

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

48 CFR Chapter 3

Acquisition Regulation Revision

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services is finalizing its acquisition regulation (HHSAR) to streamline and simplify it in accordance with the tenets of the National Performance Review. In doing so, the Department has eliminated procedural guidance which it believes is too encumbering for a simplified system and has empowered appropriate levels of management and contracting personnel with the authorities required for them to successfully accomplish their mission with the least amount of resistance and oversight.

EFFECTIVE DATE: January 17, 2001.

FOR FURTHER INFORMATION CONTACT: E. S. Lanham, Office of Acquisition Management, telephone (202) 690-7590.

SUPPLEMENTARY INFORMATION: The HHSAR was published as a proposed rule on January 8, 1999 (64 FR Vol 5 pps 1343-1390). Comments were received from several departmental contracting activities and one outside source. All comments have been analyzed and considered in the formulation of this final rule.

As a result of the publication of this regulation, the existing HHSAR at 48 CFR Chapter 3, including Appendix A, is canceled. Pertinent subject matter from Appendix A has been incorporated into this version of the HHSAR.

The Department reemphasizes that it is not making significant amendments to the existing HHSAR. The amendments being made to the HHSAR concern internal procedural matters which are administrative in nature, and will not have a major effect on the general public, or to contractors or offerors of the Department. The majority of the amendments eliminate procedural guidance no longer deemed necessary, or change contracting review and approval authorities to situate them at levels more appropriate to simplification, streamlining, and empowerment.

The Department of Health and Human Services certifies this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*); therefore, no

regulatory flexibility statement has been prepared. Since this rule conveys existing acquisition policies or procedures and does not promulgate any new policies or procedures which would impact the public, it has been determined that this rule will not have a significant economic effect on a substantial number of small entities, and, thus, a regulatory flexibility analysis was not performed.

Furthermore, this document does not contain new information collection requirements needing approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing approvals cited in 48 CFR section 301.106 remain in effect. The provisions of this regulation are issued under 5 U.S.C. 301; 40 U.S.C. 486 (c).

List of Subjects in 48 CFR Parts 301 through 370

Government procurement.

Under the authority of 5 U.S.C. 301; 40 U.S.C. 486(c), the Department of Health and Human Services revises 48 CFR Chapter 3 as set forth below.

Dated: December 14, 2000.

John J. Callahan,

Assistant Secretary for Management and Budget.

CHAPTER 3—HEALTH AND HUMAN SERVICES

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

Subpart 301.1—Purpose, Authority, Issuance

301.101 Purpose.

(a) The Department of Health and Human Services Acquisition Regulation (HHSAR) is issued to establish uniform acquisition policies and procedures for the Department of Health and Human

Services (HHS) which conform to the Federal Acquisition Regulation (FAR) System.

(b) The HHSAR implements and supplements the FAR. (Implementing material expands upon or indicates the manner of compliance with related FAR material. Supplementing material is new material which has no counterpart in the FAR.)

(c) The HHSAR contains all formal departmental policies and procedures that govern the acquisition process or otherwise control contracting relationships between the Department's contracting offices and contractors.

301.103 Authority.

(b) The HHSAR is prescribed by the Assistant Secretary for Management and Budget 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 OMB approval under the Paperwork Reduction Act.

(a) The following OMB control numbers apply to the information collection and recordkeeping requirements contained in this chapter:

HHSAR segment	OMB control No.
315.4	0990-0139
324.70	0990-0136
342.7101	0990-0131
352.224-70	0990-0137
352.224-70	0990-0136
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

(b) The OMB control number "OMB No. 0990-0115" is to be included in the upper right corner of the first page of all solicitations, purchase orders, and contracts issued by departmental contracting activities. The number represents approval of the HHS acquisition process and covers recordkeeping and reporting requirements which are unique to individual acquisitions (e.g., requirements contained in specifications, statements of work, etc.).

Subpart 301.2—Administration

301.270 Executive Committee for Acquisition.

(a) The Deputy Assistant Secretary for Grants and Acquisition Management has established the Executive Committee for Acquisition (ECA) to assist and facilitate the planning and development of departmental acquisition policies and procedures and to assist in responding to other agencies and organizations concerning policies and procedures impacting the Federal acquisition process.

(b) The ECA consists of members and alternates from the Office of Acquisition Management, Administration for Children and Families, Agency for Healthcare Research and Quality, Health Care Financing Administration, Program Support Center, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration. The ECA is chaired by the Director, Office of Acquisition Management. All meetings will be held at the call of the Chair, and all activities will be carried out under the direction of the Chair.

(c) The ECA, to facilitate the planning, development, and coordination of governmentwide and departmentwide acquisition policies and procedures, is to:

- (1) Advise and assist the Chair concerning major acquisition policy matters;
- (2) Review and appraise, at appropriate intervals, the overall effectiveness of existing policies and procedures; and
- (3) Review and appraise the impact of new major acquisition policies, procedures, regulations, and development on current acquisition policies and procedures.

(d) The Chair will periodically issue a list of current members and alternates specifying the name, title, organization, address, and telephone number of each. The member organizations are responsible for apprising the Chair whenever a new member or alternate is to be appointed to the ECA, or an organizational change retitles the individual or organization.

Subpart 301.4—Deviations From the FAR

301.403 Individual deviations.

Requests for individual deviations to either the FAR or HHSAR shall be prepared in accordance with 301.470 and forwarded through administrative

channels to the Director, Office of Acquisition Management for review and approval.

301.404 Class deviations.

Requests for class deviations to either the FAR or HHSAR shall be prepared in accordance with 301.470 and forwarded through administrative channels to the Deputy Assistant Secretary for Grants and Acquisition Management for review and approval.

301.470 Procedure.

(a) When a contracting office determines that a deviation is needed, it shall prepare a deviation request in memorandum form and forward it through administrative channels to the official designated in 301.403 or 301.404. In an exigency situation, the contracting office may request a deviation verbally, through normal acquisition channels, but is required to confirm the request in writing as soon as possible.

(b) A deviation request shall clearly and precisely set forth the:

- (1) Nature of the needed deviation;
- (2) Identification of the FAR or HHSAR citation from which the deviation is needed;
- (3) Circumstances under which the deviation would be used;
- (4) Intended effect of the deviation;
- (5) Period or applicability;
- (6) Reasons which will contribute to complete understanding and support of the requested deviation. A copy of pertinent background papers such as a contractor's request should accompany 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 or contractual commitments made to prospective contractors by persons to whom contracting authority has not been delegated. However, execution of otherwise proper contracts made by individuals without contracting authority, or by contracting officers in excess of the limits of their delegated authority, may be later ratified. The ratification must be in the form of a written document clearly stating that ratification of a previously unauthorized act is intended and must be signed by the head of the contracting activity (HCA).

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

(3) Ratification authority for actions up to \$25,000 may be redelegated by the HCA to the chief of the contracting office (CCO). No other redelegations are authorized.

(c) *Limitations.* (5) The concurrence of legal counsel concerning the payment issue is optional.

(e) *Procedures.* (1) The individual who made the unauthorized contractual commitment shall furnish the reviewing contracting officer all records and documents concerning the commitment and a complete written statement of facts, including, but not limited to: a statement as to why the contracting office was not used, a statement as to why the proposed contractor was selected, a list of other sources considered, a description of work to be performed or products to be furnished, the estimated or agreed contract price, a citation of the appropriation available, and a statement whether the contractor has commenced performance.

(2) The contracting officer will review the submitted material, and prepare the ratification document if he/she determines that the commitment may be ratifiable. The contracting officer shall forward the ratification document and the submitted material to the HCA or CCO with any comments or information which should be considered in evaluation of the request for ratification. If legal review is desirable, the HCA or CCO will coordinate the request for ratification with the Office of General Counsel, Business and Administrative Law Division.

(3) If ratification is authorized by the HCA or CCO, the file will be returned, along with the ratification document, to the contracting officer for issuance of a purchase order or contract, as appropriate.

301.603 Selection, appointment, and termination of appointment.

301.603-1 General.

(a) The appointment and termination of appointment of contracting officers shall be made by the head of the contracting activity (HCA). This authority is not delegable.

(b) The contracting officer appointment document for personnel in the GS-1101, 1102, and 1105 series, as well as personnel in any other series who will obligate the Government to the expenditure of funds in excess of the micro-purchase threshold, shall be the Standard Form (SF)—1402, Certificate of Appointment. The HCA may determine an alternative appointment

document for appointments at or below that threshold. Changes to appointments shall be made by issuing a new appointment document. Each appointment document shall be prepared and maintained in accordance with FAR 1.603-1 and shall state the limits of the individual's authority.

(c) An individual must be certified at the appropriate level under the HHS Acquisition Certification Program as a prerequisite to being appointed as a contracting officer with authority to obligate funds in excess of the micro-purchase threshold (see 301.603-3(a)). The HCA will determine and require appropriate training for individuals appointed as contracting officers at lower dollar levels. An individual shall be appointed as a contracting officer only in instances where a valid organizational need can be demonstrated. Factors to be considered in assessing the need for an appointment of a contracting officer include volume of actions, complexity of work, and structure of the organization.

301.603-2 Selection.

Nominations for appointment of contracting officers shall be submitted to the HCA through appropriate organizational channels for review. The nomination package, which is usually initiated by the prospective contracting officer's immediate supervisor, shall normally include the nominee's current personal qualifications statement or job history, including the information required by FAR 1.603-2, a copy of his/her most recent performance appraisal, and a copy of the certificate issued under the HHS Acquisition Certification Program indicating the nominee's current certification level, if applicable. The HCA will determine the documentation required, consistent with FAR 1.603-2, when the resulting appointment and authority will not exceed the micro-purchase threshold.

301.603-3 Appointment.

(a) Contracting officer appointments shall be made at levels commensurate with nominees' certification levels as follows:

(1) Level I—Purchasing Agent—Required for all personnel in the GS-1102 and 1105 series having signature authority for simplified acquisitions, including orders from GSA sources over the micro-purchase threshold.

(2) Level II—Acquisition Official—Required for all personnel in the GS-1102 series. Sufficient for delegation of contracting officer authority up to \$500,000.

(3) Level III—Senior Acquisition Official—Required for all personnel in the GS-1102 series for delegation of contracting officer authority above \$500,000.

(4) Level IV—Acquisition Manager—Required for delegation of pre-award review and approval authority as specified in subpart 304.71.

(b) If it is essential to appoint an individual who does not fully meet the certification requirements of this section for the contracting officer authority sought, an interim appointment may be granted by the HCA. Interim appointments may not exceed one (1) year in total, and shall not be granted unless the individual can meet the certification requirements within one year from the date of appointment. If the certification requirements are not met by that date, the appointment will automatically terminate and cannot be renewed.

301.603-4 Termination.

Termination of contracting officer appointments shall be accomplished in accordance with FAR 1.603-4.

301.603-70 Delegation of contracting officer responsibilities.

(a) Contracting officer responsibilities which do not involve the obligation (or deobligation) of funds or result in establishing or modifying contractual provisions may be delegated by the contracting officer by means of a written memorandum which clearly delineates the delegation and its limits.

(b) Contracting officers may designate individuals as ordering officials to make purchases or place orders under blanket purchase agreements, indefinite delivery contracts, or other pre-established mechanisms. Ordering officials, including those under NIH's DELPRO, are not contracting officers.

(c) Project officers are required to complete the training specified in 307.170, while ordering officials and others should receive sufficient instruction from the contracting officer to ensure the appropriate exercise of the responsibilities and knowledge of their limitations.

PART 302—DEFINITIONS OF WORDS AND TERMS

Subpart 302.1—Definitions

Sec.

302.101 Definitions.

Subpart 302.2—Definitions Clause

302.201 Contract clause.

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

Subpart 302.1—Definitions**302.101 Definitions.**

Chief of the contracting office (CCO) is a mid-level management official in charge of a contracting office who controls and oversees the daily contracting operation of an Operating Division (OPDIV) or major component of an OPDIV. The CCO is subordinate to the head of the contracting activity, and is located at a management level above other contracting personnel, usually as a branch chief or division director.

Head of the agency or agency head, unless otherwise specified, means the head of the Operating Division (OPDIV) for ACF, AHRQ, HCFA, PSC, CDCP, FDA, HRSA, IHS, NIH, and SAMHSA, or the Assistant Secretary for Management and Budget (ASMB) for the Office of the Secretary (OS).

Head of the contracting activity (HCA) is defined in terms of certain organizational positions within the Office of Grants and Acquisition Management (OGAM), Administration for Children and Families (ACF), Agency for Healthcare Research and Quality (AHRQ), Health Care Financing Administration (HCFA), Program Support Center (PSC), Centers for Disease Control and Prevention (CDCP), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA), as follows:

OGAM—OS—Director, Office of Acquisition Management
ACF—Director, Division of Acquisition Management
AHRQ—Director, Division of Contracts Management
HCFA—Director, Acquisition and Grants Group
PSC—Director, Division of Acquisition Management
CDCP—Director, Procurement and Grants Office
FDA—Director, Policy, Evaluation and Support Staff, Office of Facilities, Acquisition, and Central Services
HRSA—Director, Division of Grants and Procurement Management
IHS—Director, Division of Acquisitions and Grants Management
NIH—Director, Office of Acquisition Management and Policy
SAMHSA—Director, Division of Contracts Management

In addition, the Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM) is designated as an HCA. Each HCA is responsible for conducting an effective and efficient acquisition program. Adequate controls shall be established to assure compliance with applicable laws, regulations, procedures, and the dictates

of good management practices. Periodic reviews shall be conducted and evaluated by qualified personnel, preferably assigned to positions other than in the contracting office being reviewed, to determine the extent of adherence to prescribed policies and regulations, and to detect a need for guidance and/or training. The HCA shall be certified, or be certifiable, at Level IV of the HHS Acquisition Certification Program. Individuals appointed as HCA's who do not meet the Level IV requirements shall have one year from the date of appointment to obtain Level IV certification. The heads of contracting activities may redelegate their HCA authorities to the extent that re delegation is not prohibited by the terms of their respective delegations of authority, by law, by the Federal Acquisition Regulation, by the HHS Acquisition Regulation, or by other regulations. However, HCA and other contracting approvals and authorities shall not be redelegated below the levels specified in the HHS Acquisition Regulation or, in the absence of coverage in the HHS Acquisition Regulation, the Federal Acquisition Regulation. To ensure proper control of redelegated acquisition authorities, HCA's shall maintain a file containing successive delegations of HCA authority through and including the contracting officer level. Personnel delegated responsibility for acquisition functions must possess a level of experience, training, and ability commensurate with the complexity and magnitude of the acquisition actions involved.

Subpart 302.2—Definitions clause**302.201 Contract clause.**

The FAR clause, Definitions, at 52.202–1 shall be used as prescribed in FAR 2.201, except as follows:

(a) Paragraph (a) at 352.202–1 shall be used in place of paragraph (a) of the FAR clause.

(b) Paragraph (h), or its alternate, at 352.202–1 shall be added to the end of the FAR clause. Use paragraph (h) when a fixed-priced contract is anticipated; use the alternate to paragraph (h) when a cost-reimbursement contract is anticipated. This is an authorized deviation.

PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST**Subpart 303.1—Safeguards**

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303.101 Standards of conduct.

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Subpart 303.2—Contract Gratuities to Government Personnel

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303.704 Policy.

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.**

The Department of Health and Human Services' Standards of Conduct are prescribed in 45 CFR part 73.

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

Departmental personnel shall report suspected violations of the Gratuities clause in accordance with subpart M, Reporting Violations, of 45 CFR part 73. Refer to subpart B, Gifts from Outside Sources, (5 CFR 2635.201) for an explanation regarding what is prohibited and what is permitted.

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

A copy of each report of suspected antitrust violations submitted to the Attorney General by the HCA shall also be submitted to the Director, Office of Acquisition Management.

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

(c) Reports shall be made promptly to the contracting officer.

(d)(4) Suspected fraudulent or criminal matters to be reported to the Department of Justice shall be prepared in letter format and forwarded through acquisition channels to the head of the contracting activity for signature. The letter must contain all pertinent facts

and background information considered by the contracting officer and chief of the contracting office that led to the decision that fraudulent or criminal matters may be present. A copy of the signed letter shall be sent to the Director, Office of Acquisition Management.

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

303.602 Exceptions.

Approval of an exception to the policy stated in FAR 3.601 shall be made by the HCA (not delegable).

Subpart 303.7—Voiding and Rescinding Contracts

303.704 Policy.

For purposes of implementing FAR subpart 3.7, the authorities granted to the "agency head or designee" shall be exercised by the HCA (not delegable).

PART 304—ADMINISTRATIVE MATTERS

Subpart 304.6—Contract Reporting

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304.7101 Procedures.

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

Subpart 304.6—Contracting Reporting

304.602 Federal Procurement Data System (FPDS).

The Departmental Contracts Information System (DCIS) represents the Department's implementation of the FPDS. All departmental contracting activities are required to participate in the DCIS and follow the procedures stated in the Enhanced Departmental Contracts Information System Manual and amendments to it. The HCA (not delegable) shall ensure that all required contract information is collected, submitted, and received into the DCIS on or before the 15th of each month for all appropriate contract and contract modifications award of the prior month.

Subpart 304.8—Government Contract Files

304.804-70 Contract closeout audits.

(a) Contracting officers shall rely, to the maximum extent possible, on non-Federal single audits to close physically completed cost-reimbursement contracts with colleges and universities, hospitals, non-profit firms, and State and local governments. In addition, where appropriate, a sample of these contractors may be selected for audit, in accordance with the decision-making process set forth in the following paragraph (b).

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

(1) Decisions on: The need for and allocation of contract audit resources and services; the selection of contracts or contractors to be audited; the identification of the audit agency to perform the audit; and the type or scope of closeout audit to be conducted, shall be made by the Office of Inspector General (OIG) and Office of Grants and Acquisition Management, in consultation with the Department's Contract Audit Users Work Group. These decisions shall be based upon 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 via the appropriate OPDIV representative on the Contract Audit Users Work Group.

(2) Except where a contracting officer suspects misrepresentation or fraud, contract closeout field audits shall not be requested if the cost of performance is likely to exceed the potential cost recovery. Contracts that are not selected for a field audit may be closed on the basis of a desk review, subject to any later on-site audit findings. 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 the amount of any sustained audit exceptions resulting from any audit made after final payment shall be refunded to the Government."

Subpart 304.70—Acquisition Instrument Identification Numbering System

304.7000 Scope of subpart.

This subpart prescribes policy and procedures for assigning identifying

numbers to contracts and related instruments, including solicitation documents, purchase orders, and delivery orders. The HCA (not delegable) is responsible for establishing the numbering system within the OPDIV.

304.7001 Numbering acquisitions.

(a) *Acquisitions which require numbering.* The following acquisitions shall be numbered in accordance with the system prescribed in paragraphs (b) and (c) of this section:

(1) Contracts, including letter contracts and task orders under basic ordering agreements, which involve the payment of \$2,500 or more for the acquisition of personal property or nonpersonal services. (The number assigned to a letter contract shall be assigned to the superseding definitized contract).

(2) Contracts which involve the payment of \$2,000 or more for construction (including renovation or alteration).

(3) Contracts which involve more than one payment regardless of amount.

(4) Requests for proposals and invitations for bids.

(5) Requests for quotations.

(6) Basic ordering agreements.

(b) *Numbering system for contracts.* All contracts which require numbering (paragraphs (a)(1) through (3) of this section) shall be assigned a number consisting of the following:

(1) The three digit identification code assigned to the contracting office by the Office of Grants and Acquisition Management (OGAM).

(2) A two digit fiscal year designation; and

(3) A four digit serial number. For example, the initial contract executed by the Office of Acquisition Management, OS, for fiscal year 1996 would be numbered 100-96-0001. While it is required that a different series of four digit serial numbers be used for each fiscal year, serial numbers assigned need not be sequential.

(c) *Numbering system for other acquisitions.* The HCA is responsible for developing a numbering system for the acquisitions other than contracts listed in paragraphs (a)(4) through (a)(6) of this section, and any other types of acquisitions that may be used.

(d) *Assignment of identification codes.* Each contracting office of the Department shall be assigned a three digit identification code by the OGAM. Requests for the assignment of codes for newly established contracting offices shall be submitted by the headquarters acquisition staff office of the contracting activity to the OGAM. A listing of the

contracting office identification codes currently in use is contained in the Enhanced Departmental Contracts Information System Manual.

Subpart 304.71—Review and Approval of Proposed Contract Awards

304.7100 Policy.

This subpart requires each HCA (not delegable) to establish review and approval procedures for proposed contracts actions to ensure that:

(a) Contract awards are in conformance with law, established policies and procedures, and sound business practices;

(b) Contractual documents properly reflect the mutual understanding of the parties; and

(c) The contracting officer is informed of deficiencies and items of questionable acceptability, and corrective action is taken.

304.7101 Procedures.

(a) All contractual documents, regardless of dollar value, are to be reviewed by the contracting officer prior to award.

(b) The HCA is responsible for establishing review and approval procedures and designating acquisition officials to serve as reviewers. Each HCA is responsible for determining the criterion (criteria) to be used in determining which contracts are to be reviewed, and that a sampling of proposed contracts not included in the "to be reviewed" group are reviewed and approved.

(c) Officials assigned responsibility for review and approval of contract actions must possess qualifications in the field of acquisition commensurate with the level of review performed, and, at a minimum, possess those acquisition skills expected of a contracting officer. However, if any official is to serve as the contracting officer and sign the contractual document, the review and approval function shall be performed by an appropriate official at least one level above.

PART 305—PUBLICIZING CONTRACT ACTIONS

Subpart 305.2—Synopsis of Proposed Contract Actions

Sec.
305.202 Exceptions.

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 a contracting office believes that it has a situation where advance notice is not appropriate or reasonable, it shall prepare a memorandum citing all pertinent facts and details and send it, through normal acquisition channels, to the Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM) requesting relief from synopsisizing. The DASGAM shall review the request and decide whether an exception to synopsisizing is appropriate or reasonable. If it is, the DASGAM shall take the necessary coordinating actions required by FAR 5.202 (b). Whatever the decision is on the request, the DASGAM shall promptly notify the contracting office when a determination has been made.

Subpart 305.3—Synopsis of Contract Awards

305.303 Announcement of contract awards.

(a) *Public announcement.* Any contract, contract modification, or delivery order in the amount of \$3 million or more shall be reported by the contracting officer to the Office of the Deputy Assistant Secretary for Legislation (Congressional Liaison), Room 406G, Hubert H. Humphrey Building. Notification shall be accomplished by providing 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 for an announcement to be made by 5 p.m. Washington, DC time on the day of award.

Subpart 305.5—Paid Advertisements

305.502 Authority.

The contracting officer is authorized to publish advertisements, notices, and notices that proposals are being sought in newspapers and periodicals in accordance with the requirements and conditions referenced in FAR subpart 5.5.

PART 306—COMPETITION REQUIREMENTS

Subpart 306.2—Full and Open Competition After Exclusion of Sources

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306.202 Establishing or maintaining alternative sources.

Subpart 306.3—Other Than Full and Open Competition

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306.303-2 Content.
306.304 Approval of the justification.

Subpart 306.5—Competition Advocates

306.501 Requirement.

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 cited in 306.501.

(b)(1) The required determination and findings (D&F) shall be prepared by the contracting officer based on the data provided by program personnel, and shall be signed by the appropriate competition advocate. The D&F signatory is not delegable.

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) (ii) Follow-on contracts for the continuation of major research and development studies on long-term social and health programs, major 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 the Department's or OPDIV's requirements.

(b) *Application.* (4) When the head of the program office has determined that a specific item of technical equipment or parts must be obtained to meet the activity's program responsibility to test and evaluate certain kinds and types of products, and only one source is available. (This criterion is limited to testing and evaluation purposes only and may not be used for initial outfitting or repetitive acquisitions. Project officers should 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.* An "approval package" must be prepared by the contracting officer and staffed through departmental acquisition channels to the Secretary. The package shall include a determination and findings for the Secretary to sign that contains all pertinent information to support justification for exercising the exemption to competition, and a letter for the Secretary to sign 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) Preliminary arrangements or agreements with the proposed contractor shall have no effect on the rationale used to support an acquisition for other than full and open competition.

(f) When a program office desires to obtain certain goods or services by contract without full and open competition, it shall, at the time of forwarding the requisition or request for contract, furnish the contracting office a justification explaining why full and open competition is not feasible. All justifications shall be initially reviewed by the contracting officer.

(1) Justifications 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 called a "JOFOC" (Justification for Other Than Full and Open Competition). Justifications at or below the simplified acquisition threshold may be in the form of a paragraph or paragraphs contained in the requisition or request for contract.

(2) Justifications, whether over or under the simplified acquisition threshold, shall fully describe what is to be acquired, offer reasons which go beyond inconvenience, and explain why it is not feasible to obtain competition. The justifications shall be supported by verifiable facts rather than mere opinions. Documentation in the justification should be sufficient to permit an individual with technical competence in the area to follow the rationale.

306.303-2 Content.

(a)(1) The program office and name, address, and telephone number of the project officer shall also be included.

(2) This item shall include project identification such as the authorizing

program legislation, to include citations or other internal program identification data such as title, contract number, etc.

(3) The description may be in the form of a statement of work, purchase description, or specification. A statement is to be included to explain whether the acquisition is an entity in itself, whether it is one in a series, or part of a related group of acquisitions.

(c) Each JOFOC shall conclude with at least signature lines for the project officer, project officer's immediate supervisor, contracting officer, and approving official.

306.304 Approval of the justification.

(a)(2) The competition advocates are listed in 306.501. This authority is not delegable.

(3) The competition advocate 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 authority is not delegable.

(4) The senior procurement executive of the Department is the Assistant Secretary for Management and Budget.

(c) A class justification shall be processed the same as an individual justification.

Subpart 306.5—Competition Advocates**306.501 Requirement.**

The Department's competition advocate is the Deputy Assistant Secretary for Grants and Acquisition Management. The competition advocates for the Department's primary contracting officers are as follows:

ACF—Director, Office of Management Services
HCFA—Director, Office of Internal Customer Support
OS—Deputy Assistant Secretary for Grants and Acquisition Management
PSC—Director, Administrative Operations Service
AHRQ—Executive Officer
CDCP—Director, Office of Program Support
FDA—Director, Office of Facilities, Acquisition, and Central Services
HRSA—Associate Administrator for Operations and Management
IHS—Director, Office of Management and Support
NIH—(R&D)—Director, Office of Extramural Research (Other than R&D)—Director, Office of Intramural Research
SAMHSA—Associate Administrator for Management

PART 307—ACQUISITION PLANNING**Subpart 307.1—Acquisition Plans**

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

Subpart 307.1—Acquisition Planning**307.104 General procedures.**

(d) Each contracting activity shall prepare an Annual Acquisition Plan (AAP). The AAP is a macro plan, containing a list of anticipated contract actions over the simplified acquisition threshold and their associated funding, as well as the aggregate planned dollars for simplified acquisitions by quarter, developed for each fiscal year. The AAP shall conform to reasonable budget expectations and shall be reviewed at least quarterly and modified as appropriate. The chief of the contracting office (CCO) shall obtain this information from the program planning/budget office of the contracting activity and use the AAP to provide necessary reports and monitor the workload of the contracting office. For contract actions, the plan shall contain, at a minimum:

- (1) A brief description (descriptive title, perhaps one or two sentences if necessary);
- (2) Estimated award amount;
- (3) Requested award date;
- (4) Name and phone number of contact person (usually the project officer);
- (5) Other information required for OPDIV needs.

(e) Once the AAP is obtained, the contracting officer/contract specialist shall initiate discussions with the assigned project officer for each planned negotiated acquisition over \$100,000 except for:

- (1) Acquisitions made under interagency agreements, and

(2) Contract modifications which exercise options, make changes authorized by the Changes clause, or add funds to an incrementally funded contract. (The HCA may prescribe procedures for contract actions not covered by this subpart.)

(f) The purpose of the discussions between the contracting and project officers is to develop an individual acquisition planning schedule and to address the things that will need to be covered in the request for contract (RFC), including clearances, acquisition strategy, sources, etc. The project officer must either have a statement of work (SOW) ready at this time or must discuss in more detail the nature of the services/supplies that will be required.

(g) Standard lead-times for processing various types of acquisitions and deadlines for submission of acceptable RFCs (that is, RFCs which include all required elements such as clearances, funding documents, and an acceptable SOW) for award in a given fiscal year shall be established by the HCA or designee not lower than the CCO.

(h) The outcome of the discussions referenced in paragraph (f) of this section between the project officer and the contracting officer/contracting specialist will be an agreement concerning the dates of significant transaction-specific acquisition milestones, including the date of submission of the RFC to the contracting officer. This milestone schedule document will be prepared with those dates and will be signed by the project officer and the contracting officer. The milestones cannot be revised except by mutual agreement of these same individuals. If the planning schedule indicates the need to obtain approval of a Justification for Other than Full and Open Competition, the CCO must sign the milestone agreement. This document shall be retained in the contract file. All other considerations that will affect the acquisition (technical, business, management) shall be addressed in the RFC (see 307.71).

307.105 Contents of written acquisition plans.

The written acquisition plan required by FAR 7.105 must be contained in the request for contract, as specified in subpart 307.71, and is the final product of the planning process.

307.170 Program training requirements.

(i) All program personnel selected to serve as project officers for HHS contracts shall have successfully completed either the Department's appropriate "Basic Project Officer"

course, or an equivalent course (see paragraph (c) of this section).

(b) At least fifty percent of the HHS program personnel performing the function of technical proposal evaluator on a technical evaluation team or panel for any competitively solicited HHS contract shall have successfully completed the appropriate "Basic Project Officer" course, or an equivalent course (see paragraph (c) of this section). This requirement applies to the initial technical proposal evaluation and any subsequent technical evaluations that may be required.

(c) Determination of course equivalency shall be made by the HCA (not delegable) of the cognizant contracting activity. The contracting officer is responsible for ensuring that the project officer and technical proposal evaluators have successfully completed the required training discussed in 307.170-2.

307.170-1 Policy exceptions.

In the event there is an urgent requirement for a specific individual to serve as a project officer and that individual has not successfully completed the prerequisite training course, the HCA (not delegable) may waive the training requirement and authorize the individual to perform the project duties, provided that:

(a) The individual first meets with the cognizant contracting officer to review the DHHS Project Officers' Contracting Handbook," and to discuss the important aspects of the contracting—program office relationship as appropriate to the circumstances; and

(b) The individual attends the next scheduled and appropriate "Basic Project Officer" course.

307.170-2 Training course prerequisites.

(a) *Project officers.* (1) Newly appointed project officers, and project officers with less than three years experience and no previous related training, are required to take the appropriate "Basic Project Officer" course. (The grade level for project officers attending the course should be GS-7 and above.) All project officers are encouraged to take the appropriate "Writing Statements of Work" course.

(2) Project officers with more than three years experience, and project officers with less than three years experience who have successfully completed the appropriate basic course, are qualified (and encouraged) to take the "Advanced Project Officer" course.

(3) Additional information on prerequisites for attendance of these courses may be found in the "DHHS

Acquisition Training and Certification Program Handbook."

(b) *Technical proposal evaluators.* Technical proposal evaluators, regardless of experience, are required to take the appropriate "Basic Project Officer" course or its equivalent. Upon successful completion of the basic course, it is recommended that they take the appropriate "Advanced Project Officer" course. Peer and objective reviewers are excluded from these requirements.

Subpart 307.3—Contractor Versus Government Performance

307.302 General.

(a) General Administration Manual (GAM) Chapter 18-10, Commercial-Industrial Activities of the Department of Health and Human Services Providing Products or Services for Government Use, assigns responsibilities for making method-of-performance decisions (contract vs. in-house performance) to various management levels within the Department depending on the dollar amount of capital investment or annual operating costs. It also requires that each operating division (OPDIV) and staff division (STAFFDIV) designate a "Commercial-Industrial Control Officer" (CICO) to be responsible for ensuring compliance with the requirements of the Chapter.

307.303 Determining availability of private commercial sources.

In accordance with the provisions of GAM Chapter 18-10, OPDIVs and STAFFDIVs must prepare and maintain a complete inventory of all individual commercial or industrial activities. They must also conduct periodic reviews of each activity and contract in the inventory to determine if the existing performance, in-house or by contract, continues to be in accordance with the policy guidelines of GAM Chapter 18-10.

307.304 Procedures.

Contracting officers shall ensure that no acquisition action involving a commercial-industrial activity is initiated unless it is in compliance with the requirements of GAM Chapter 18-10. The contracting officer must check each request for contract expected to result in a contract in excess of \$100,000 to ensure that it contains a statement as to whether the proposed contract is or is not subject to review under GAM Chapter 18-10 requirements. If the contracting officer has any questions regarding the determination of applicability or nonapplicability, or if the required statement is missing, the

program office submitting the request for contract should be contacted and the situation rectified. If the issue cannot be resolved with the program office, the contracting office shall refer the matter to the CICO for a final determination. The HCA is responsible for ensuring that contracting activities are in full compliance with FAR Subpart 7.3.

307.307 Appeals.

The review and appeals procedure discussed in FAR 7.307 are addressed in GAM Chapter 18–10.

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 consistent with 31 U.S.C. 6301–6308. This subpart explains the use of the contract as the award instrument for acquisition relationships, and the grant or cooperative agreement as the instrument for assistance relationships. This subpart provides guidance for determining whether to use the acquisition or assistance process to fulfill program needs.

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 recipients to accomplish a public purpose of support or stimulation authorized by Federal statute.

(b) A contract is to be used as the legal instrument to reflect a relationship between the Federal Government and a recipient whenever:

(1) The 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 Federal Government; *or*

(2) The Department determines in a specific instance that the use of a type of contract is appropriate. That is, it is determined 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 only with the prior approval of the Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM).

(c) A grant or cooperative agreement is to be used as the legal instrument to reflect a relationship between the

Federal Government and a recipient whenever the principal purpose of the relationship is the transfer of money, property, services, or anything of value to the recipient to accomplish a public purpose of support or stimulation authorized by Federal statute.

(1) A grant is the legal instrument to be used when no substantial involvement is anticipated between the Department and the recipient during performance of the contemplated activity.

(2) A cooperative agreement is the legal instrument to be used when substantial involvement is anticipated between the Department and the recipient during performance of the contemplated activity.

(d) As a general rule, contracts are to be used 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) Planning for Government use.

(7) Production of publications or audiovisual materials required primarily for the conduct of the direct operations of the Government.

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

(9) Conferences conducted on behalf of the Government.

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

307.7002 Procedures.

(a) OPDIV program officials should use existing budget and program planning procedures to propose new activities and major changes in ongoing programs. It is the responsibility of these program officials to meet with the HCA and the principal grants management official, or their designees,

to distinguish the relationships and determine whether award is to be made through the acquisition process or assistance process. This determination should be made prior to the time when the annual acquisition plan is reviewed and approved so that the plan will reflect all known proposed contract actions. The cognizant contracting officer will confirm the appropriateness of the use of the contract instrument when reviewing the request for contract.

(b) Shifts from one award instrument to another must be fully documented in the appropriate files to show a fundamental change in program purpose that unequivocally justifies the rationale for the shift.

(c) OPDIVs must ensure that the choice of instrument is determined in accordance with 31 U.S.C. 6301–6308 and applicable departmental 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, guidance should be obtained from the DASGAM, through normal channels, before proceeding with a determination.

(d) Any public notice, program announcement, solicitation, or request for applications or proposals must indicate whether the intended relationship will be one of acquisition or assistance and specify the award instrument to be used.

Subpart 307.71—Requests for Contract

307.7100 Scope of subpart.

This subpart prescribes the format and contents of the request for contract (RFC) and provides procedures for its preparation and submission.

307.7101 General.

The program office's preparation of the RFC and submission to the contracting office completes the presolicitation phase of the acquisition planning process and commences the solicitation phase. The RFC is the formal document which initiates the preparation of the solicitation by the contracting office and sets the acquisition process in motion. It is the result of the planning by the project officer and contracting officer and contains much of the pertinent information necessary for the development of a sound, comprehensive solicitation.

307.7102 Procedures.

The program office should submit the RFC to the contracting office no later than the date agreed to by the

contracting officer and the project officer in the milestone schedule (see 307.104(h)), unless a revised due date has been established by mutual agreement.

307.7103 Responsibilities.

(a) It is the responsibility of the project officer to prepare the RFC so that it complies with the requirements of this subpart and any OPDIV guidance issued in accordance with this subpart.

(b) Prior to the submission of the RFC to the contracting office, the head of the program office sponsoring the project shall review the RFC to ensure that all required information is provided in the prescribed format, and a technical review of the statement of work has been made. The level and extent of the technical review is to be commensurate with the estimated cost, importance, and complexity of the proposed acquisition, and must be thorough enough to ensure that vague and ambiguous language is eliminated, the statement of work is structured by phases or tasks, if appropriate, and methods are available for assessing the contractor's technical, cost, and delivery performance.

307.7104 Transmittal.

The RFC must be conveyed to the contracting office by use of a covering memorandum or other form of transmittal. The transmittal document must be signed by the head of the sponsoring program office and include both a statement attesting to the conclusiveness of the review described in 307.7103(b) and a list identifying all attachments to the RFC.

307.7105 Format and content.

The Department does not prescribe a standard format for the RFC. A format similar to what is in this section is recommended. However, any document or group of documents will be acceptable as an RFC as long as all of the required information (paragraph (a) of this section), and as much of the optional information (paragraph (b) of this section) as is relevant, is included.

(a) The RFC must include:

(1) *Purpose of the contract.* A brief, general description of the requirement, including the citation of the legislation which authorizes the program or project, and a statement as to the intended purpose/use of the proposed contract.

(2) *Period of performance.* The number of months (or other time period) required for total performance and, if applicable, for each phase of work indicated in the statement of work, as well as the proposed starting date.

(3) *Estimated cost and funds citation.*

An estimate of the total cost of the proposed contract and, if applicable, the estimate for each phase indicated in the statement of work. The project officer must provide a cost breakdown of all contributing cost factors, an estimate of the technical staff hours, direct material, subcontracting, travel, etc., and may consult with contracting and cost advisory personnel in developing this information. This section must include the certification of funds availability for the proposed acquisition, along with the appropriation and accounting information citations. When funds for the proposed acquisition are not currently available for obligation but are anticipated, a statement of intent to commit funds from the financial management officer shall be included in lieu of the certification of funds availability. (Contracts cannot be awarded unless funds are available, but see FAR 32.703-2).

(4) *Specification, purchase description, or statement of work.* A description of the work to be performed that may be in the form of a specification, purchase description, or statement of work. Guidance concerning the statement of work and its contents is contained in 307.7106. Use of the specification is primarily limited to supply or service contracts where the material end item or service to be delivered is well defined by the Government. To the maximum extent possible, requirements should be defined as performance-based statements of work that focus on outcomes or results. If the RFC for a service contract is not utilizing a performance-based statement of work, with associated measures and a quality surveillance plan, the rationale for this determination must be documented. If a performance-based service contract is utilized, the RFC must detail the performance standards that must be met, the quality surveillance plan that will be implemented and the performance incentives to be used, if applicable.

(5) *Schedule of deliverables/reporting requirements.* A description of what is to be delivered, including, if applicable, technical and financial progress reports and any final report, and the required date of delivery for each deliverable. Reporting requirements should be tailored to the instant acquisition and should not be unnecessarily extensive or detailed. All delivery and reporting requirements shall include the quantities, the place of delivery, and time of delivery.

(6) *Sources for solicitation.* A list of known potential sources by name, size,

type of ownership, and mailing address. The project officer is encouraged to use trade and professional journals and publications and conduct a thorough market research to identify new prospective sources to supplement the list of known sources. Efforts to identify set-aside possibilities, e.g., 8(a), HUBZone, and small business, and efforts to identify sources such as small disadvantaged and women-owned small businesses must be documented.

(7) *Project officer and alternate.* The project officer's name, title, organization, mailing address, and telephone number, along with the same data for the project officer's alternate, and a statement that these individuals have completed the Department's project officer training course (see 307.170)

(b) The RFC must include, if applicable to the acquisition:

(1) *Background and need.* The background, history, and necessity for the proposed contract. This section is to include prior, present, and planned efforts by the program office in the same or related areas, and a description of efforts by other departmental activities and Federal agencies in the same or related program areas, if known. In addition, specific project information, such as the relevance or contribution to overall program objectives, reasons for the need, priority, and project overlap are to be provided.

(2) *Reference materials.* A list, by title and description, of study reports, plans, drawings, and other data to be made available to prospective offerors for use in preparation of proposals and/or the contractor for use in performance of the contract. The project officer must indicate whether this material is currently available or when it will be available, and how it may be accessed by potential offerors.

(3) *Technical evaluation criteria and instructions.* Technical evaluation criteria, which have been developed based on the requirements of the specific project, and any instructions and information which will assist in the preparation of prospective offerors' technical proposals. Evaluation factors may include understanding of the problem, technical approach, experience, personnel, facilities, etc. Criteria areas discussed in the statement of work and the relative order of importance or weights assigned to each of these areas for technical evaluation purposes must be identified.

(4) *Special program clearances or approvals.* Any required clearance or approval. The following special program clearances or approvals should be reviewed for applicability to each

acquisition. The ones which are applicable should be addressed during the planning discussions between the project officer and contracting officer/contract specialist (see 307.104(f)) and immediate action should be initiated by the project officer to obtain the necessary clearances or approvals. Comprehensive checklists of these and any OPDIV special approvals, clearances, and requirements shall be provided for reference purposes to program offices by the servicing contracting activity. If the approval or clearance has been requested and is being processed at the time of RFC submission, a footnote to this effect, including all pertinent details, must be included in this section.

(i) *Commercial activities.* (OMB Circular No. A-76). A request for contract (RFC) must contain a statement as to whether the proposed solicitation is or is not to be used as part of an OMB Circular No. A-76 cost comparison. (See General Administration Manual (GAM) Chapter 18-10; FAR subpart 7.3, subpart 307.3; OMB Circular No. A-76.)

(ii) *Printing.* The acquisition of printing and high volume duplicating by contract is prohibited unless it is authorized by the Joint Committee on Printing of the U.S. Congress. Procedures to be followed are contained in the "Government Printing and Binding Regulations" and the HHS Printing Management Manual and FAR subpart 8.8.

(iii) *Paperwork Reduction Act.* Under the Paperwork Reduction Act of 1995, a Federal agency shall not collect information or sponsor the collection of information from ten or more persons (other than Federal employees acting within the scope of their employment) unless, in advance, the agency has submitted a request for Office of Management and Budget (OMB) review, to the OMB, and the OMB has approved the proposed collection of information. Procedures for the approval may be obtained by contacting the OPDIV reports clearance officer. (See 5 CFR part 1320).

(iv) *Publications.* All projects that will result in contracts which include publications development (print products, electronic bulletin boards, posting on the internet) require review and approval by the Office of the Assistant Secretary for Public Affairs (OASPA). Form HHS-615, Publication Planning and Clearance Request, must be forwarded to OASPA through the OPDIV public affairs officer. Publications are defined in Chapter 5-00-15 of the Public Affairs Management Manual.

(v) *Public affairs services.* Projects for the acquisition of public affairs services in excess of \$5,000 must be submitted to the Office of the Assistant Secretary for Public Affairs (OASPA) for review and approval on Form HHS-524, Request for Public Affairs Services Contract.

(vi) *Audiovisual.* All projects which will result in contracts which include audiovisuals, regardless of the audio, video, or audiovisual medium employed, require review and approval by the Office of the Assistant Secretary for Public Affairs (OASPA). Form HHS-524A, Publication Planning and Clearance Request, must be forwarded to OASPA through the OPDIV public affairs officer. Audiovisuals are defined in chapter 6-00-15 of the Public Affairs Management Manual.

(vii) *Privacy Act (5 U.S.C. 552a).* Whenever the Department contracts for the design, development, operation, or maintenance of a system of records on individuals on behalf of the Department to accomplish a departmental function, the Privacy Act is applicable. The program official, after consultation with the activity's Privacy Act Coordinator and the Office of General Counsel, as necessary, shall include a statement in the request for contract as to the applicability of the Act. Whenever an acquisition is subject to the Act, the program official prepares a "system notice" and has it published in the **Federal Register**. (See HHS Privacy Act regulation, 45 CFR part 5b; FAR subpart 24.1 and subpart 324.1.)

(viii) *Foreign research.* All foreign research contract projects to be conducted in a foreign country and financed by HHS funds (U.S. dollars) must have clearance by the Department of State with respect to consistency with foreign policy objectives. This clearance should be obtained prior to negotiation. Procedures for obtaining this clearance are set forth in the HHS General Administration Manual, Chapter 20-60.

(5) *Identification and disposition of data.* Identification of the data expected to be generated by the acquisition and an indication of whether the data are to be delivered to the Department or to be retained by the contractor is required. The project officer must also include information relative to the use, maintenance, disclosure, and disposition of data. The project officer must include a statement as to whether or not another acquisition, based upon the data generated by the proposed acquisition, is anticipated.

(6) *Government property.* If known, the type of Government property, individual items, and quantities of Government property to be furnished to,

or allowed to be acquired by, the resultant contractor should be indicated. The project officer must specify when the Government property is to be made available.

(7) *Special terms and conditions.* Any suggested special terms and conditions not already covered in the statement of work or the applicable contract general provisions is required.

(8) *Justification for other than full and open competition.* If the proposed acquisition is to be awarded using other than full and open competition, a justification prepared in accordance with FAR subpart 6.3 and subpart 306.3 is required.

307.7106 Statement of work.

(a) *General.* A statement of work (SOW) differs from a specification and purchase description primarily in that it describes work or services to be performed in reaching an end result rather than a detailed, well defined description or specification of the end product. The SOW may enumerate or describe the methods (statistical, clinical, laboratory, etc.) that will be used. However, it is preferable for the offeror to propose the method of performing the work. The SOW should specify the desired results, functions, or end items without telling the offeror what has to be done to accomplish those results unless the method of performance is critical or required for the successful performance of the contract. The SOW should be clear and concise and must completely define the responsibilities of the Government and the contractor. The SOW should be worded so as to make more than one interpretation virtually impossible because it has to be read and interpreted by persons of varied backgrounds, such as attorneys, contracting personnel, cost estimators, accountants, scientists, educators, functional specialists, etc. The SOW must clearly define the obligations of both the contractor and the Government so as to protect the interests of both. Ambiguous statements of work can create unsatisfactory performance, delays, and disputes, and can result in higher costs.

(b) *Term (level of effort) vs. completion work statement.* Careful distinctions must be drawn between term (level of effort) SOWs, which essentially require the furnishing of technical effort and which may include a report thereof, and completion type work statements, which require development of tangible items designed to meet specific performance and/or design characteristics. (See FAR 16.306(d) for distinction).

(1) *Term (or level of effort)*. A term or level of effort type SOW is appropriate for research where one seeks to discover the feasibility of later development, or to gather general information. A term or level of effort type SOW may only specify 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 type SOW is appropriate to development work where the feasibility of producing an end item is already known. A completion type 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 must be completed and approved before the contractor may proceed to the next. 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 may include stages of accomplishment such as research, development, and demonstration. Within each phase, there may be a number of tasks which should be included in the SOW. When phases of work can be identified, the SOW will provide for phasing and the request for proposals will require the submission of proposed costs by phases. The resultant contract will 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 provisions of the Limitation of Cost clause shall apply to the estimated cost of each phase. Contractors shall not be allowed to incur costs for phases which are dependent upon successful completion of earlier phases until written acceptance of the prior work is obtained from the contracting officer.

(d) *Elements of the SOW*. The elements of the SOW will vary with the

objective, complexity, size, and nature of the acquisition. In general, it should cover the following matters as appropriate.

(1) *A general description of the required objectives and desired results*. Initially, a broad, nontechnical statement of the nature of the work to be performed. This should summarize the actions to be performed by the contractor and the results that the Government expects.

(2) *Background information helpful to a clear understanding of the requirements and how they evolved*. Include a brief historical summary as appropriate and the relationship to overall program objectives.

(3) *A detailed description of the technical requirements*. A comprehensive description of the work to be performed to provide whatever details are necessary for prospective offerors to submit meaningful proposals.

(4) *Subordinate tasks or types of work*. A listing of the various tasks or types of work (it may be desirable in some cases to indicate that this is not all-inclusive). The degree of task breakout is directly dependent on the size and complexity of the work to be performed and the logical groupings. A single cohesive task should not be broken out merely to conform to a format. Indicate whether the tasks are sequential or concurrent for offeror planning purposes.

(5) *Reference material*. All reference material to be used in the conduct of the project that tells how the work is to be carried out must be identified. Applicability should be explained, and a statement made as to where the material can be obtained.

(6) *Level of effort*. When a level of effort is required, the number and type of personnel required should be stated. If known, the type and degree of expertise should be specified.

(7) *Special requirements*. (as applicable). An unusual or special contractual requirement, which would impact on contract performance, should be included as a separate section.

(8) *Deliverables reporting requirements*. All deliverables and/or reports must be clearly and completely described.

307.7107 Review.

Upon receipt of the RFC, the contracting officer shall review its contents to ensure that all pertinent information has been provided by the program office and that it includes an acceptable SOW. If pertinent information is missing or the SOW is inadequate, the contracting officer shall obtain or clarify the information as soon as possible so that the acquisition

schedule can be met. If the program office delays furnishing the information or clarification, the contracting officer should notify the head of the sponsoring program office, in writing, of the possible slippage in the acquisition schedule and the need for an expeditious remedy. The contracting officer should also notify the chief of the contracting office. A program office's or project officer's continued failure to adhere to agreed on milestones should also be reported to the head of the contracting activity.

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 Nonprocurement 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 of debarment, 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, shall mean, unless otherwise stated in this subpart, the head of the contracting activity. Acting in the capacity of the acquiring agency's head, the head of the contracting activity may make the required justifications or determinations, and take the necessary actions, specified in FAR 9.405, 9.406 and 9.407 for his or her respective activity, but only after obtaining the written approval of the debarring or suspending official, as the case may be.

Debarring official means the Assistant Secretary for Management and Budget, or his/her designee.

Initiating official means either the contracting officer, the head of the contracting activity, the Deputy Assistant Secretary for Grants and Acquisition Management, or the Inspector General.

Suspending official means the Assistant Secretary for Management and Budget, or his/her designee.

309.404 List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

(c) The Office of Grants and Acquisition Management (OGAM) shall perform the actions required by FAR 9.404(c).

(4) OGAM shall maintain all documentation submitted by the initiating official recommending the debarment or suspension action and all correspondence and other pertinent documentation generated during the OGAM review.

309.405 Effect of listing.

(a) The head of the contracting activity (HCA) (not delegable) may, with the written concurrence of the debarring or suspending official, make the determinations referenced in FAR 9.405(a), regarding contracts for their respective activities.

(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 acquisition channels to the head of the contracting activity. The documentation must include the date by which approval is required and a compelling reason for the proposed action. Some examples of circumstances that may constitute a compelling reason for the award to, or consent to a subcontract with, a debarred or suspended contractor include:

(i) The property or services to be acquired are available only from the listed contractor;

(ii) The urgency of the requirement dictates that the Department deal with the listed contractor; or

(iii) There are other compelling reasons which require business dealings with the listed contractor.

(2) If the HCA decides to approve the requested action, he/she 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.* Whenever an apparent cause for debarment becomes known to an initiating official, that person shall prepare a report incorporating the information required by 309.470-2, if known, and forward it through appropriate channels with a written recommendation, to the debarring official. Contracting officers shall

forward their reports in accordance with 309.470-1. The debarring official shall initiate an investigation through such means as he/she deems appropriate.

(b) *Decisionmaking process.* The debarring official shall review the results of the investigation, if any, and make a written determination whether or not debarment procedures are to be commenced. A copy of the determination shall be promptly sent through appropriate channels to the initiating official, and the contracting officer, if necessary. If the debarring official determines to commence debarment procedures, he/she shall, after consultation with the Office of the General Counsel, notify the contractor in accordance with FAR 9.406-3(c). If the proposed action is not based on a conviction or judgement 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 Office of the General Counsel shall represent the Department 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.* Whenever an apparent cause for suspension becomes known to an initiating official, that person shall prepare a report incorporating the information required by 309.470-2, if known, and forward it through appropriate channels, with a written recommendation, to the suspending official. Contracting officers shall forward their reports in accordance with 309.470-1. The suspending official shall initiate an investigation through such means as he/she deems appropriate.

(b) *Decisionmaking process.* The suspending official shall review the results of the investigation, if any, and make a written determination whether or not suspension should be imposed. A copy of this determination shall be promptly sent through appropriate channels to the initiating official and the contracting officer, if necessary. If the suspending official determines to

impose suspension, he/she shall, after consultation with the Office of the General Counsel, 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 suspension has been imposed, 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.

A report incorporating the information required by 309.470-2 shall be forwarded, in duplicate, by the contracting officer through acquisition channels to OGAM when:

(a) A contractor 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) A contractor 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.

Each report prepared under 309.470-1 shall be coordinated with the Office of the General Counsel and shall include the following information, where available:

(a) Name and address of contractor.

(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 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 action of the contractor, including an explanation of the method used in making the estimate.

(k) The comments and recommendations of the contracting officer and statements regarding whether the contractor should be suspended or debarred, whether any limitations should be applied to the action, 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 313—SIMPLIFIED ACQUISITION PROCEDURES

Subpart 313.3—Simplified Acquisition Methods

Sec.

313.301 Governmentwide commercial purchase card.

313.303 Blanket purchase agreements (BPAs).

313.303-5 Purchases under BPAs.

313.305 Imprest funds and third party drafts.

313.305-1 General.

313.306 SF 44, Purchase Order—Invoice—Voucher.

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

Subpart 313.3—Simplified Acquisition Methods.

313.301 Governmentwide commercial purchase card.

(b) The Department has issued general guidance concerning the use of governmentwide commercial purchase cards, and has authorized the OPDIVs to establish procedures for the use, administrative and management controls, and training necessary to comply with FAR 13.301.

313.303 Blanket Purchase Agreements (BPAs).

313.303-5 Purchases under BPAs.

(e)(5) Delivery documents, invoices, etc., signed by the Government employee receiving the item or service will be forwarded to the fiscal office or other paying office as designated by the

OPDIV. Payment will be made on the basis of the signed document, invoice, etc. Contracting offices will ensure that established procedures allowing for availability of funds are in effect prior to placement of orders.

313.305 Imprest funds and third party drafts.

313.305-1 General.

Requests to establish imprest funds shall be made to the responsible fiscal office. At larger activities where the cashier may not be conveniently located near the purchasing office, a Class C Cashier may be installed in the purchasing office. Documentation of cash purchases shall be in accordance with instructions contained in the HHS Voucher Audit Manual Part 1, Chapter 1-10.

313.306 SF 44, Purchase Order—Invoice—Voucher.

(d) Since the Standard Form (SF) 44 is an accountable form, a record shall be maintained of serial numbers of the form, to whom issued, and date issued. SF 44's shall be kept under adequate lock and key to prevent unauthorized use. A reservation of funds shall be established to cover total anticipated expenditures prior to use of the SF 44.

PART 314—SEALED BIDDING

Subpart 314.2—Solicitation of Bids

Sec.

314.202 General rules for solicitation of bids.

314.202-7 Facsimile bids.

314.213 Annual submission of representations and certifications.

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 314.2—Solicitation of Bids

314.202 General rules for solicitation of bids.

314.202-7 Facsimile bids.

If the head of the contracting activity (HCA) (not delegable) has determined that the contracting activity will allow use of facsimile bids and proposals, the HCA shall prescribe internal procedures, in accordance with the FAR, to ensure uniform processing and control.

314.213 Annual submission of representations and certifications.

Each HCA (not delegable) shall determine whether the contracting activity will allow use of the annual submission of representations and certifications by bidders.

Subpart 314.4—Opening of Bids and Award of Contract

314.404 Rejection of bids.

314.404-1 Cancellation of invitations after opening.

The chief of the contracting office (CCO) (not delegable) shall make the determinations required to be made by the agency head in FAR 14.404-1.

314.407 Mistakes in bids.

314.407-3 Other mistakes disclosed before award.

(e) Authority has been delegated to the Departmental Protest Control Officer, Office of Acquisition Management, Office of Grants and Acquisition Management, to make administrative determinations in connection with mistakes in bid alleged after opening and before award. This authority may not be redelegated.

(f) Each proposed determination shall have the concurrence of the Chief, Business Law Branch, Business and Administrative Law Division, Office of General Counsel.

(i) Doubtful cases shall not be submitted by the contracting officer directly to the Comptroller General, but shall be submitted to the Departmental Protest Control Officer.

314.407-4 Mistakes after award.

(c) Authority has been delegated to the Departmental Protest Control Officer to make administrative determinations in connection with mistakes in bid alleged after award. This authority may not be redelegated.

(d) Each proposed determination shall have the concurrence of the Chief, Business Law Branch, Business and Administrative Law Division, Office of the General Counsel.

PART 315—CONTRACTING BY NEGOTIATION

Subpart 315.2—Solicitation and Receipt of Proposals and Information

Sec.

315.204 Contract format.

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

- 315.305 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.

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

Subpart 315.2—Solicitation and Receipt of Proposals and Information

315.204 Contract format.

315.204-5 Part IV—Representations and Instructions.

(a) *Section K, Representations, certifications, and other statements of offerors.*

(1) This section shall begin with the following and continue with the applicable representations and certifications:

To Be Completed by the Offeror: (The Representations and Certifications must be executed by an individual authorized to bind the offeror.) The offeror makes the following Representations and Certifications as part of its proposal (check or complete all appropriate boxes or blanks on the following pages).

(Name of Offeror)

(RFP No.)

(Signature of Authorized Individual)

(Date)

(Typed Name of Authorized Individual)

Note: The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

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

(1) *General.* (i) The evaluation factors must be developed by the project officer and submitted to the contracting officer in the request for contract (RFC) for inclusion in the request for proposal (RFP). Development of these factors and the assignment of the relative importance or weight to each require the exercise of judgment on a case-by-case basis because they must be tailored to

the requirements of the individual acquisition. Since the factors will serve as a standard against which all proposals will be evaluated, it is imperative that they be chosen carefully to emphasize those considered to be critical in the selection of a contractor.

(ii) The finalized evaluation factors cannot be changed except by a formal amendment to the RFP issued by the contracting officer. No factors other than those set forth in the RFP shall be used in the evaluation of proposals.

(2) *Review of evaluation factors.*
(i) The evaluation factors should be reviewed by the contracting officer in terms of the work statement. 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 should then review the evaluation factors together to ascertain the following:

(A) The factors are described in sufficient detail to provide the offerors (and evaluators) with a total understanding of the factors to be involved in the evaluation process;

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

(C) The factors are specifically applicable to the instant acquisition and are not merely restatements of factors from previous acquisitions which are not relevant to this acquisition; and

(D) The factors are selected to represent only the significant areas of importance which must be emphasized rather than a multitude of factors. (All factors tend to lose importance if too many are included. Using too many factors will 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 are intended to assist in the development of actual evaluation factors for a specific acquisition and should only be used if they are applicable to that acquisition. They are not to be construed as actual examples of evaluation factors to be included in the RFP.

(i) Understanding of the problem and statement of work;

(ii) Method of accomplishing the objectives and intent of the statement of work;

(iii) Soundness of the scientific or technical approach for executing the requirements of the statement of work (to include, 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 and/or practicality of successfully accomplishing the requirements (to include 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, to include 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; and

(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) When the head of the contracting activity (HCA) for a health agency determines that certain classes of biomedical or behavioral research and development acquisitions should be subject to conditions other than those specified in FAR 52.215-1(c)(3), the HCA may authorize the use of the provision at 352.215-70 in addition to the provision at FAR 52.215-1. This is an authorized 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) Paragraph (e) of the provision at 352.215-1 shall be used in place of that specified at FAR 52.215-1(e). This is an authorized deviation.

(g) If the head of the contracting activity (HCA)(not delegable) has determined that the contracting activity will allow the use of the annual submission of representations and certifications by offerors, the provisions of FAR 14.213 shall be followed.

Subpart 315.3—Source Selection

315.305 Proposal evaluation.

(a)(1) *Cost or price evaluation.* The contracting officer shall evaluate business proposals adhering to the requirements for cost or price analysis included in FAR 15.404. The contracting officer must determine the extent of analysis in each case depending on the amount of the proposal, the technical complexity, and related cost or price. The contracting officer should request the project officer to analyze items such as the number of labor hours proposed for various labor categories; the mix of labor hours and categories of labor in relation to the technical requirements of the project; the kinds and quantities of material, equipment, and supplies; types, numbers and hours/days of proposed consultants; logic of proposed subcontracting; analysis of the travel proposed including number of trips, locations, purpose, and travelers; and kinds and quantities of information technology. The project officer shall provide his/her opinion as to whether these elements are necessary and reasonable for efficient contract performance. Exceptions to proposed elements shall be supported by adequate rationale to allow for effective negotiations or award if discussions are not conducted. The contracting officer should also request the assistance of a cost/price analyst when considered necessary. In all cases, the negotiation memorandum must include the rationale used in determining that the price or cost is fair and reasonable.

(2) *Past performance evaluation.*

When evaluating past performance, the contracting officer is responsible for conducting reference checks to obtain information concerning the performance history of offerors. 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) A technical evaluation plan may be required by the contracting officer, at his/her discretion, when an acquisition is sufficiently complex as to warrant a formal plan.

(B) The technical evaluation plan should include at least the following:

(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 justification for using non-Government technical evaluation panel members. (Justification is not required if non-Government evaluators will be used in accordance with standard contracting activity procedures or policies);

(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 be used to assure consistency with the evaluation criteria; and

(5) A brief description of the general evaluation approach.

(C) The technical evaluation plan must be signed by an official within the program office in a position at least one level above the project officer, or in accordance with contracting activity procedures.

(D) The technical evaluation plan should be submitted to the contracting officer for review and approval before the solicitation is issued. The contracting officer shall make sure that the significant factors and subfactors relating to the evaluation are reflected in the evaluation criteria 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 which are expected to exceed \$500,000 and in which technical evaluation is considered a key element in the award decision. The contracting officer has the discretion to require a technical evaluation panel for acquisitions not exceeding \$500,000 based on the complexity of the acquisition.

(2) The technical evaluation process requires careful consideration regarding

the size, composition, expertise, and function of the technical evaluation panel. The efforts of the panel can result in the success or failure of the acquisition.

(B) *Role of the project officer.* (1) The project officer is the contracting officer's technical representative for the acquisition action. The project officer may be a voting member of the technical evaluation panel, and may also serve as the chairperson of the panel, unless he/she is prohibited by law or contracting activity procedures to do so.

(2) The project officer is responsible for recommending panel members who are knowledgeable in the technical aspects of the acquisition and who are competent to identify strengths and weaknesses of the various proposals. The program training requirements specified in 307.170 must be adhered to when selecting prospective panel members (government employees).

(3) The project officer shall ensure that persons possessing expertise and experience in addressing issues relative to sex, race, national origin, and handicapped discrimination are included as panel members in acquisitions which address those issues. The intent is to balance the composition of the panel so that qualified and concerned individuals may provide insight to other panel members regarding ideas for, and approaches to be taken in, the evaluation of proposals.

(4) The project officer is to submit the recommended list of panel members to an official within the program office in a position at least one level above the project officer, or in accordance with contracting activity procedures. This official will review the recommendations 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 his/her designated representative within the contracting office.

(2) The contracting officer shall not serve as a member of the technical evaluation panel but should be available to:

(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, he/she shall be removed from the panel and replaced with another evaluator. 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 is responsible for evaluating the original proposals, making recommendations to the chairperson regarding weaknesses and deficiencies of proposals, and, if required by the contracting officer, assisting the contracting officer during communications and discussions, and reviewing supplemental, revised and/or final proposal revisions. To the extent possible, the same evaluators should 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; or

(iii) The rankings of the offerors are not affected because the revisions to the proposals are relatively minor.

(2) The chairperson, with the concurrence of the contracting officer, may decide not to have the panel evaluate the revised proposals. Whenever this decision is made, it must be fully documented by the chairperson and approved by the contracting officer.

(3) When technical evaluation panel meetings are considered necessary by the contracting officer, 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 and/or replace the individual after discussing the situation with the contracting officer and obtaining his/her concurrence and the approval of the official responsible for appointing the panel members.

(4) Whenever continuity of the evaluation process is not possible, and either new evaluators are selected or a reduced panel is decided upon, each proposal which is being reviewed at any stage of the acquisition shall be reviewed at that stage by all members of the revised panel unless it is impractical to do so because of the receipt of an unusually large number of proposals.

(F) *Use of outside evaluators.* (1) The National Institutes of Health (NIH) and the Substance Abuse and Mental Health Services Administration (SAMHSA) are required to have a peer review of research and development contracts in accordance with Public Law 93-352 as amended by Public Law 94-63; 42 U.S.C. 289 a and 42 U.S.C. 290aa-3 respectively. This legislation requires peer review of projects and proposals, and not more than one-fourth of the members of a peer review group may be officers or employees of the United States. NIH and SAMHSA are therefore exempt from the provisions of 315.305(a)(3)(ii) to the extent that 42 U.S.C. 289a and 290aa-3 apply. Conflicts of interest are addressed at 42 CFR part 52h. Other agencies subject to statutory scientific peer review requirements are also exempt from the requirements of paragraph (a)(3)(ii) of this section to the extent that these requirements are inconsistent with their legislative requirements.

(2) In general, decisions to disclose proposals outside the Government for evaluation purposes shall be made by the official responsible for appointing panel members for the acquisition, after consultation with the contracting officer and in accordance with operating division procedures. The decision to disclose either a solicited or unsolicited proposal outside the Government for the purpose of obtaining an evaluation shall take into consideration the avoidance of organizational conflicts of interest and any competitive relationship between the submitter of the proposal and the prospective evaluator(s).

(3) When it is determined to disclose a solicited proposal outside the Government for evaluation purposes, the following or similar conditions shall be included in the written agreement with 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 only for evaluation purposes.

The foregoing requirement does not apply to data obtained from another source without restriction.

Any notice or legend placed on the proposal by either the Department 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 the Government furnished copy of the proposal or abstract, and all copies thereof, to the Departmental office which initially furnished the proposal for evaluation.

Unless authorized by the Department's initiating office, the evaluator shall not contact the submitter of the proposal concerning any aspects of its contents.

The evaluator is obligated to obtain commitments from its employees and subcontractors, as necessary, to effect the purposes of these conditions.

(iii) Receipt of proposals.

(A) After the closing date set by the solicitation for the receipt of proposals, the contracting officer will use a transmittal memorandum to forward the technical proposals to the project officer or chairperson for evaluation. The business proposals will be retained by the contracting officer for evaluation.

(B) The transmittal memorandum shall include at least the following:

(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 to conduct discussions.

(4) A requirement for a technical evaluation report in accordance with paragraph (a)(3)(vi) of this section; and

(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 will convene to evaluate the proposals. However, there may be situations when the contracting officer determines that it is not feasible for the panel to convene. Whenever this decision is made, care must be taken to assure that the technical review is closely monitored to produce acceptable results.

(B) When a panel is convened, the chairperson is responsible for the control of the technical proposals provided to him/her by the contracting officer for use during the evaluation process. The chairperson will generally distribute the technical proposals prior to the initial panel meeting and will establish procedures for securing the proposals whenever they are not being evaluated to insure their confidentiality. After the evaluation is complete, all proposals must be returned to the contracting officer by the chairperson.

(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 he/she is unable to attend the initial panel meeting. The guidance should include:

- (1) Explanation of conflicts of interest;
 - (2) The necessity to read and understand the solicitation, especially the statement of work and evaluation criteria, prior to reading the proposals;
 - (3) The need for evaluators to restrict the review to only the solicitation and the contents of the technical proposals;
 - (4) The need for each evaluator to review all the proposals;
 - (5) The need to watch for ambiguities, inconsistencies, errors, and deficiencies which should be surfaced during the evaluation process;
 - (6) An explanation of the evaluation process and what will be expected of the evaluators throughout the process;
 - (7) The need for the evaluators to be aware of the requirement to have complete written documentation of the individual strengths and weaknesses which affect the scoring of the proposals; and
 - (8) An instruction directing the evaluators that, until the award is made, information concerning the acquisition must not be disclosed to any person not directly involved in the evaluation process.
- (v) Rating and ranking of proposals. The evaluators will individually read each proposal, describe tentative strengths and weaknesses, and independently develop preliminary scores in relation to each evaluation factor set forth in the solicitation. After this has been accomplished, the evaluators shall 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 will score each proposal, and then the technical evaluation panel will collectively rank the proposals. Generally, ranking will be determined by adding the numerical scores assigned to the evaluation factors and finding the average for each offeror. The evaluators should then identify whether each proposal is acceptable or unacceptable. Predetermined cutoff scores shall not be employed.
- (vi) Technical evaluation report. A technical evaluation report shall be prepared and furnished to the contracting officer by the chairperson and maintained as a permanent record in the contract file. The report must reflect the ranking of the proposals and identify each proposal as acceptable or unacceptable. The report must also

include a narrative evaluation specifying the strengths and weaknesses of each proposal, a copy of each signed rating sheet, and any reservations, qualifications, or areas to be addressed that might bear upon the selection of sources for negotiation and award. Concrete technical reasons supporting a determination of unacceptability with regard to any proposal must be included. The report should also include specific points and questions which are to be raised in discussions or negotiations.

315.306 Exchanges with offerors after receipt of proposals.

(d) *Exchanges with offerors after establishment of the competitive range.* The contracting officer and project officer should discuss the uncertainties and/or deficiencies that are included in the technical evaluation report for each proposal in the competitive range. Technical questions should be developed by the project officer and/or the technical evaluation panel and should be included in the technical evaluation report. The management, past performance and cost or price questions should be prepared by the contracting officer with assistance from the project officer and/or panel as required. The method of requesting offerors in the competitive range to submit the additional information will vary depending on the complexity of the questions, the extent of additional information requested, the time needed to analyze the responses, and the time frame for making the award. However, to the extent practicable, all questions and answers should be in writing. Each offeror in the competitive range shall be given an equitable period of time for preparation of responses to questions to the extent practicable. The questions should be developed so as to disclose the ambiguities, uncertainties, and deficiencies of the offeror.

315.307 Proposal revisions.

(b) Final proposal revisions are subject to 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, and an evaluation of technical factors by the technical evaluation panel, as necessary. Proposals may be technically rescored and reranked by the technical evaluation panel and a technical evaluation report prepared. To the extent practicable, the evaluation shall be performed by the same evaluators who reviewed the original proposals. A final evaluation of past performance will be made by the contracting officer and project officer.

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, finalization of details with the selected offeror may be conducted if deemed necessary. However, no factor which could have any effect on the selection process may be introduced after the common cutoff date for receipt of final proposal revisions. The finalization process shall not in any way prejudice the competitive interest or rights of the unsuccessful offerors. Finalization of details with the selected offeror shall be restricted to definitizing the final agreement on terms and conditions, assuming none of these factors were involved in the selection process.

(b) Caution must be exercised by the contracting officer to insure that the finalization process is not used to change the requirements contained in the solicitation, nor to make any other changes which would impact on the source selection decision. Whenever a material change occurs in the requirements, the competition must be reopened and all offerors submitting final proposal revisions must be given an opportunity to resubmit proposals based on the revised requirements. Whenever there is a question as to whether a change is material, the contracting officer should obtain the advice of technical personnel and legal counsel before reopening the competition. Significant changes in the offeror's cost proposal may also necessitate a reopening of competition if the changes alter the factors involved in the original selection process.

(c) Should finalization details beyond those specified in paragraph (a) of this section be required for any reason, discussions must be reopened with all offerors submitting final proposal revisions.

(d) Upon finalization of details, the contracting officer should obtain a confirmation letter from the successful offeror which includes any revisions to the technical proposal, the agreed to price or cost, and, as applicable, a certificate of current cost or pricing data.

315.371 Contract preparation and award.

(a) The contracting officer must perform the following actions after finalization details have been completed:

(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 contract should be transmitted to the prospective contractor for signature. The prospective contractor must be informed that the contract is not effective until accepted by the contracting officer.

(c) The contract shall not be issued until the finance office certifies that the funds are available for obligation.

315.372 Preparation of negotiation memorandum.

The negotiation memorandum or summary of negotiations is a complete record of all actions leading to award of a contract and is prepared by the contract negotiator to support the source selection decision discussed in FAR 15.308. It should be in sufficient detail to explain and support the rationale, judgments, and authorities upon which all actions were predicated. The memorandum will document the negotiation process and reflect the negotiator's actions, skills, and judgments in concluding a satisfactory agreement for the Government. Negotiation memorandums shall contain discussion of the following or a statement of nonapplicability; however, information already contained in the contract file need not be reiterated. A reference to the document which contains the required information is acceptable.

(a) *Description of articles and services and period of performance.* A description of articles and services, quantity, unit price, total contract amount, and period of contract performance should be set forth (if Supplemental Agreement—show previous contract amount as revised, as well as information with respect to the period of performance).

(b) *Acquisition planning.* Summarize or reference any acquisition planning activities that have taken place.

(c) *Synopsis of acquisition.* A statement as to whether the acquisition has or has not been publicized in accordance with FAR Subpart 5.2. A brief statement of explanation should be included with reference to 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.* The extent to which full and open competition was solicited and obtained must be discussed. The discussion shall 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 past performance evaluation and reference checks.

(i) *Competitive range (if applicable).* Describe how the competitive range was determined and state the offerors who were included in the competitive range and the ones who were not.

(j) *Cost breakdown and analysis.* Include a complete cost breakdown together with the negotiator's analysis of the estimated cost by individual cost elements. The negotiator's analysis should contain information such as:

(1) A comparison of cost factors proposed in the instant case 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 of 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 and rationale of the cost analysis.

(5) If the contract is an incentive type, discuss all elements of profit and fee structure.

(6) A justification of the reasonableness of the proposed contractor's estimated profit or fixed fee, considering the requirements of FAR 15.404-4 and HHSAR 315.404-4.

(k) *Cost realism.* Describe the cost realism analysis performed on proposals.

(l) *Government-furnished property and Government-provided facilities.*

With respect to Government-furnished or Government-provided facilities, equipment, tooling, or other property, include the following:

(1) Where no property is to be provided, a statement to that effect.

(2) Where property is to be provided, a full description, the estimated dollar value, the basis of price comparison with competitors, and the basis of rental charge, if rental is involved.

(3) Where the furnishing of any property or the extent has not been determined and is left open for future resolution, a detailed explanation.

(m) *Negotiations.* Include a statement as to the date and place negotiations were conducted, and identify members of both the Government and contractor negotiating teams by area of responsibility. Include negotiation details relative to the statement of work, terms and conditions, and special provisions. The results of cost or price negotiations must include the information required by FAR 31.109 and 15.406-3. In addition, if cost or pricing data was required to be submitted, the negotiation record must also contain the extent to which the contracting officer relied upon the factual cost or pricing data submitted and used in negotiating the cost or price.

(n) *Other considerations.* Include coverage of areas such as:

(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 payment, advance payment, etc., is necessary. Also cite any required D & F's.

(4) Information with respect to obtaining of 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) should be reflected. Also, a determination should be made that the Government has obtained enough actual or potential value from the work previously performed to warrant continuation with the same contractor. (Project officer should furnish the necessary information.)

(7) If the contract was awarded by full and open competition, state where the unsuccessful offerors' proposals are filed.

(8) State that equal opportunity provisions of the proposed contract have been explained to the contractor, and it is aware of its responsibilities. Also state whether or not a clearance is required.

(9) If the contract is for services, a statement must be made, in accordance with FAR 37.103, that the services to be acquired 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, incremental funding, anticipatory costs, deviations from standard clauses, etc. The basis and rationale for inclusion of any special terms and conditions must be stated and, where applicable, the document which granted approval for its use identified.

(p) *Recommendation.* A brief statement setting forth the recommendations for award.

(q) *Signature.* The memorandum must be signed by the contract negotiator who prepared the memorandum.

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, contracting officers 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 is to 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 (ACO), 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 Audits' Regional Audit Director. 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 to be followed by a 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.) One copy of the audit request letter that was submitted to the Regional Audit Director and a complete copy of the contract price proposal shall be submitted to OIG/OA/DAC. Whenever, an audit review has been conducted by the Office of Audits, two (2) copies of the memorandum of negotiation shall be forwarded to OIG/OA/DAC by the contracting officer.

315.404-4 Profit.

(b) *Policy.* (1) The structured approach for determining profit or fee (hereafter referred to as profit) provides contracting officers with a technique that will ensure consideration of the relative value of the appropriate profit factors described in paragraph (d) of this section in the establishment of a profit objective for the conduct of negotiations. The contracting officer's analysis of these profit factors is based on information available to him/her prior to negotiations. The information is furnished in proposals, audit data, assessment reports, preaward surveys and the like. The structured approach also provides a basis for documentation of this objective, including an explanation of any significant departure from this objective in reaching an agreement. The extent of documentation should be directly related to the dollar value and complexity of the proposed acquisition. Additionally, the negotiation process does not require agreement on either estimated cost elements or profit elements. The profit objective is a part of an overall negotiation objective which, as a going-in objective, bears a distinct relationship to the cost objective and any proposed sharing arrangement. Since profit is merely one of several interrelated variables, the Government negotiator generally should not complete the profit negotiation without simultaneously agreeing on the other variables. Specific agreement on the exact weights or values of the individual profit factors is not required and should not be attempted.

(ii) The profit-analysis factors set forth at FAR 15.404-4(d) shall be used for establishing profit objectives under the following listed circumstances. Generally, it is expected that this method will be supported in a manner

similar to that used in the structured approach (profit factor breakdown and documentation of the profit objective); however, factors within FAR 15.404-4(d) considered inapplicable to the acquisition will be excluded from the profit objective.

- (A) Contracts not expected to exceed \$100,000;
- (B) Architect-engineer contracts;
- (C) Management contracts for operations and/or maintenance of Government facilities;
- (D) Construction contracts;
- (E) Contracts primarily requiring delivery of material supplies by subcontractors;
- (F) Termination settlements; and
- (G) Cost-plus-award-fee contracts

(However, contracting officers may find it advantageous to perform a structured profit analysis as an aid in arriving at an appropriate fee arrangement). Other exceptions may be made in the negotiation of contracts having unusual pricing situations, but shall be justified in writing by the contracting officer in situations where the structured approach is determined to be unsuitable.

(c) *Contracting officer responsibilities.* 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 objective should realistically reflect the total overall task to be performed and the requirements placed on the contractor. Development of a profit objective should not begin until a thorough review of proposed contract work has been made; a review of all available knowledge regarding the contractor pursuant to FAR subpart 9.1, including audit data, preaward survey reports and financial statements, as appropriate, has been conducted; and an analysis of the contractor's cost estimate and comparison with the Government's estimate or projection of cost has been made.

(d) *Profit—analysis factors* (1) *Common factors.* The following factors shall be considered in all cases in which profit is to be negotiated. The weight ranges listed after each factor shall be used in all instances where the structured approach is used.

Profit factors	Weight ranges (in percent)
Contractor effort:	
Material acquisition	1 to 5.
Direct labor	4 to 15.
Overhead	4 to 9.
General management (G&A).	4 to 8.

Profit factors	Weight ranges (in percent)
Other costs	1 to 5.
Other factors:	
Cost risk	0 to 7.
Investment	- 2 to +2.
Performance	- 1 to +1.
Socioeconomic programs	- .5 to +.5.
Special situations..	

(i) Under the structured approach, the contracting officer shall first measure "Contractor Effort" by the assignment of a profit percentage within the designated weight ranges to each element of contract cost recognized by the contracting officer. The amount calculated for the cost of money for facilities capital is not to be included for the computation of profit as part of the cost base. The suggested categories under "Contractor Effort" are for reference purposes only. Often individual proposals will be in a different format, but since these categories are broad and basic, they provide sufficient guidance to evaluate all other items of cost.

(ii) After computing a total dollar profit for "Contractor Effort," the contracting officer shall then calculate the specific profit dollars assigned for cost risk, investment, performance, socioeconomic programs, and special situations. This is accomplished by multiplying the total Government Cost Objective, exclusive of any cost of money for facilities capital, by the specific weight assigned to the elements within the "Other Factors" category. Form HHS-674, Structured Approach Profit/Fee Objective, should be used, as appropriate, to facilitate the calculation of this profit objective. Form HHS-674 is illustrated in 353.370-674.

(iii) In making a judgment of the value of each factor, the contracting officer should be governed by 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, if appropriate adjustments are made to reflect differences between profit and nonprofit organizations, the structured approach can be used as a basis for arriving at profit objectives for nonprofit organizations. Therefore, the structured approach, as modified in paragraph (d)(1)(iv)(B) of this section, shall be used to establish profit 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 of the Internal Revenue Code.

(B) For contracts with nonprofit organizations where profit is involved, an adjustment of up to 3 percentage points will be subtracted from the total profit objective percentage. In developing this adjustment, it will be necessary to consider the following factors;

- (1) Tax position benefits;
- (2) Granting of financing through advance payments; and
- (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 the contractor must do 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 should reflect the extent and nature of the contractor's contribution to total performance. A major consideration, particularly in connection with experimental, developmental, or research 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 and/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 will be required to develop complex specifications. Consideration

shall also be given to the managerial and technical efforts necessary for the prime contractor to select subcontractors and to perform subcontract administration functions. In application of this criterion, it should be recognized that the contribution of the prime contractor to its purchasing program may be substantial. Normally, the lowest unadjusted weight for direct material is 2 percent. A weighting of less than 2 percent would 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 should 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, consideration should be given to the amount of notable scientific talent or unusual or scarce talent needed in contrast to nonprofessional effort. The assessment should consider the contribution this talent will provide toward the achievement of contract objectives. Since nonprofessional labor is relatively plentiful and rather easily obtained by the contractor and is less critical to the successful performance of contract objectives, it cannot be weighted nearly as high as professional or semiprofessional labor. Service contract labor should be evaluated in a like manner by assigning higher weights to engineering or professional type skills required for contract performance. Similarly, the variety of manufacturing and other categories of labor skills required and the contractor's manpower resources for meeting these requirements should be considered. For purposes of evaluation, categories of labor (*i.e.*, quality control, receiving and inspection, etc.) which do not fall within the definition for professional, service or manufacturing labor may be categorized as appropriate. However, the same evaluation considerations as outlined in this paragraph will be applied.

(iii) *Overhead and general management (G&A).* (A) Analysis of these overhead items of cost should include the evaluation of the makeup of these expenses and how much they contribute to contract performance. To the extent practicable, analysis should include a determination of the amount of labor within these overhead pools and how this labor should be treated if it were considered as direct labor under

the contract. The allocable labor elements should be given the same profit considerations that they would receive if they were treated as direct labor. The other elements of these overhead pools should be evaluated 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 will 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, could 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) Management problems surface in various degrees and the management expertise exercised to solve them should be considered as an element of profit. For example, a contract for a new program for research or an item which is on the cutting edge of the state of the art will 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, follow-ons should be adjusted downward because many of the problems should have been solved. In any event, an evaluation should be made of 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 an

analysis of the profit weight to be assigned to the overhead pool has been made, that weight assigned may be used for future acquisitions with the same contractor until there is a change in the cost composition of the overhead pool or the contract circumstances, or the factors discussed in paragraph (d)(2)(iii)(C) of this section are involved.

(iv) *Other costs.* Analysis of this factor should include all other direct costs associated with contractor performance (e.g., travel and relocation, direct support, and consultants). Analysis of these items of cost should 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 1%. Also, the contractor may designate individuals as "consultants" but in reality these individuals may be obtained by the contractor to supplement its workforce in the performance of routine duties required by contract. These costs would normally receive a minimum weight. However, there will be instances when the contractor may be required to locate and obtain the services of consultants having expertise in fields such as medicine or human services. In these instances, the contractor will be required to expend greater managerial and technical effort to obtain these services and, consequently, the costs should 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 should be less than where the contractor assumes all the risk.

(A) In developing the prenegotiation profit objective, the contracting officer will need to consider the type of contract anticipated to be negotiated and the contractor risk associated therewith when selecting the position in the weight range for profit that is appropriate for the risk to be borne by the contractor. This factor should be one of the most important in arriving at prenegotiation profit objective. Evaluation of this risk requires a determination of the degree of cost responsibility the contractor assumes; the reliability of the cost estimates in relation to the task assumed; and the complexity of the task assumed by the contractor. This factor is specifically

limited to the risk of contract costs. Thus, risks on the part of the contractor such as reputation, losing a commercial market, risk of losing potential profits in other fields, or any risk which falls on the contracting office, such as the risk of not acquiring a satisfactory report, 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-a-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-a-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. Where proper contract selection has been made, the regard for risk by contract type would usually fall 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 related efforts. An excessive cost estimate reduces the possibility 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 incident to 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. Where proper contract-type selection has been made, 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 developed by using the structured approach for

research and development 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 developed by using 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 that is closely priced 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 assumed by the contractor 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 or risk under a contract form. It could cause risk to increase or decrease in terms of both cost and performance. This consideration should be a part of the contracting officer's overall evaluation in selecting a factor to apply for cost risk. It may be determined, 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. The contract cost risk evaluation should not be lowered, however, merely on the basis that a substantial portion of the contract costs represents subcontracts without any substantial transfer of contractor's risk.

(H) In making a contract cost risk evaluation in an acquisition action that involves definitization of a letter contract, unpriced change orders, and unpriced orders under basic ordering agreements, consideration should be given to the effect on total contract cost risk as a result of having partial performance before definitization. Under some circumstances it may be reasoned that the total amount of cost risk has been effectively reduced. Under other circumstances it may be apparent that the contractor's cost risk remained substantially unchanged. To be equitable, the determination of profit weight for application to the total of all recognized costs, both those incurred and those yet to be expended, must be made with consideration to all attendant circumstances—not just the portion of costs incurred or percentage of work completed prior to definitization.

(I) Time and material and labor hour contracts will be considered to be cost-plus-a-fixed-fee contracts for the purpose of establishing profit weights unless otherwise exempt under paragraph (b)(1)(ii) of this section in the evaluation of the contractor's assumption of contract cost risk.

(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 should include an analysis of the following:

(A) *Facilities.* (Including equipment). To evaluate 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. Contractors who furnish their own facilities which significantly contribute to lower total contract costs should be provided with additional profit. On the other hand, contractors who rely on the Government to provide or finance needed facilities should receive a corresponding reduction in profit. Cases between these examples

should be evaluated on their merits with either positive or negative adjustments, as appropriate, in profit being made. However, where a highly facilitated contractor is to perform a contract which does not benefit from this facilitation or where a contractor's use of its facilities has a minimum cost impact on the contract, profit need not be adjusted. When applicable, the prospective contractor's computation of facilities capital cost of money for pricing purposed under CAS 414 can help the contracting officer identify the level of facilities investment to be employed in contract performance.

(B) *Payments.* In analyzing this factor, consideration should be given to 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 should be given for advance payments and payments more frequent than monthly with maximum reduction being given as the contractor's working capital approaches zero. Positive consideration should be given for payments less frequent than monthly with additional consideration given for a capital turn-over rate on the contract which is less than the contractor's or the industry's normal capital turn-over rate.

(iii) *Performance.* (Cost-control and other past accomplishments.) The contractor's past performance should be evaluated in such areas as quality of service or product, meeting performance schedules, efficiency in cost control (including need for and reasonableness of cost incurred), accuracy and reliability of previous cost estimates, degree of cooperation by the contractor (both business and technical), timely processing of changes and compliance with other contractual provisions, 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 should be reflected in determining what constitutes a fair and reasonable 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 such as small business, small disadvantaged business, women-owned small business, and energy conservation efforts. The contractor's policies and procedures which energetically support

Government socioeconomic programs and achieve successful results should be given positive considerations.

Conversely, failure or unwillingness on the part of the contractor to support Government socioeconomic programs should be viewed as evidence of poor performance for the purpose of establishing a profit objective.

(v) *Special situations* (A) *Inventive and developmental contributions*. The extent and nature of contractor-initiated and financed independent development should be considered in developing the profit objective, provided that the contracting officer has made a determination that the effort will benefit the contract. The importance of the development in furthering health and human services purposes, the demonstrable initiative in determining the need and application of the development, the extent of the contractor's cost risk, and whether the development cost was recovered directly or indirectly from Government sources should be weighed.

(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 contractor should receive favorable consideration in developing the 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, a reduction in the profit objective shall be made in an amount equal to the amount of facilities capital cost of money allowed in accordance with the Facilities Capital Cost-of Money Cost Principal. If the contractor does not propose this cost, a provision must be inserted in the contract that facilities capital cost of money is not an allowable cost.

Subpart 315.6—Unsolicited Proposals

315.605 Content of unsolicited proposals.

(d) Certification by offeror—To ensure against contacts between Department employees and prospective offerors which would exceed the limits of advance guidance set forth in FAR

15.604 resulting in an unfair advantage to an offeror, the contracting officer shall ensure that the following certification is furnished to the prospective offeror and the executed certification is included as part of the 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 employees of the Department of Health and Human Services has been within the limits of appropriate advance guidance set forth in FAR 15.604.

(d) No prior commitments were received from departmental employees regarding acceptance of this proposal.

Date: _____

Organization: _____

Name: _____

Title: _____

(This certification shall be signed by a responsible official of the proposing organization or 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 his/her designee shall be the point of contract for coordinating the receipt and handling of unsolicited proposals.

315.606-1 Receipt and initial review.

(d) An unsolicited proposal shall not be refused consideration merely because it was initially submitted as a grant application. However, contracts shall not be awarded on the basis of unsolicited proposals which have been rejected for grant support on the grounds that they lack scientific merit.

315.609 Limited use of data.

The legend, Use and Disclosure of Data, prescribed in FAR 15.609(a) is to be used by the offeror to restrict the use of data for evaluation purposes only. However, data contained within the unsolicited proposal may have to be disclosed as a result of a request submitted pursuant to the Freedom of Information Act. Because of this possibility, the following notice shall be furnished to all prospective offerors of unsolicited proposals whenever the legend is provided in accordance with FAR 15.604(a)(7):

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.) nor 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 involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. Records which the offeror considers to be trade secrets and commercial or financial information and privileged or confidential must be identified by the offeror as indicated in the referenced legend.

PART 316—TYPES OF CONTRACTS

Subpart 316.3—Cost-Reimbursement Contracts

Sec.

316.307 Contract clauses.

Subpart 316.6—Time-and-Materials, Labor-Hour, and Letter Contracts

316.603 Letter contracts.

316.603-3 Limitations.

316.603-70 Information to be furnished when 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.

316.770-1 Letter of intent.

316.770-2 Memorandums 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 the contract is with a hospital (profit or nonprofit) for research and development, 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 at 352.216-72, Additional Cost Principles, in all solicitations and resultant cost-reimbursement contracts.

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 execute the prescribed written statement.

316.603-70 Information to be furnished when requesting authority to issue a letter contract.

The following information should be included by the contracting officer in any memorandum requesting approval to issue 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) 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, a justification for that obligation must be included which would indicate the basis and necessity for the 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 must assure 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, complete justification must be given.
- (l) Statement of any substantive matters that need to be resolved.

316.603-71 Approval for modifications to letter contracts.

All letter contract modifications (amendments) must be approved one level above the contracting officer. Request for authority to issue letter contract modifications shall be processed in the same manner as requests for authority to issue letter contracts and shall include the following:

- (a) Name and address of the contractor.
- (b) Description of work and services.
- (c) Date original request was approved and indicate approving official.
- (d) Letter contract number and date issued.

(e) Complete justification as to why the letter contract cannot be definitized at this time.

(f) Complete justification as to why the level of funding must be increased.

(g) Complete justification as to why the period of effectiveness is 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 information required by 316.603-70(j) must be included.

Subpart 316.7—Agreements**316.770 Unauthorized types of agreements.****316.770-1 Letters of intent.**

A letter of intent is an informal unauthorized agreement between the Government and a prospective contractor which indicates that products or services will be produced after completion of funding and/or other contractual formalities. Letters of intent are often solicited by prospective contractors or may be originated by Government personnel. Letters of intent are not authorized by the FAR and are prohibited for use by Department personnel.

316.770-2 Memorandums of understanding.

A "memorandum of understanding" is an unauthorized agreement, usually drafted during the course of negotiations, to modify mandatory FAR and HHSAR provisions in such a manner as to make them more acceptable to a prospective contractor. It may be used to bind the contracting officer in attempting to exercise rights given the Government under the contract, or may contain other matters directly contrary to the language of the solicitation or prospective contractual document. Use of memorandums of understanding is not authorized. Any change in a solicitation or contract shall be made by amendment or modification to that document. When a change to a prescribed contract clause is considered necessary, a deviation shall be requested.

PART 317—SPECIAL CONTRACTING METHODS**Subpart 317.2—Options**

Sec.
317.201 Definition.

Subpart 317.71—Supply and Service Acquisitions Under the Government Employees Training Act.

317.7100 Scope of subpart.
317.7101 Applicable regulations.

317.7102 Acquisition of training.

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

Subpart 317.2—Options**317.201 Definitions.**

An option must:

- (a) Identify the supplies or services as a discrete option quantity in addition to the basic quantity of supplies or services to be delivered under the initial contract award;

- (b) Establish a price or specify a method of calculation which will make the price certain;

- (c) Be agreed to and included in the initial contract award; and

- (d) Permit the Government the right to exercise the option unilaterally.

Subpart 317.71—Supply and Service Acquisitions Under the Government Employees Training Act**317.7100 Scope of subpart.**

This subpart provides alternate methods for obtaining training under the Government Employees Training Act (GETA), 5 U.S.C. Chapter 41.

317.7101 Applicable regulations.

Basic policy, standards, and delegations of authority to approve training are contained in HHS Personnel Manual Instruction 410-1.

317.7102 Acquisition of training.

- (a) Off-the-shelf training, whether for individuals or for groups of employees, shall be acquired under the GETA by officials delegated authority in HHS Transmittal 95.5, Personnel Manual (3/30/95).

- (b) Training must be acquired through the contracting office if there are costs for training course development or for modification of off-the-shelf training courses.

PART 319—SMALL BUSINESS PROGRAMS**Subpart 319.2—Policies**

Sec.
319.201 General policy.

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 the Department's Small Business Program, (small, HUBZone, small disadvantaged, and women-owned small business programs) are delegated to the Director of the Office of Small and Disadvantaged Business Utilization (OSDBU).

(e) (1) The Department's Small Business Program shall be carried out by appointed small business specialists (SBS) at the OPDIV Level. Appointments, and termination of appointments, shall be made in writing by the head of the OPDIV after consultation and concurrence by the Director, OSDBU. The small business specialist shall be responsible directly to the appointing authority and shall be at an organizational level outside the direct acquisition chain of command, i.e., should report directly to the head of the OPDIV or designee. The Director, OSDBU will exercise functional management authority over small business specialists regarding the small business programs.

(2) The head of each OPDIV shall appoint a qualified full-time small business specialist (SBS) in the following activities: Administration for Children and Families (ACF), Agency for Healthcare Research and Quality (AHRQ), Health Care Financing Administration (HCFA), Substance Abuse and Mental Health Services Administration (SAMHSA), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDCP), and Program Support Center (PSC). A SBS shall also be appointed for the Office of the Secretary (OS). As deemed necessary, additional small business specialists may be appointed in larger contracting activities. When the volume of contracting does not warrant assignment of a full-time SBS, an individual shall be appointed as the specialist on a part-time basis. The responsibilities of this assignment shall take precedence over other responsibilities.

Subpart 319.5—Set-Asides For Small Business

319.501 General.

(d) Subsequent to the contracting officer's recommendation on Form HHS653, Small Business Set-Aside Review Form, the SBS shall review each

proposed acquisition and either concur or non-concur with the contracting officer's recommendation. If the contracting officer disapproves the SBS's set-aside recommendation, the reasons must be documented on the Form HHS-653, and the form placed in the contract file. The contracting officer will 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 telephone notification regarding all set-aside withdrawals to the OSDBU Director.

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 SBA PCR shall be allowed a period of one to five working days to review the contract award package, depending upon the circumstances and complexity of the individual acquisition.

PART 323—ENVIRONMENT, CONSERVATION, 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.

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. Walsh-Healy Act; Service Contract Act) require adherence to minimum safety and health standards by contractors engaged in potentially hazardous work. The guidance contained in FAR subpart 23.3 shall be used for hazardous materials as the primary reference. When the guidance is judged insufficient or does not meet the safety

and health situation in the instant acquisition, this subpart shall be followed.

323.7002 Actions required.

(a) *Contracting activities.* Contracting activities shall use the clause set forth in 352.223-70, or a clause reading substantially the same, in prospective contracts and subcontracts involving hazardous materials or operations for the following:

(1) Services or products;

(2) Research, development, or test projects;

(3) Transportation of hazardous materials; and

(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 should be included in 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 a request for contract, 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 office 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.

PART 324—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

Subpart 324.1—Protection of Individual Privacy

Sec.

324.100 Scope of subpart.

324.102 General.

324.103 Procedures.

Subpart 324.2—Freedom of Information Act

324.202 Policy.

Subpart 324.70—Confidentiality of Information

324.7001 General.

324.7002 Policy.

324.7003 Applicability.

324.7004 Required clause.

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

Subpart 324.1—Protection of Individual Privacy

324.100 Scope of subpart.

This subpart implements 45 CFR Part 5b, Privacy Act Regulations, and FAR Subpart 24.1, Protection of Individual Privacy, which implements the Privacy Act of 1974 (Public Law 93-579, December 31, 1974; 5 U.S.C. 552a) and OMB Circular No. A-108, July 9, 1975.

324.102 General.

(a) It is the Department's policy to protect the privacy of individuals to the maximum possible extent while permitting the exchange of records required to fulfill the Department's 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 Department's 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 a departmental function is involved. Therefore, the Privacy Act requirements apply to a departmental contract when, under the contract, the contractor must maintain or operate a system of records to accomplish a departmental function.

(e) The program official, and, as necessary, the official designated as the activity's Privacy Act Coordinator and the Office of General Counsel, shall determine the applicability of the Act to each proposed acquisition. The program official is required to include a statement in the request for contract indicating whether the Privacy Act is or is not applicable to the proposed acquisition.

(f) Whenever the 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 subpart 324.70).

324.103 Procedures.

(a) All requests for contract shall be reviewed by the contracting officer to determine whether the Privacy Act requirements are applicable. If applicable, the contracting officer shall include the solicitation notification and contract clause required by FAR 24.104 in the solicitation, and the contract clause in the resultant contract. In

addition, the contracting officer shall ensure that the solicitation notification, contract clause, and other pertinent information specified in this subpart are included in any contract modification which results in the Privacy Act requirements becoming applicable to a contract.

(b)(1) The contracting officer shall identify the system(s) of records on individuals in solicitations, contracts, and contract modifications to which the Privacy Act and the implementing regulations are applicable.

(2) The contracting officer shall include a statement in the contract notifying the contractor that the contractor and its employees are subject to criminal penalties for violations of the Act (5 U.S.C. 552a(i)) to the same extent as employees of the Department. The statement shall require that the contractor assure that each contractor employee knows the prescribed rules of conduct, and each contractor employee is aware that he/she can be subjected to criminal penalties for violations of the Act. The contracting officer shall provide the contractor with a copy of the rules of conduct and other requirements set forth in 45 CFR part 5b.

(c) The contracting officer shall include in the contract the disposition to be made of the system(s) of records on individuals upon completion of performance of the contract. For example, the contract may require the contractor to completely destroy the records, to remove personal identifiers, to turn the records over to the Department, or to keep the records but take certain measures to keep the records confidential and protect the individuals' privacy.

(d) Whenever an acquisition is determined to be subject to the Privacy Act requirements, a "system notice," prepared by the program official and describing the Department's 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, is required to be published in the **Federal Register**. A copy of the "system notice" shall be attached to the request for contract or purchase request. If a "system notice" is not attached, the contracting officer shall inquire about its status and shall obtain a copy from the program official 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 publication is verified by the contracting officer.

Subpart 324.2—Freedom of Information Act

324.202 Policy.

(a) The Department's 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 Department and operating division procedures. As necessary, actions should be coordinated with the cognizant Freedom of Information (FOI) Officer and the Business and Administrative Law Division of the Office of General Counsel. The contracting officer must remember that only the FOI Officer has the authority to release or deny release of records. While the contracting officer should be familiar with the entire FOIA regulation in 45 CFR part 5, particular attention should be focused on §§ 5.65 and 5.66; also of interest are §§ 5.32, 5.33, and 5.35.

Subpart 324.70—Confidentiality of Information

324.7001 General.

In performance of certain HHS contracts, it is necessary for the contractor to generate data, or be furnished data by the Government, which is about individuals, organizations, or Federal programs. This subpart and the accompanying contract clause require contractors to prudently handle disclosure of certain types of information not subject to the Privacy Act or the HHS human subject regulations set forth in 45 CFR part 46. This subpart and contract clause address the kinds of data to be generated by the contractor and/or data to be furnished by the Government that are considered confidential and how it should be treated.

324.7002 Policy.

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

324.7003 Applicability.

(a) The "Confidentiality of Information" clause, set forth in 352.224-70, should be used in

solicitations and resultant contracts whenever the need exists to keep information confidential. Examples of situations where the clause may be appropriate include:

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

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

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

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

324.7004 Required clause.

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

PART 325—FOREIGN ACQUISITION

Subpart 325.1—Buy American Act—Supplies

Sec.

325.102 Policy.

325.108 Excepted articles, materials, and supplies.

Subpart 325.3—Balance of Payments Program

325.302 Policy.

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

Subpart 325.1—Buy American Act—Supplies

325.102 Policy.

(b) The head of the contracting activity (not delegable) shall make the determinations required by FAR 25.102(a)(1) through (5) and 25.102(b)(2).

325.108 Excepted articles, materials, and supplies.

(b) Articles, materials, and supplies not listed in FAR 25.108(d) may be excepted only after a written determination has been made by the head of the contracting activity (not delegable). These determinations are required only in instances where it has been determined that only suppliers of foreign source end items shall be solicited. However, approvals and determinations covering individual acquisitions in the following categories may be made by the contracting officer:

- (1) Acquisition of spare and replacement parts for foreign manufactured items, if the acquisition must be restricted to the original manufacturer or its supplier; and
- (2) Acquisition of foreign drugs when it has been determined, in writing, by the responsible program official, that only the requested foreign drug will fulfill the requirement.

Subpart 325.3—Balance of Payments Program

325.302 Policy.

All determinations addressed in FAR 25.302 shall be made by the head of the contracting activity (not delegable).

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 Department 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 will be limited to 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 at 352.228-7, Insurance—Liability to Third Persons, in all solicitations and resulting cost-reimbursement contracts, in lieu of the clause at FAR 52.228-7 required by FAR 28.311-1. This is an authorized 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.

(c) The requirements of FAR 30.201-5 shall be exercised by the Director, Office of Acquisition Management (DOAM). Requests for waivers shall be forwarded through normal acquisition channels to the DOAM.

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 Costs

332.501 General.

332.501-2 Unusual progress payments.

Subpart 332.7—Contract Funding

332.702 Policy.

332.703 Contract funding requirements.

332.703-1 General.

332.704 Limitations of cost or funds.

332.705 Contract clauses.

332.705-2 Clauses for limitation of costs or funds.

Subpart 332.9—Prompt Payment

332.902 Definitions.

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 determination that the making of an advance payment is in the public interest (see FAR 32.402(c)(1)(iii)(A)) shall be made by the respective chief of the contracting office (CCO)(not delegable).

332.403 Applicability.

All contracts for research work 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 (not delegable) is authorized to make the determinations in FAR 32.407(d) and as follows. In addition to the interest-free advance payments for the types of contracts listed in FAR 32.407(d), advance payments without interest may be approved for nonprofit contracts which are without fee with educational institutions and other nonprofit organizations, whether public or private, which are for the performance of work involving health services, educational programs, or social service programs, including, but not limited to, programs such as:

- (1) Community health representative services for an Indian Tribe or Band;
- (2) Narcotic addict rehabilitative services;
- (3) Comprehensive health care service program 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 handicapped persons including captioned films for the hearing impaired;
- (8) Operation of language or area centers;
- (9) Conduct of biomedical research and support services;
- (10) Research surveys or demonstrations involving the training and placement of health manpower and health professionals, and dissemination of related information; and
- (11) Surveys or demonstrations in the field of social service.

332.409 Contracting officer action.**332.409-1 Recommendation for approval.**

The information in FAR 32.409-1 (or FAR 32.409-2) shall be transmitted to

the HCA in the form of a briefing memorandum.

Subpart 332.5—Progress Payments Based on Cost**332.501 General.****332.501-2 Unusual progress payments.**

(a)(3) The approval of an unusual progress payment shall be made by the head of the contracting activity (HCA)(not delegable).

Subpart 332.7—Contract Funding**332.702 Policy.**

An incrementally funded contract is a contract in which the total work effort is to be performed over multiple time periods and funds are allotted to cover discernible phases or increments of performance.

(a) Incremental funding may be applied to cost-reimbursement type contracts for the acquisition of research and development and other types of nonpersonal, nonseverable services. It shall not be applied to contracts for construction services, architect-engineer services, or severable services. Incremental funding allows nonseverable cost-reimbursement contracts, awarded for more than one year, to be funded from succeeding fiscal years.

(b) It is departmental policy that contracts for projects of multiple year duration be fully funded, whenever possible, to cover the entire project. However, incrementally funded contracts may be used when:

- (1) A project, which is part of an approved program, is anticipated to be of multiple year duration, but funds are not currently available to cover the entire project;
- (2) The project represents a valid need for the fiscal year in which the contract is awarded and of the succeeding fiscal years of the project's duration, during which additional funds may be obligated by increasing the allotment to the contract;
- (3) The project is so significant to the approved program that there is reasonable assurance that it will command a high priority for proposed appropriations to cover the entire multiple year duration; and
- (4) The statement of work is specific and is defined by separate phases or increments so that, at the completion of each, progress can be effectively measured.

332.703 Contract funding requirements.**332.703-1 General.**

(b) The following general guidelines are applicable to incrementally funded contracts:

(1) The estimated total cost of the project (all planned phases or increments) is to be taken into consideration when determining the requirements which must be met before entering into the contract; i.e., justification for noncompetitive acquisition, approval or award, etc.

(2) The RFP and resultant contract are to include a statement of work which describes the total project covering the proposed multiple year period of performance and indicating timetables consistent with planned phases or increments and corresponding allotments of funds.

(3) Offerors will be expected to respond to RFPs with technical and cost proposals for the entire project indicating distinct break-outs of the planned phases or increments, and the multiple year period of performance.

(4) Negotiations will be conducted based upon the total project, including all planned phases or increments, and the multiple year period of performance.

(5) Sufficient funds must be obligated under the basic contract to cover no less than the first year of performance, unless the contracting officer determines it is advantageous to the Government to fund the contract for a lesser period. In that event, the contracting officer shall ensure that the obligated funds are sufficient to cover a complete phase or increment of performance representing a material and measurable part of the total project, and the contract period shall be reduced accordingly.

(6) Because of the magnitude of the scope of work and multiple year period of performance under an incrementally funded contract, there is a critical need for careful program planning. Program planning must provide for appropriate surveillance of the contractor's performance and adequate controls to ensure that projected funding will not impinge on the program office's ability to support, within anticipated appropriations, other equally important contract or grant programs.

(7) An incrementally funded contract must contain precise requirements for progress reports to enable the project officer to effectively monitor the contract. The project officer should be required to prepare periodic performance evaluation reports to facilitate the program office's ultimate decision to allot additional funds under the contract.

332.704 Limitation of cost or funds.

For detailed instruction regarding administrative actions in connection with anticipated cost overruns, see subpart 342.71

332.705 Contract clauses.**332.705-2 Clauses for limitation of costs or funds.**

(c)(1) When using the Limitation of Funds clause (FAR 52.232-22) in the solicitation and resultant incrementally funded contract, the contracting officer shall insert the following legend between the clause title and the clause text:

(This clause supersedes the Limitation of Cost clause found in the General Provisions of this contract.)

(2) The contracting officer shall also include a clause reading substantially as that shown in 352.232-74 in the Special Provisions of the resultant incrementally funded contract.

(3) The request for proposals must inform prospective offerors of the Department's intention to enter into an incrementally funded contract. Therefore, the contracting officer shall include the provision at 352.232-75 in the request for proposals whenever the use of incremental funding is contemplated.

Subpart 332.9—Prompt Payment**332.902 Definitions.**

Fiscal office means the office responsible for: determining whether interest penalties are due a contractor and, if so, the amount; determining whether an invoice offers a financially advantageous discount; maintaining records for and submission of prompt payment reports to the Deputy Assistant Secretary, Finance (DASF), ASMB, OS; and processing payments to the Treasury Department to allow for payment to a contractor when due. The fiscal office may fulfill the roles of the "designated billing office" and the "designated payment office."

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.

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

Subpart 333.1—Protests**333.102 General.**

(a) Contracting officers shall consider all protests or objections regarding the award of a contract, whether submitted before or after award, provided the protests are filed in a timely manner and are submitted by interested parties. To be considered timely, protests based on alleged improprieties in any type of solicitation which are apparent before bid opening or the closing date for receipt of proposals shall be filed prior to bid opening or the closing date for receipt of proposals. In the case of negotiated acquisitions, alleged improprieties which do not exist in initial solicitations, but which are subsequently incorporated by amendment, must be protested not later than the next closing date for receipt of proposals following the incorporation of the amendment. In other cases, protests shall be filed not later than ten (10) calendar days after the basis for protest is known or should have been known, whichever is earlier. Provided a protest has been filed initially with the contracting officer, any subsequent protest to the Secretary or GAO filed within ten (10) calendar days of notification of adverse action will be considered. Written confirmation of all oral protests shall be requested from protestants and must be timely filed.

(g)(1) The Office of Acquisition Management (OAM) has been designated as the headquarters office to serve as the liaison for protests lodged with GAO. Within the OAM, the Departmental Protest Control Officer (DPCO) has been designated as the individual to be contacted by GAO.

(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. The protest control officer should be a senior acquisition specialist in the headquarters acquisition staff office. In addition, contracting activities should designate similar officials within their principal components to the extent practicable and feasible. A copy of each appointment and termination of appointment of protest control officers shall be forwarded to the Director, OAM.

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 Office of General Counsel—Business and Administrative Law Division (OGC-BAL). If the protest has been lodged with the Secretary, is addressed to the Secretary, or requests referral to the Secretary, approval shall also be obtained from the Director, OAM before making the award.

(2) The contracting officer shall require written confirmation of any oral protest. To be considered timely, the written confirmation must be filed in accordance with the applicable provisions in 333.102(a). In the following cases, written protests received by the contracting officer before award shall be forwarded, through acquisition channels, to the DPCO for processing. Files concerning these protests shall be submitted in duplicate, or as otherwise specified by the DPCO and sent in the most expeditious manner, marked "IMMEDIATE ACTION—PROTEST BEFORE AWARD", and contain the documentation referenced in 333.104(a)(3).

(i) The protestant requests referral to the Secretary of Health and Human Services;

(ii) The protest is known to have been lodged with the Comptroller General or the Secretary, or is addressed to either; or

(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 protest be considered by the Secretary or the Comptroller General. Otherwise, protests addressed to the contracting officer may be answered by the contracting officer, with the concurrence of the contracting activity's protest control officer and OGC-BAL.

(3) Protests received after award shall be treated as indicated in FAR 33.103(b)(3).

333.104 Protests to GAO.

(a) *General procedures.* (3) Protests lodged with GAO, whether before or after award, shall be processed by the DPCO. Protest files shall be prepared by the contracting office and distributed as follows: two copies to the DPCO, one copy to the contracting activity's protest control officer, and one copy to OGC-BAL. Files shall include the following documentation:

(i) The contracting officer's statement of facts and circumstances, including a discussion of the merits of the protest, and conclusions and recommendations,

including documentary evidence on which they are based.

(ii) A copy of the IFB or RFP.

(iii) A copy of the abstract of bids or proposals.

(iv) A copy of the bid or proposal of the successful offeror to whom award has been made or is proposed to be made.

(v) A copy of the bid or proposal of the protestant, if any.

(vi) The current status of award. 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.

(vii) A copy of any mutual agreement to suspend work on a no-cost basis, when appropriate (see FAR 33.104(c)(4)).

(viii) Copies of the notice of protest given offerors and other parties when the notice is appropriate (see FAR 33.104(a)(2)).

(ix) A copy of the technical evaluation report, when applicable, and a copy of each evaluator's rating for relevant proposals.

(x) A copy of the negotiation memorandum, when applicable.

(xi) The name and telephone number of the person in the contracting office who may be contacted for information relevant to the protest.

(xii) A copy of the competitive range memorandum, and

(xiii) Any document which is referred to in the contracting officer's statement of facts. The files shall be assembled in an orderly manner and shall include an index of enclosures.

(4) The DPCO is responsible for making the necessary distributions referenced in FAR 33.104 (a)(4).

(5) The contracting officer shall furnish the protest file containing the documentation specified in paragraph (a)(3) of this section, except the item in paragraph (a)(3)(i), to the DPCO within fourteen (14) calendar days from receipt of the protest. The contracting officer shall provide the documentation required by item (a)(3)(i) of this section to the DPCO within twenty-one (21) 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. The DPCO shall prepare the report and submit it and the protest file to GAO in accordance with FAR 33.104(a)(4)(i).

(6) Since the DPCO will furnish the report to GAO, the protestor, and other interested parties, comments on the report from the protestor and other

interested parties will be requested to be sent to the DPCO.

(7) The Office of Acquisition Management (OAM) has been designated as the headquarters office, and the DPCO as the individual, that GAO should contact concerning all 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 head of the contracting activity (HCA)(not delegable), and forward it, along with a written request for approval to make the award, to the Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM).

(2) If the request to make an award notwithstanding the protest is approved by the DASGAM, the DPCO shall notify GAO. Whether the request is approved or not, the DPCO shall telephonically notify the contracting activity's protest control officer of the decision of the DASGAM, and the contracting activity's protest control officer shall immediately notify the contracting officer. The DPCO shall confirm the decision by memorandum to the contracting activity's protest control officer.

(4) The contracting officer shall prepare the protest file in accordance with paragraph (a)(3) of this section, and forward the required number of copies to the DPCO (see paragraph (a)(5) of this section).

(c) *Protests after award.* (2) If the contracting officer believes performance should be allowed to continue notwithstanding the protest, a finding shall be prepared by the contracting officer using the criteria in FAR 33.104(c)(2), executed by the HCA (not delegable), and forwarded, along with a written request for approval, to the Director, OAM. The same procedures for notification stated in paragraph (b)(2) of this section shall be followed.

(6) The contracting officer shall prepare the protest file in accordance with paragraph (a)(3) of this section, and forward the required number of copies to the DPCO (see paragraph (a)(5) of this section).

(d) *Findings and notice.* The contracting officer shall perform the actions required by FAR 33.104 (d); however, notification to GAO and other interested parties shall be made by the DPCO.

(g) *Notice to GAO.* The Deputy Assistant Secretary for Grants and Acquisition Management shall be the 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 the DPCO in time to meet the submittal date established by GAO. The DPCO will notify the contracting officer of the submittal date after GAO has finalized its requirements.

Subpart 333.2—Disputes and Appeals

333.203 Applicability.

(c) The Armed Services Board of Contract Appeals (ASBCA) has been designated by the Secretary 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 Office of the Inspector General for investigation.

333.211 Contracting officer's decision.

(a)(2) The contracting officer shall refer a proposed final decision to the Office of General Counsel, Business and Administrative Law Division (OGC-BAL), for advice as to the legal sufficiency and format before sending the final decision to the contractor. The contracting officer shall provide OGC-BAL with the pertinent documents with the submission of each proposed final decision.

(a)(4)(v) When using the paragraph in FAR 33.211 (a)(4)(v), the contracting officer shall insert the words "Armed Services" 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 his/her final decision. If an appeal from the final decision has been taken to the ASBCA, the contracting officer will forward his/her recommended action to OGC-BAL with the supplement to the contract file which supports the recommended correction or amendment.

333.212 Contracting officer's duties upon appeal.

(a) Appeals shall be governed by the rules set forth in the "Rules of the Armed Services Board of Contract Appeals", or by the rules established by the U.S. Court of Federal Claims, as appropriate.

(b) OGC-BAL is designated as the Government Trial Attorney to represent the Government in the defense of appeals before the ASBCA. A decision by the ASBCA will be transmitted by the Government Trial Attorney to the

appropriate contracting officer for compliance in accordance with the ASBCA's decision.

(c) If an appeal is filed with the ASBCA, the contracting officer shall assemble a file within 30 days of receipt of an appeal, or advice that an appeal has been filed, that consists of all documents pertinent to the appeal, including:

(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 Board; and

(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, one for the ASBCA, 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 concerned contracting officer, acting under the guidance of the Government Trial Attorney, shall be responsible for arranging for the presence of Government witnesses and specified physical and documentary evidence at both the pre-hearing conference and hearing.

(e) If a contractor which has filed an appeal with the ASBCA 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 will notify the ASBCA of the disposition of the dispute in accordance with Rule 27 of the ASBCA.

(f) If the contractor has elected to appeal to the U.S. Court of Federal Claims, the U.S. Department of Justice will represent the Department. However, the contracting officer shall still coordinate all actions through OGC-BAL.

333.212-70 Formats.

(a) The following format is suggested for use in transmitting appeal files to the ASBCA:

Your reference: _____
(Docket No.)

(Name)

Recorder, Armed Services Board of Contract Appeals

Skyline Six
5109 Leesburg Pike
Falls Church, Virginia 22041

Dear (Name):

Transmitted herewith are documents relative to the appeal under Contract No. _____ with the _____
(Name of contractor)

in accordance with the procedures under Rule 4. The Government Trial Attorney for this case is

(Insert Division of Business and Administrative Law, 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 should be addressed to:

(Insert name and address of cognizant finance office.)

Sincerely yours,
Contracting Officer
Enclosures

(b) The following format is suggested for use in notifying the appellant that the appeal file was submitted to the ASBCA:

(Contractor Address)

Dear _____:

An appeal file has been compiled relative to the appeal under Contract No. _____, and has been submitted to the Armed Services Board of Contract Appeals (ASBCA). The enclosed duplicate of the appeal file is identical to that submitted to the Board, except that contract documents which you already have been excluded. You may furnish or suggest any additional information deemed pertinent to the appeal to the Armed Services Board of Contract Appeals according to their rules.

The ASBCA will provide you with further information concerning this appeal.

Sincerely yours,
Contracting Officer
Enclosure

333.213 Obligation to continue performance.

(a) The Disputes clause at FAR 52.233-1 shall be used 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, he/she must request approval for its use from the chief of the contracting office.

PART 334—MAJOR SYSTEM ACQUISITION

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

334.003 Responsibilities.

The Department's implementation of OMB Circular No. A-109 may be found in Chapter 1-150 of the General Administration Manual.

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) The use of cost-sharing type contracts should be encouraged to contribute to the cost of performing research where there is a probability that the contractor will receive present or future benefits from participation, such as, increased technical know-how, training to employees, acquisition of equipment, use of background knowledge in future contracts, etc. Cost-sharing is intended to serve the mutual interests of the Government and the performing organization by helping to assure efficient utilization of the resources available for the conduct of research projects and by promoting sound planning and prudent fiscal policies by the performing organization. Encouragement should be given to organizations to contribute to the cost of performing research under contracts unless the contracting officer determines that a request for cost-sharing would not be appropriate because of the following circumstances:

(1) The particular research 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 request for proposals for a specific project.

(2) The research effort has only minor relevance to the non-Federal activities of the performing organization, and the organization is proposing to undertake the research 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. Cost-sharing should generally not be requested if cost-sharing would require the Government to provide funds through some other means (such as fees) to enable the organization to cost-share. It should be recognized that those organizations which are predominantly engaged in research and development and have little or no production or other service activities may not be in a favorable position to make a cost contribution.

(b) The responsibility for negotiating cost-sharing is that of the contracting office. Each research contract file should show whether the contracting officer considered cost-sharing appropriate for that particular contract and in what amount. If cost-sharing was not considered appropriate, the file must indicate the 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 may wish to coordinate with the project officer before documenting this decision.

(c) If the contracting officer considers cost-sharing to be appropriate for a research contract and the contractor refuses to accept this type of contract, the award may be made without cost-sharing, if the contracting officer concludes that payment of the full cost of the research effort is necessary in order to obtain the services of that particular contractor.

335.070-2 Amount of cost-sharing.

When cost-sharing is determined to be appropriate, the following guidelines shall be utilized in determining the amount of cost participation by the contractor.

(a) The amount of cost participation should depend to a large extent on whether the research 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. It should be recognized that those organizations which are predominantly engaged in research and development have little or no production or other service activities and may not be in a favorable position to derive a monetary benefit from their research under Federal agreements. Therefore, contractor cost participation could reasonably range from as little as 1 percent or less of the total project cost, to more than 50 percent of the total project cost. Ultimately, the contracting

officer should bear in mind that cost-sharing is a negotiable item. As such, the amount of cost-sharing should be proportional to the anticipated value of the contractor's gain.

(b) If the performing organization will not acquire title or the right to use inventions, patents, or technical information resulting from the research project, it would generally be appropriate to obtain less cost-sharing than in cases in which the performer acquires these rights.

(c) A fee or profit will usually not be paid to the performing organization if the organization is to contribute to the cost of the research 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 research is expected to be of only minor value to the performing organization and if cost-sharing is not required by statute, 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, in the view of the operating divisions or their subordinate elements, an area of research 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. Costs so contributed may not be charged to the Government under any other grant or contract (including allocations to other grants or contracts as part of any independent research and development program).

335.070-4 Contract award.

In consonance with the Department's objectives of competition and support of the small business program, award of contracts should not be made solely on the basis of ability or willingness to cost-share. Awards should be made primarily on the contractor's competence and only after adequate competition has been obtained among large and small business organizations whenever possible. The offeror's willingness to share costs should not be

considered in the technical evaluation process but as 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 for health agencies shall sign individual and class determinations and findings 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 a research contract pursuant to 42 U.S.C. 241(a)(7).

PART 342—CONTRACT ADMINISTRATION

Subpart 342.7—Indirect Cost Rates

342.705 Final indirect cost rates.

Subpart 342.70—Contract Monitoring

Sec.

342.7001 Purpose.

342.7002 Contract monitoring responsibilities.

342.7003 Withholding of contract payments.

342.7003-1 Policy.

342.7003-2 Procedures.

342.7003-3 Withholding payments.

Subpart 342.71—Administrative Actions for Cost Overruns

342.7001 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 342.7—Indirect Cost Rates

342.705 Final indirect cost rates.

The Director, Division of Cost Allocation of the Program Support Center within the servicing HHS regional office has been delegated the authority to establish indirect cost rates, research patient care rates, and, as necessary, fringe benefit, computer, and other special costing rates for use in contracts and grants awarded to State and local governments, colleges and universities, hospitals, and other nonprofit organizations.

Subpart 342.70—Contract Monitoring

342.7001 Purpose.

Contract monitoring is an essential element of contract administration and the acquisition process. This subpart describes the Department's operating concepts regarding contract monitoring, performed jointly by the project officer and the contracting officer, to ensure

that the required monitoring is performed, timely remedial action is taken when necessary, and a determination is made that contract objectives have been met.

342.7002 Contract monitoring responsibilities.

(a) Upon execution of the contract, the mutual obligations of the Government and the contractor are established by, and limited to, the written stipulations in the contract. Unless authorized by the contracting officer, HHS personnel shall not direct or request the contractor to assume any obligation or take any actions not specifically required by the contract. Only the contracting officer may impose a requirement which will result in a change to the contract. All contract changes must be directed in writing or confirmed in writing by the contracting officer.

(b) The contracting officer is responsible for assuring compliance with all terms of the contract, especially the statutory, legal, business, and regulatory provisions. Whether or not a postaward conference is held, the contracting officer shall inform the contractor by letter (if not already stipulated by contract provisions) of the authorities and responsibilities of the Government personnel with whom the contractor will be dealing throughout the life of the contract.

(c) The contracting officer must depend on program, technical, and other personnel for assistance and advice in monitoring the contractor's performance, and in other areas of postaward administration. The contracting officer must assure that responsibilities assigned to these personnel are understood and carried out. 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 to assist or advise the contracting officer (or act as his/her representative when so designated by the contracting officer) in activities such as:

(i) Providing technical monitoring during contract performance, and issuing letters to the contractor and contracting officer relating to delivery, acceptance, or rejection in accordance with the terms of the contract;

(ii) Assessing contractor performance, including inspection and testing of products and evaluation of reports and data;

(iii) Recommending necessary changes to the schedule of work and period of performance in order to accomplish the objectives of the

contract. This shall be accomplished by a written request to the contracting officer, together with an appropriate justification and funds availability citation;

(iv) Reviewing invoices/vouchers and recommending approval/disapproval action by the contracting officer, to include comments regarding anything unusual discovered in the review;

(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 role of the project officer in performing required aspects of the contract monitoring process. In addition to those applicable activities set forth in paragraph (c)(1) of this section, the project officer shall:

(i) Submit periodic reports to the contracting officer that concisely explain the status of the contract, and include recommended actions for any problems reported. Provide the contracting officer with written notification of evaluation and approval/disapproval of contract deliverables and of completion of tasks or phases. The contracting officer will, in turn, provide the contractor with written notification of approval or disapproval unless the responsibility has been delegated by the contracting officer, in which case the person responsible for such action will notify the contractor and provide a copy to the contracting officer for inclusion in the contract file;

(ii) Monitor the technical aspects of the contractor's business and technical progress, identify existing and potential problems that threaten performance, and immediately inform the contracting officer of deviations from contract objectives, or from any technical or delivery requirements, so that remedial measures may be instituted accordingly;

(iii) Provide immediate notification to the head of the program office responsible for the program whenever it is determined that program objectives are not being met, together with specific recommendations of action to be taken. A copy of the project officer's report and recommendation shall be transmitted to the contracting officer for appropriate action;

(iv) Submit, within 120 days after contract completion, a final assessment report to the contracting officer. The report should include analysis of the contractor's performance, including the contract and program objectives achieved and missed. A copy of the final assessment report shall be forwarded to the head of the program

office responsible for the program for management review and follow-up, as necessary; and

(v) Accompany and/or provide, when requested, technical support to the HHS auditor in the conduct of floor checks.

(3) The role of the contract administrator, auditor, cost analyst, and property administrator in assisting or advising the contracting officer in postaward administration activities such as:

(i) Evaluation of contractor systems and procedures, to include 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 of disputes under the Disputes clause and any resultant appeals;

(iii) Modification or termination of the contract; and

(iv) Determination of the allowability of cost charges to incentive or cost-reimbursement type contracts and progress payments under fixed-price contracts. This is especially important when award is made to new organizations or those with financial weaknesses.

(d) The contracting officer is responsible for assuring that contractor performance and contract monitoring are carried out in conformance with contract provisions. If performance is not satisfactory or if problems are anticipated, it is essential that the contracting officer take immediate action to protect the Government's rights under the contract. The contracting officer shall notify his/her immediate supervisor of problems that cannot be resolved within contract limitations and whenever contract or program objectives are not met. The notification shall include a statement of action being taken by the contracting officer.

342.7003 Withholding of contract payments.

342.7003-1 Policy.

(a) All solicitations and resultant contracts shall contain the withholding of contract payments clause at 352.232-9, and an excusable delays clause, or a clause which incorporates the definition of excusable delays. The excusable delays clause at 352.249-14 shall be used when the solicitation and resultant contract (other than purchase orders) does not contain a default or other excusable delays clause.

(b) The transmittal letter used to convey the contract to each contractor shall contain a notice which highlights

the contractor's agreement with the withholding of contract payments clause.

(c) No contract payment shall be made when any report required to be submitted by the contractor is overdue, or the contractor fails to perform or deliver work or services as required by the contract.

(d) The contracting officer shall issue a ten-day cure notice or initiate appropriate termination action for any failure in the contractor's performance as stated in paragraph (c) of this section.

342.7003-2 Procedures.

(a) The contracting officer is responsible for initiating immediate action to protect the Government's rights whenever the contractor fails to comply with either the delivery or reporting provisions of the contract. Compliance with the reporting provisions includes those reports to be submitted directly to the payment office. If such a report is not submitted on time, the contracting officer is to be notified promptly by the payment officer.

(b) When the contract contains a termination for default clause, the contractor's failure to either submit any required report when due or perform or deliver services or work when required by the contract is to be considered a default in performance. In either circumstance, the contracting officer is to immediately issue a formal ten-day cure notice pursuant to the default clause. The cure notice is to follow the format prescribed in FAR 49.607 and is to include a statement to the effect that contract payments will be withheld if the default is not cured or is not determined to be excusable.

(1) If the default is cured or is determined to be excusable, the contracting officer is not to 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 is to initiate withholding action on all contract payments and is to 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 contractor's failure to either submit any required report when due or perform or deliver services or work when required by the contract is to be considered a failure to perform. In either circumstance, the contracting officer is to immediately issue a written notice to the contractor specifying the failure and providing a period of ten days, or longer

period as determined necessary by the contracting officer, in which the contractor is to cure the failure or establish an excusable delay. The contracting officer is to include a statement in the written notice to the effect that contract payments will be withheld if the failure is not cured or is not determined to be excusable.

(1) If the failure is cured or is determined to be excusable, the contracting officer is not to initiate the withholding action.

(2) If the failure is not determined to be excusable or a response is not received within the allotted time, the contracting officer is to initiate withholding action on all contract payments and is to determine whether termination for convenience or other action would be in the best interest of the Government.

(d) The contracting officer should consult FAR subpart 49.4 for further guidance before taking any of the actions described in this section.

342.7003-3 Withholding payments.

(a) When making the determination that contract payments should be withheld in accordance with the Withholding of Contract Payments clause, the contracting officer is to immediately notify the servicing finance office in writing of the determination to suspend payments. The notice of suspension is to contain all elements of information required by the payment office to properly identify the contract and the applicable accounts involved.

(b) The contracting officer is to 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 is to immediately notify, in writing, all recipients of the notice of suspension that the suspension is to be lifted and contract payments are to be resumed.

(d) When exercising actions regarding the withholding of payment procedures, the contracting officer must be careful not to waive any of the Government's rights when corresponding with the contractor or when taking any other actions.

Subpart 342.71—Administrative Actions for Cost Overruns

342.7100 Scope of subpart.

This subpart sets forth the procedures to be followed when a cost overrun is anticipated; i.e., the allowable actual cost of performing a cost-reimbursement type contract is expected to exceed 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 is to include:

(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, overhead, etc.) to be furnished in the following format:

(i) Original estimate,

(ii) Costs incurred to date,

(iii) Estimated cost to completion,

(iv) Revised estimate, and

(v) Amount of adjustment.

(5) The factors responsible for the increase, i.e., error in estimate, changed conditions, etc.

(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 an impending overrun, the contracting officer shall:

(1) Immediately advise the appropriate program office and furnish 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 follow-up with the program office to obtain a timely decision as to whether the work under the contract should be continued and additional funds provided, or the contract terminated. The decision of the program office must be supported by an appropriate written statement and funding authority, or a formal request for termination, when applicable. After a programming and funding decision is

received from the program office, the contracting officer shall promptly notify the contractor in writing that:

(i) A specified amount of additional funds has been allotted to the contract by a contractual instrument; or

(ii) Work will be discontinued when the funds allotted to the contract have been exhausted, and that any work performed after that date is at the contractor's risk; or

(iii) The Government is considering whether additional funds should be allotted to the contract and will notify the contractor as soon as possible, but that any work performed after the funds then allocated to the contract have been exhausted is at the contractor's risk. Timely, formal notification of the Government's intention is essential in order to preclude loss of contractual rights in the event of dispute, termination, or litigation.

(c) If program requirements permit, contracting officers should refrain from issuing any contractual documents which will require new work or an extension of time, pending resolution of an overrun or additional fund request.

342.7102 Contract modifications.

(a) Modifications to contracts containing the Limitation of Cost clause shall include either:

(1) A provision increasing the estimated or ceiling amount referred to in the Limitation of Cost clause of the contract and stating that the clause will thereafter apply in respect to the increased amount; or

(2) A provision stating that the estimated or ceiling amount referred to in the contract is not changed by the modification and that the Limitation of Cost clause will continue to apply with respect to the amount in effect prior to the modification.

(b) A fixed-fee provided in a contract shall not be changed when funding a cost overrun. Changes in fixed-fee will be made only to reflect changes in the scope of work which justify an increase or decrease in fee.

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Subpart 352.2—Texts of Provisions and Clauses

Sec.

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

Subpart 352.2—Texts of Provisions and Clauses

352.202-1 Definitions.

As prescribed in 302.201, the FAR Definitions clause at 52.202-1 is to be used as modified:

Definitions (Jan. 2001)

(a) Substitute the following as paragraph (a):

“(a) The term “Secretary” or “Head of the Agency” (also called “Agency Head”) means the Secretary, Under 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) Add the following paragraph (h) or its alternate, as appropriate:

“(h) The term “Project Officer” means the person representing the Government for the purpose of technical monitoring of contract performance. The Project Officer is not authorized to issue any instructions or directions which effect any increases or decreases in the scope of work or which would result in the increase or decrease of the price of this contract or a change in the delivery dates or performance period of this contract.”

or

Alternate:

“(h) The term “Project Officer” means the person representing the Government for the purpose of technical monitoring of contract performance. The Project Officer is not authorized to issue any instructions or directions which effect any increases or decreases in the scope of work or which would result in the increase or decrease of the cost of this contract or a change in performance period of this contract. In addition, the Project Officer is not authorized to receive or act upon the Contractor's notification of a revised cost estimate pursuant to the Limitation of Cost or Limitation of Funds clause of this contract.”

352.215-1 Instructions to offerors— Competitive acquisition.

Insert the following paragraph (e) in place of paragraph (e) of the provision at FAR 52.215-1:

(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, and 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 legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

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, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department 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 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 should 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 legends or

statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

352.215-70 Late proposals and revisions.

As prescribed in 315.208, the following provision may be included in the solicitation:

Late Proposals and Revisions (Nov. 1986)

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

352.216-72 Additional cost principles.

As prescribed in 316.307(j), insert the following clause in all solicitations and resultant cost-reimbursement contracts:

Additional Cost Principles (Oct. 1990)

(a) *Bid and proposal costs.* (1) Bid and proposal 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) Bid and proposal costs of the current accounting period are allowable as indirect costs.

(3) Bid and proposal 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) Bid and proposal costs do not include independent research and development costs covered by the following paragraph, or preaward costs covered by paragraph 38 of Attachment B to OMB Circular A-122.

(b) *Independent research and development costs.* (1) Independent research and development is research and development conducted by an organization which is not sponsored by Federal or non-Federal contracts, grants, or other agreements.

(2) Independent research and development 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 independent research and development, including its proportionate share of indirect costs, are unallowable.

(End of clause)

352.223-70 Safety and health.

The following clause, or one reading substantially the same, shall be used as prescribed in 323.7002:

Safety and Health (Jan. 2001)

(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 and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the project or other appropriate officers, 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, an equitable adjustment will be made 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; and/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. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of Clause)

352.224-70 Confidentiality of information.

The following clause is covered by the policy set forth in subpart 324.70 and is to be used in accordance with the instructions set forth in 324.7004.

Confidentiality of Information (Apr. 1984)

(a) Confidential information, as used in this clause, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(b) In addition to the types of confidential information described in paragraph (a) of this clause, information which might require special consideration with regard to the timing of its disclosure may derive from studies or research, during which public disclosure of preliminary unvalidated findings could create erroneous conclusions which might threaten public health or safety if acted upon.

(c) The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

(d) If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

(e) Confidential information, as defined in paragraph (a) of this clause, that is information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization, shall not be disclosed without the prior written consent of the individual, institution, or organization.

(f) Written advance notice of at least 45 days will be provided to the Contracting Officer of the Contractor's intent to release findings of studies or research, which have the possibility of adverse effects on the public or the Federal agency, as described in paragraph (b) of this clause. If the Contracting Officer does not pose any objections in writing within the 45-day period, the Contractor may proceed with disclosure. Disagreements not resolved by the Contractor and the Contracting Officer will be settled pursuant to the "Disputes" clause.

(g) Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this clause, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

(h) Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

(i) The provisions of paragraph (e) of this clause shall not apply when the information is subject to conflicting or overlapping

provisions in other Federal, State or local laws.

(End of clause)

352.228-7 Insurance—Liability to third persons.

As prescribed in 328.311-2, contracting officers shall include the following clause in all cost-reimbursement contracts, in lieu of the clause at FAR 52.228-7:

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 Contractor shall not be reimbursed 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 the offer that the offeror is *partially* immune from tort liability as a State agency, 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, to 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 the offer that the offeror is totally immune from tort liability as a State agency, 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 required by the Government, 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)

352.232-9 Withholding of contract payments.

Insert the following clause in all solicitations and contracts other than purchase orders:

Withholding of Contract Payments (Apr. 1984)

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, will 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 shall promptly notify the Contractor of its intention to withhold payment of any invoice or voucher submitted.

(End of clause)

352.232-74 Estimated cost and fixed fee-incrementally funded contract.

The following clause, or one reading substantially as it, shall be included in

the Special Provisions of an incrementally funded contract:

Consideration-Estimated Cost and Fixed Fee (Apr. 1984)

(a) It is estimated that the total cost to the Government for full performance of this contract will be \$_____, of which the sum of \$_____ represents the estimated reimbursable costs and \$_____ represents the fixed-fee.

(b) Total funds currently available for payment and allotted to this contract are \$_____, of which \$_____ represents the estimated reimbursable costs and \$_____ represents the fixed-fee. For further provisions on funding, see the Limitation of Funds clause.

(c) It is estimated that the amount currently allotted will cover performance of Phase I which is scheduled to be completed by (date)_____.

(d) The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

(End of clause)

352.232-75 Incremental funding.

The following provision shall be included in all requests for proposals whenever the use of incremental funding is contemplated:

Incremental Funding (Jan. 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

352.233-70 Litigation and claims.

Insert the following clause in all solicitations and resultant cost-reimbursement contracts:

Litigation and Claims (Apr. 1984)

The Contractor shall give the Contracting Officer immediate notice in writing 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." 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. If the settlement or defense of an action or claim is undertaken by the Government, 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 Contractor shall not be reimbursed or indemnified by the Government 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)

352.242-71 Final decisions on audit findings.

Insert the following clause in all solicitations and resultant cost-reimbursement contracts.

Final Decisions on Audit Findings (Apr. 1984)

For the purpose of issuing final decisions under the Disputes clause of this contract concerning monetary audit findings, the Contracting Officer shall be that person with ultimate responsibility for making that decision in accordance with Chapter 1-105, Resolution of Audit Findings, of the Department's Grants Administration Manual.

(End of clause)

352.249-14 Excusable delays.

Insert the following clause in all solicitations and resultant contracts other than purchase orders which do not have either a default or excusable

delays clause, as prescribed in 342.7003-1(a):

Excusable Delays (Apr. 1984)

(a) Except with respect to failures of subcontractors, the Contractor shall not be considered to have failed in performance of this contract if such failure arises out of causes beyond the control and without the fault or negligence of the Contractor.

(b) Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, and unusually severe weather, but in every case the failure to perform must be beyond the control and without the fault or negligence of the Contractor. If the failure to perform is caused by the failure of a subcontractor to perform, and if such failure arises out of causes beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either of them, the Contractor shall not be deemed to have failed in performance of the contract, unless: the supplies or services to be furnished by the subcontractor were obtainable from other sources, the Contracting Officer shall have ordered the Contractor in writing to procure such supplies or services from such other sources, and the Contractor shall have failed to comply reasonably with such order. Upon request of the Contractor, the Contracting officer shall ascertain the facts and extent of such failure and, if he/she shall determine that any failure to perform was occasioned by any one or more of the said causes, the delivery schedule shall be revised accordingly, subject to the rights of the Government under the termination clause hereof. (As used in this clause, the terms "subcontractor" and "subcontractors" mean subcontractor(s) at any tier.)

(End of clause)

352.270-1 Accessibility of meetings, conferences, and seminars to persons with disabilities.

The following clause is to be used in accordance with 370.102:

Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (Jan. 2001)

The Contractor agrees as follows:

(a) *Planning.* The Contractor will 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 plan shall be submitted to the project officer for approval prior to initiating action. (A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars may be submitted in lieu of separate plans.)

(b) *Facilities.* Any facility to be utilized 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, any slope over 1:12 must be approved by the Project Officer 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 insure their complete participation in the meeting, conference, or seminar.

(3) As 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 will 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 will 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 is responsible for making a reasonable effort to ascertain the number of individuals with sensory impairments who plan to attend the meeting, conference, or seminar. However, if it can be determined that there will be no person with sensory impairment in attendance, the provision of those services under paragraph (c) of this clause for the nonrepresented group, or groups, is not required.

(End of clause)

352.270–2 Indian preference.

The following clause shall be used as prescribed in 370.202(a):

Indian Preference (Apr. 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, those needs may be satisfied by selection of 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 business concerns, small disadvantaged business concerns, and women-owned small business concerns.

(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 thirty (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); and

(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.

The following clause shall be used as prescribed in 370.202(b):

Indian Preference Program (Apr. 1984)

(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:

(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 twenty (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: A clear description of the supplies or services required, including quantities, specifications, and delivery schedules which facilitate the participation of Indian firms; 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)); Definitions for the terms "Indian organization" and "Indian-owned economic enterprise" as prescribed under the "Indian Preference" clause of this contract; A statement to be completed by the bidder or offeror that it is an Indian organization or Indian-owned economic enterprise; and 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 responsive 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: The numbers of Indians seeking employment for each employment position available under this contract; The number and types of positions filled by Indians and non-Indians, and the total number of Indians employed under this contract; 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; Actions taken to give preference to Indian organizations and Indian-owned economic enterprises for subcontracting opportunities which exist under this contract; 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 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 until expiration of one (1) 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 Pricing of adjustments.

Insert the following clause in all solicitations and resultant fixed-priced contracts other than purchase orders.

Pricing of Adjustments (Jan. 2001)

When costs are a factor in determination of a contract price adjustment pursuant to the "Changes" clause or any provision of this contract, such costs shall be determined in accordance with the applicable cost principles and procedures set forth below:

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 institutions.

(End of clause)

352.270-5 Key personnel.

Insert the following clause in all solicitations and resultant cost-reimbursement contracts.

Key Personnel (Apr. 1984)

The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate.

(End of clause)

352.270-6 Publications and Publicity.

Insert the following clause in all solicitations and resultant contracts.

Publications and Publicity (Jul. 1991)

(a) Unless otherwise specified in this contract, the Contractor is encouraged to publish the results of its work under this contract. A copy of each article submitted by the Contractor for publication shall be promptly sent to the Project Officer. The Contractor shall also inform the Project Officer when the article or other publication is published, and furnish a copy of it as finally published.

(b) The Contractor shall include in any publication resulting from work performed under this contract a disclaimer reading as follows:

The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.”

(End of clause)

352.270-7 Paperwork Reduction Act.

Insert the following clause in all solicitations and contracts.

Paperwork Reduction Act (Jan. 2001)

(a) In the event that it subsequently becomes a contractual 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, the Paperwork Reduction Act of 1995 (Pub. L. 104-13) 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 first obtaining clearance from the Office of Management and Budget (OMB). Contractors and Project Officers should 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 obtain the required OMB clearance through the Project Officer before expending any funds or making public contracts for the collection of data. The authority to expend funds and proceed with the collection of information shall be in writing by the Contracting Officer. The Contractor must plan at least 120 days for OMB clearance. Excessive delays caused by the Government which arises out of causes beyond the control and without the fault or negligence of the Contractor will be considered in accordance with the Excusable Delays or Default clause of this contract (End of clause)

352.270-8 Protection of human subjects.

(a) The following provision shall be included in solicitations expected to involve human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (Jan. 2001)

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, 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 the Department.

(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 National Institutes of Health 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, prior consultation with OPRR, (telephone: 301-496-7014), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OPRR 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 assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

(f) It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

(b) The following clause shall be included in solicitations and resultant contracts involving human subjects:

Protection of Human Subjects (Jan. 2001)

(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 Protection from Research Risks (OPRR), National Institutes of Health (NIH). 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 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. Nothing in this contract shall be deemed 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 judgement 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 the OPRR, NIH, 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. 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 OPRR, NIH, terminate this contract in a whole or in part, and the Contractor's name may be removed

form the list of those contractors with approved Health and Human Services Human Subject Assurances.
(End of clause)

352.270-9 Care of laboratory animals.

(a) The following provision shall be included in solicitations expected to involve vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects (Sep. 1985)

The PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions 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 for Protection from Research Risks (OPRR), National Institutes of Health (NIH), a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OPRR. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OPRR negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OPRR may be contacted at NIH, Bethesda, Maryland 20892 (301-496-7041).

(End of provision)

(b) The following clause shall be included in all solicitations and resultant contracts involving research on vertebrate animals:

Care of Live Vertebrate Animals (Jan.2001)

(a) Before undertaking performance of any contract involving animal related activities, 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 and use of any live vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on

Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources 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 be used.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or 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 OPRR, 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 PHS Animal Welfare 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.

(End of Clause)

PART 353—FORMS

Subpart 353.3—Illustrations of Forms

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. For copies of the form, contact the Program Support Center at (301) 443-6740.

PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

Subpart 370.1—Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities

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370.101 Policy.
370.102 Responsibilities.

Subpart 370.2—Indian Preference in Employment, Training, and Subcontracting Opportunities

370.201 Statutory requirements.
370.202 Applicability.
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Subpart 370.3—Acquisitions Involving Human Subjects

370.300 Scope of subpart.
370.301 Policy.
370.302 Types of assurances.
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370.400 Scope of subpart.
370.401 Policy.
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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.

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 the policy of HHS 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 statement of work 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 include the clause in 352.270-1 in every solicitation and resulting contract when the statement of work requires the contractor to conduct meetings, conferences, or seminars in accordance with 370.101(b).

(b) The project officer shall be responsible for obtaining, reviewing, and approving 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 will be acceptable. The project officer, prior to approving the plan, should consult with the Office of Engineering Services serving the region where the meeting, conference, or seminar is to be held, to assure that the contractor's plan meets the accessibility requirements of the contract clause. The Office of Engineering Services should determine the adequacy of the contractor's plan, and notify the project officer, in writing, within ten (10) working days of receiving the request from the project officer.

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

(b) 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 have been developed to implement section 7 (b) of Public Law 93-638 for all activities of the Department. The clauses shall be used by any affected departmental contracting activity as follows, except 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 Indian Preference clause (352.270-2) shall be included in each solicitation and resultant contract, regardless of dollar amount:

(1) When the contract is to be awarded pursuant to an act specifically authorizing contracts with Indian organizations; or

(2) Where the work to be performed under the contract 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 Indian Preference Program clause (352.270-3) shall be included in each solicitation and resultant contract 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 to be included in the solicitation and resultant contract; and

(3) The determination is made, prior to solicitation, that the work to be performed under the resultant contract will take place in whole or in substantial part on or near an Indian reservation(s). In addition, the Indian Preference Program clause may be included in any solicitation and resultant contract 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 activity, 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 thirty (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 concerned contracting activity shall be responsible for conducting periodic reviews to insure contractor compliance with the requirements of the clauses set forth in 352.270-2 and 352.270-3. These reviews may be conducted with the assistance of the Indian Tribe(s) concerned.

(b) Complaints of noncompliance with the requirements of the clauses set forth in 352.270-2 and 352.270-3 which are filed in writing with the contracting activity shall be promptly investigated and resolved by the contracting officer.

370.205 Tribal preference requirements.

(a) Where the work under a contract is to be performed on an Indian reservation, the contracting activity may supplement the clause set forth in 352.270-3 by adding specific Indian preference requirements of the Tribe on whose reservation the work is to be performed. The supplemental requirements shall be jointly developed for the contract by the contracting activity and the Tribe. Supplemental preference requirements must represent a further implementation of the requirements of section 7(b) of Public Law 93-638 and must be approved by the affected program director and approved for legal sufficiency by the Business and Administrative Law Division, OGC, or a regional attorney before being added to a solicitation and resultant contract. Any supplemental preference requirements to be added to the clause in 352.270-3 shall be included in the solicitation and clearly identified in order to insure uniform understanding of the additional requirements by all prospective bidders or offerors.

(b) Nothing in this part shall be interpreted to 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 subpart 370.2, and must 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 research and development activities involving human subjects conducted under contract (see 45 CFR 46.102(d) and (f)).

370.301 Policy.

It is the policy of the Department of Health and Human Services (DHHS) that no contract involving human subjects shall be awarded until acceptable assurance has been given that the activity will be subject to initial and continuing review by an appropriate Institutional Review Board (IRB) as described in DHHS regulations at 45 CFR 46.103. An applicable Multiple Project Assurance (MPA) or Single Project Assurance (SPA), approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), shall be required of each contractor, subcontractor, or cooperating institution having responsibility for human subjects involved in performance of the contract. The OPRR, NIH, is responsible for negotiating assurances covering all DHHS-supported or DHHS-conducted activities involving human subjects. Contracting officers shall be guided by OPRR regarding nonaward or termination of a contract due to inadequate assurance or breach of assurance for protection of human subjects.

370.302 Types of assurances.

Assurances may be one of two types:

(a) *Multiple Project Assurance (MPA)*. An MPA describes the oversight procedures applicable to all DHHS-supported human subjects activities within an institution having a significant number of concurrent projects. An MPA listed in OPRR's current "List of Institutions Which Have an Approved MPA" will be considered acceptable for purposes of this policy.

(b) *Single Project Assurance (SPA)*. An SPA describes the oversight procedures applicable to a single DHHS-supported human subjects activity. SPAs may be approved in modified form to meet unusual requirements. SPAs are not solicited from institutions

with OPRR approved MPAs. Copies of proposals selected for negotiation and requiring one or more SPAs shall be forwarded to the Human Subjects Assurance Branch, OPRR, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible so that timely action may be taken to secure the SPA(s).

370.303 Notice to offerors.

(a) Solicitations shall contain the notice to offerors in 352.270-8(a) whenever contract performance is expected to involve human subjects.

(b) IRB approval of proposals submitted by institutions having an OPRR-approved MPA should be certified in the manner required by instructions for completion of the contract proposal; or by completion of a DHHS Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration; or by letter indicating the institution's OPRR-assigned MPA 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) SPAs for contractors, subcontractors, or cooperating institutions generally will not be requested prior to determination that a contract proposal has been selected for negotiation. When an SPA is submitted, 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 noncompetitive renewal proposal shall be certified in the manner described in the preceding paragraph.

370.304 Contract clause.

The clause set forth in 352.270-8(b) shall be inserted in all solicitations and resultant contracts involving human subjects.

Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

370.400 Scope of subpart.

This subpart applies to all research, 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 the policy of the Department of Health and Human Services (DHHS) and the Public Health Service agencies that no contract involving live

vertebrate animals shall be awarded until acceptable assurance has been given that the activity 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. An applicable Full Animal Welfare Assurance or Interinstitutional Agreement/Assurance, approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), shall be required 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 OPRR, NIH, is responsible for negotiating assurances covering all DHHS/PHS-supported or DHHS/PHS-conducted activities involving the care and use of live vertebrate animals. Contracting officers shall be guided by OPRR 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 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 OPRR's list of institutions which have an approved full AWA will be considered acceptable for purposes of this policy.

(2) *Interinstitutional 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) Copies of proposals selected for negotiation and requiring an assurance shall be forwarded to the Assurance Branch, Division of Animal Welfare, OPRR, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible in order that timely action may be taken 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 because the GOCO site normally covers the contractor services in the GOCO site assurance.

370.403 Notice to offerors.

Solicitations shall contain the notice to offerors in 352.270-9(a) whenever contract performance is expected to involve the use of live vertebrate animals.

(a) For offerors having a full AWA on file with OPRR, IACUC approval of the use of animals shall be submitted 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 review and approval must not be more than 36 months prior to the deadline for proposal submission.]

(b) Non-assured offerors are not required to submit assurances or IACUC approval with proposals. OPRR will contact contractors, subcontractors and cooperating institutions to negotiate necessary assurances and verify IACUC approvals when requested by appropriate DHHS/PHS staff.

370.404 Contract clause.

The clause set forth in 352.270-9(b) shall be included in all solicitations and resultant contracts involving the care and use of live 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. Applicability of this subpart is limited to acquisitions made by or on behalf of the Indian Health Service of the Public Health Service.

370.501 Policy.

(a) The Indian Health Service will 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 set out in 25 U.S.C. 47, the Buy Indian Act provides as follows:

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) The functions, responsibilities, authorities, and duties of the Secretary of the Interior for maintenance and operation of hospital and health facilities for Indians and for the conservation of the health of Indians are

transferred to the Surgeon General of the United States under the supervision of the Secretary of Health and Human Services, 42 U.S.C. 2001 (a).

Accordingly, the Secretary of Health and Human Services 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 the Indian Health Service and is not available for use by any other HHS component (unless that component is making an acquisition on behalf of the Indian Health Service).

(c) Use of the Buy Indian Act negotiation authority has been emphasized in subsequent legislation, particularly Public Law 94-437 and Public Law 96-537.

370.502 Definitions.

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 the Indian Health Service.

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 Health and Human Services. The Secretary of Health and Human Services in making determinations may take into account the determination of the tribe with which affiliation is claimed.

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)).

Product of Indian industry means anything produced by Indians through physical labor or by intellectual effort involving the use and application of skills by them.

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 joint venture must be approved by the contracting officer 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, performance and payment bonds are required by the Miller Act (40 U.S.C. 270a-270f) and FAR part 28. In the case of contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe, bonds are not required. However, bonds are required when dealing with private business entities which are owned by an Indian tribe or members of an Indian tribe. Bonds may be required of private business entities which 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 Indian Preference clause set forth in 352.270-2 shall be included in all Buy Indian solicitations and resultant contracts. The Indian Preference Program clause set forth in 352.270-3 shall be used as specified in 370.202(b). All requirements set forth in subpart 370.2 which are applicable to the instant Buy Indian acquisition shall be followed by the contracting officer, e.g., sections 370.204 and 370.205.

(e) *Subcontracting.* Not more than 50 percent of the work to be performed under a prime contract awarded pursuant to the Buy Indian Act shall be subcontracted to other than Indian firms. For this purpose, work to be performed does not include the provision of materials, supplies, or equipment.

(f) *Wage rates.* A determination of the minimum wage rates by the Secretary of Labor as required by the Davis-Bacon Act (40 U.S.C. 276a) shall be included 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 wage rate determination is to be included 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 to be awarded under the Buy Indian Act shall be subject to competition among Indians or Indian concerns to the maximum extent that

competition is determined by the contracting officer to be practicable. When competition is determined not to be practicable, a Justification for Other than Full and Open Competition shall be prepared in accordance with 306.303 and subsequently retained in the contract file.

(b) Solicitations must be synopsisized and publicized in the Commerce Business Daily and copies of the synopses sent 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 synopsis should state that the acquisition is restricted to Indian firms under the Buy Indian Act.

370.505 Responsibility determinations.

(a) A contract may be awarded under the Buy Indian Act only if it is first determined that the project or function to be contracted for is likely to be satisfactorily performed under that contract and the project or function is likely to be properly completed or maintained under that contract.

(b) The determination called for by paragraph (a) of this section, to be made prior to the award of a contract, will be made in writing by the contracting officer reflecting an analysis of the standards set forth in FAR 9.104-1.

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