particularly Public Law 94-437 and Public Law 96-537, have emphasized the use of the Buy Indian Act negotiation authority.

#### **370.502 Definitions.**

(a) *Buy Indian contract* means any contract involving activities covered by the Buy Indian Act that is negotiated

under the provisions of 41 U.S.C. 252(c) and 25 U.S.C. 47 between an Indian firm and a Contracting Officer representing IHS.

(b) *Indian* means a member of any Tribe, pueblo, band, group, village or community that is recognized by the Secretary of the Interior as being Indian or any individual or group of individuals that is recognized by the Secretary of the Interior or the Secretary of HHS. The Secretary of HHS in making determinations may take into account the determination of the Tribe with which affiliation is claimed.

(c) *Indian firm* means a sole enterprise, partnership, corporation, or other type of business organization owned, controlled, and operated by one or more Indians (including, for the purpose of sections 301 and 302 of Public Law 94-437, former or currently Federally recognized Indian tribes in the State of New York) or by an Indian firm; or a nonprofit firm organized for the benefit of Indians and controlled by Indians (see 370.503(a)).

(d) *Product of Indian industry* means anything produced by Indians through either physical labor or intellectual effort involving the use and application of their skills.

#### **370.503 Requirements.**

(a) *Indian ownership.* The degree of Indian ownership of an Indian firm shall be at least 51 percent during the period covered by a Buy Indian contract.

(b) *Joint ventures.* An Indian firm may enter into a joint venture with other entities for specific projects as long as the Indian firm is the managing partner. However, the Contracting Officer shall approve the joint venture prior to the award of a contract under the Buy Indian Act.

(c) *Bonds.* In the case of contracts for the construction, alteration, or repair of public buildings or public works, the Miller Act (40 U.S.C. 270a-270f) and *FAR part 28* require performance and payment bonds. Bonds are not required in the case of contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian Tribe. However, bonds are required when dealing with private business entities that are owned by an Indian Tribe or members of an Indian Tribe. The Contracting Officer may require bonds of private business entities that are joint ventures with, or subcontractors of, an Indian Tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian Tribe. A bid guarantee or bid bond is required

only when a performance or payment bond is required.

(d) *Indian preference in employment, training and subcontracting.* Contracts awarded under the Buy Indian Act are subject to the requirements of section 7(b) of the Indian Self-Determination and Education Assistance Act 25 U.S.C. 450e, which requires that preference be given to Indians in employment, training, and subcontracting. The Contracting Officer shall include the Indian Preference clause specified in 352.270-2 in all Buy Indian solicitations and resultant contracts. The Contracting Officer shall use the Indian Preference Program clause specified in 352.270-3 as prescribed in 370.202(b). The Contracting Officer shall follow all requirements specified in subpart 370.2 which are applicable to a Buy Indian acquisition (e.g., sections 370.204 and 370.205).

(e) *Subcontracting.* A contractor shall not subcontract to other than Indian firms more than 50 percent of the work under a prime contract awarded pursuant to the Buy Indian Act. For this purpose, work to be performed does not include the provision of materials, supplies, or equipment.

(f) *Wage rates.* The Contracting Officer shall include a determination of the minimum wage rates by the Secretary of Labor as required by the Davis-Bacon Act (40 U.S.C. 276a) in all contracts awarded under the Buy Indian Act for over \$2,000 for construction, alteration, or repair, including painting and decorating, of public buildings and public works, except contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian Tribe. The Contracting Officer shall include the wage rate determination in contracts with private business entities, even if they are owned by an Indian Tribe or a member of an Indian Tribe and in connection with joint ventures with, or subcontractors of, an Indian Tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian Tribe.

#### **370.504 Competition.**

(a) Contracts awarded under the Buy Indian Act are subject to competition among Indians or Indian concerns to the maximum extent practicable. When the Contracting Officer determines that competition is not practicable, a JOFOC is required in accordance with 306.303.

(b) The Contracting Officer shall: synopsisize and publicize solicitations in FedBizOpps and provide copies of the synopses to the Tribal office of the Indian Tribal government directly concerned with the proposed

acquisition as well as to Indian concerns and others having a legitimate interest. The synopses shall state that the acquisitions are restricted to Indian firms under the Buy Indian Act.

#### **370.505 Responsibility determinations.**

(a) The Contracting Officer may award a contract under the Buy Indian Act only if the Contracting Officer determines that the project or function to be contracted is likely to be: satisfactorily performed under that contract; and properly completed or maintained under that contract.

(b) The Contracting Officer shall make the determination specified in paragraph (a) of this section in writing prior to the award of a contract. The determination shall reflect an analysis of the standards set forth in *FAR* 9.104-1.

#### **Subpart 370.6—Conference Funding and Sponsorship**

##### **370.600 Policy.**

It is HHS policy that the conferences it funds or sponsors shall: be consistent with HHS missions, objectives, and policies; represent an efficient and effective use of taxpayer funds; and be able to withstand public scrutiny.

##### **370.601 Funding and sponsorship.**

Funding a conference through an HHS contract does not automatically imply HHS (OPDIV/STAFFDIV) conference sponsorship, unless the conference is funded entirely by HHS. Also, HHS staff attendance or participation at a conference does not imply HHS conference sponsorship. Accordingly, for other than conference contracts funded entirely by HHS, prior to a contractor claiming HHS conference sponsorship, the contractor must provide to the Contracting Officer a written request for permission to claim HHS as the conference sponsor—see

370.602. The OPDIV/STAFFDIV head, or designee, shall approve such requests.

##### **370.602 Contract clause.**

To ensure that a contractor:

(a) Properly requests approval to claim HHS as the conference sponsor, where HHS is not the sole provider of conference funding; and

(b) Includes an appropriate Federal funding disclosure and content disclaimer statement on conference materials, the Contracting Officer shall include the clause in 352.270-7, Conference Sponsorship Request and Conference Materials Disclaimer, in solicitations, contracts, and orders that provide funding, in whole or in part, to support a conference.

#### **Subpart 370.7—Acquisitions Under the Leadership Act**

##### **370.700 Scope of subpart.**

This subpart sets forth the acquisition requirements regarding implementation of HIV/AIDS programs under the President's Emergency Plan for AIDS Relief under the Leadership Act of 2003, and under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (Emergency Plan reauthorization legislation), which was signed by the President on July 30, 2008.

##### **370.701 Contract clause.**

The Contracting Officer shall insert the clause in 352.270-8, Prostitution and Related Activities, in solicitations, contracts, and orders, and in existing contracts and orders (whenever they are modified to extend the period of performance or add funds, including any options that may be exercised): in connection with the implementation of HIV/AIDS programs under the President's Emergency Plan for AIDS Relief; or where the contractor will

receive funding under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003. (Note: See 370.702 and 352.270-9 for the "Non-discrimination for Conscience" provision that must also be included in applicable solicitations.) In resolving any issues/complaints that offerors/contractors may raise about meeting the requirements specified in the clause, the Contracting Officer shall consult with the Office of Global Health Affairs, Office of the General Counsel, the Project Officer, and other HHS officials, as appropriate.

##### **370.702 Solicitation provision.**

The Contracting Officer shall insert the provision in 352.270-9, Non-discrimination for Conscience, in solicitations valued at more than the micro-purchase threshold: in connection with the implementation of HIV/AIDS programs under the President's Emergency Plan for AIDS Relief; or where the contractor will receive funding under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003. (Note: See 370.701 and 352.270-8 for the "Prostitution and Related Activities" clause that must also be included in applicable solicitations, contracts, and orders.) In resolving any issues/complaints that offerors may raise about meeting the requirements specified in the provision, the Contracting Officer shall consult with the Office of Global Health Affairs, Office of the General Counsel, the Project Officer, and other HHS officials, as appropriate.

Dated: September 28, 2009.

**E.J. Holland, Jr.**

*Assistant Secretary for Administration and Management, Office of the Secretary, U.S. Department of Health and Human Services.*

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