Department of Health and Human Services

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(Parts PHS 300 to PHS 399)

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SUBCHAPTER A—GENERAL

PART PHS 301—PHS ACQUISITION REGULATION SYSTEM

Subpart PHS 301.1—Purpose, Authority, Issuance

Sec.
PHS 301.101 Purpose.
PHS 301.102 Authority.
PHS 301.103 Applicability.
PHS 301.104 Issuance.
PHS 301.104-1 Publication and code arrangement.
PHS 301.104-2 Arrangement of regulations.
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PHS 301.105 OMB approval under the Paperwork Reduction Act.

Subpart PHS 301.2—Administration

PHS 301.201 Maintenance of the PHSAR.
PHS 301.270 Procurement Management Advisory Committee.
PHS 301.271 Timing of PHSAR revisions.

Subpart PHS 301.4—Deviations From the FAR

PHS 301.470 Procedure.

Source: 49 FR 36237, Sept. 14, 1984, unless otherwise noted.

Subpart PHS 301.1—Purpose, Authority, Issuance

PHS 301.101 Purpose.
(a) The Public Health Service Acquisition Regulation (PHSAR) is issued to establish uniform acquisition policies and procedures throughout PHS which are necessary to implement or supplement the Department of Health and Human Services Acquisition Regulation (HHSAR).
(b) PHS issuances do not reiterate material published in the HHSAR or the Federal Acquisition Regulation (FAR).
(c) The PHSAR implements and supplements the HHSAR. Implementing material expands upon or indicates the manner of compliance with the related HHSAR. Supplementing material is new material which has no counterpart in the HHSAR. The omission of sections or subsections in PHSAR means no further explanation or qualification is necessary for implementation within PHS. Therefore, in order to obtain comprehensive coverage and assure consideration of all acquisition policies and procedures pertinent to PHS, the FAR, HHSAR, and PHSAR should be read.

PHS 301.102 Authority.
(a) The HHSAR authorizes supplementation or implementation of the FAR and HHSAR in accordance with prescribed procedures (see 301.301) in order to publish essential acquisition instructions, policies, and procedures that do not conflict with, supersede or duplicate that prescribed by the FAR and the HHSAR.

PHS 301.103 Applicability.
The FAR, HHSAR and PHSAR issuances apply to all acquisitions made by PHS procuring activities as defined in FAR 1.103.

PHS 301.104 Issuance.
PHS 301.104-1 Publication and code arrangement.
(a) The PHSAR is published in the same forms as indicated in FAR 1.104-1(a).
(b) PHS issuances will be published on yellow pages in looseleaf form for insertion into the HHSAR.

PHS 301.104-2 Arrangement of regulations.
(a) General. The PHSAR conforms to the FAR and HHSAR with respect to divisional arrangements; i.e., subchapters, parts, subparts, sections, subsections, and paragraphs.
(c) References and citations.
(2) This regulation shall be referred to as the Public Health Service Acquisition Regulation (PHSAR), Appendix A to the Department of Health and Human Services Acquisition Regulation. Any reference shall be cited as “PHS” followed by the appropriate number.
(3) Citations of authority shall be incorporated where necessary. All FAR reference numbers shall be preceded by “FAR.” References to the HHSAR shall
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state only the number without the pre-
fix “HHSAR.”

**PHS 301.104-3 Copies.**

Copies of the PHSAR in Federal Register form may be purchased by the public from the Superintendent of Documents, Government Printing Office (GPO), Washington, DC 20402. Looseleaf copies of the PHSAR may be obtained by departmental personnel having a need for the document by placing an order with a Directives Distribution Coordinator in accordance with General Administration Manual Chapter 1-00, Exhibit G, HHS Staff Manual System.

**PHS 301.105 OMB approval under the Paperwork Reduction Act.**

The following OMB control numbers apply to the information collection and recordkeeping requirements contained in this regulation:

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<tr>
<td>All segments (excluding PHS 352.223-70 and PHS 352.232-70)</td>
<td>0990-0128</td>
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<td>PHS 352.223-70</td>
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<td>PHS 352.232-70</td>
<td>0990-0134</td>
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**Subpart PHS 301.2—Administration**

**PHS 301.201 Maintenance of PHSAR.**

The PHSAR is maintained by the Division of Grants and Contracts, Office of Resource Management, Office of Management, PHS. The Director, Division of Grants and Contracts is responsible for developing and preparing material to be included in the PHSAR.

**PHS 301.270 Procurement Management Advisory Committee.**

(a) The Director, Division of Grants and Contracts has established the Procurement Management Advisory Committee (PMAC) to assist and facilitate the planning and development of acquisition policies and procedures, and the resolving of operational problems affecting all acquisition activities in the PHS.

(b) The PMAC consists of members and alternates from the Office of the Assistant Secretary for Health, Alcohol, Drug Abuse, and Mental Health Administration, Centers for Disease Control, Food and Drug Administration, Health Resources and Services Administration, and National Institutes of Health.


**PHS 301.271 Timing of PHSAR revisions.**

PHSAR revisions will be issued throughout the year as the need arises. PHS issuances shall be effective on the date cited in the Federal Register issuance or on the date of the transmittal notice which distributes it to PHSAR Staff Manual holders, unless otherwise directed.

**Subpart PHS 301.4—Deviations From the FAR**

**PHS 301.470 Procedure.**

(a) Requests for deviations from the FAR, HHSAR or any PHSAR issuance for implementation or supplementation shall be submitted in writing by the PHS agency principal official responsible for acquisition to the Director, Division of Grants and Contracts, ORM/OM/PHS for approval and/or further processing as may be required. When it is recognized that a deviation will be required prior to the issuance of a solicitation, the request for deviation must be processed and approved prior to release of the solicitation. When completion of a contract action is contingent on approval of a deviation, the request for deviation must be processed and approval granted by the appropriate level, prior to contract execution. In an exigency situation, initial verbal contact should be made with the Chief, Contracts Management Branch, DGC/ORM/OM/PHS or his/her designee. Only deviations to the PHSAR may be granted by the Director, Division of Grants and Contracts.

(b) Each request for deviation shall provide sufficient information to permit PHS compliance with the HHSAR. Generally, such requests shall contain the following in addition to the information required by 301.470(b):

1. The name of the contractor and contract number, or the name of the
Appendix A—Public Health Service

proposed contractor and the solicitation number.
(2) A statement indicating whether or not the deviation had been previously requested. If so, outline the circumstances involved and the disposition of that request.

PART PHS 302—DEFINITIONS OF WORDS AND TERMS


Subpart PHS 302.1—Definitions

PHS 302.170 Definitions of terms.
The following terms, when utilized in PHS supplementing or implementing issuances to the HHSAR, have the meanings set forth below.

PHS agencies identifies collectively that group of organizational entities within the PHS which have assigned major health functions as currently shown in the PHS Organization Handbook. The PHS agencies are as follows:
Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)
Centers for Disease Control (CDC)
Food and Drug Administration (FDA)
Health Resources and Services Administration (HRSA)
National Institutes of Health (NIH)

PHS agency heads identifies collectively those individuals who are given the responsibility and authority to manage and direct the efforts of the PHS agencies. These are the Administrators of ADAMHA and HRSA, Commissioner of FDA, and Directors of NIH and CDC.

PHS contracting activities identifies collectively those organizational elements of the PHS staff offices and the PHS agencies which have functional responsibility to contract for the acquisition of personal property and nonpersonal services.
[49 FR 36238, Sept. 14, 1984]
PHS 304.670 (ii) These reports shall be submitted to DGC/ORM/OM/PHS within 20 days following the expiration of the reporting period. A consolidated PHS report will be prepared for submission to the Deputy Assistant Secretary for Procurement, Assistance, and Logistics as specified in 304.170.

Subpart PHS 304.6—Contract Reporting

PHS 304.670 PHS Contract Information System (PHSCIS).

The PHS Contract Information System consolidates all PHS contract data for the Department-wide Contract Information System (DCIS) from the PHS contracting activities.

PHS 304.670-1 Policy

The PHS principal officials responsible for acquisition (PORA) are responsible for ensuring that all required information is collected, submitted, and received into the PHSCIS in accordance with the central PHSCIS User Manual.


PHS 304.670-2 PHS agency implementation.

It is the responsibility of the PORAs to develop and implement appropriate procedures within their activities to ensure that data submissions to the PHSCIS are timely, error free, and contain all the required information.

Subpart PHS 304.71—Review and Approval of Proposed Contract Awards

PHS 304.7101 Contracts requiring review and approval.

(b)2(ii) In addition to the reviews required by 304.7101(a) and PHS 304.7101(c), internal reviews are to be conducted of acquisitions made by the following contracting offices in the National Institutes of Health for contract awards that fall below the dollar threshold for review and approval set forth in PHS 304.7101(c) but exceed the dollar threshold set forth herein:

National Cancer Institute—$750,000
National Heart, Lung, and Blood Institute—$500,000
National Institute of Environmental Health Sciences—$250,000
National Institute of Allergy and Infectious Diseases—$250,000
National Institute of Child Health and Human Development—$250,000
Centralized procuring activity for all other National Institutes of Health Research Organizations (Research Contracts Branch)—$250,000

These internal reviews shall be conducted by senior personnel with each contracting office. Typically, the chief of contracting office or his/her deputy should be involved in the review. Personnel involved in the contract action shall not perform the review. Each review shall be documented in writing, and any substantive issues identified shall be resolved prior to award.

(ii) Furthermore, to assure that an adequate review of smaller dollar acquisitions is made prior to award, a statistically significant sample of contract actions of dollar values, less than those amounts referenced in this section is required to be approved prior to award. This review and approval will be by the designated Reviewing Official listed in paragraph (c) (but see PHS 304.7102(a)). Records of such review actions will be maintained and will include documentation of the resolution of any significant issue raised by the review.

(iii) Contract awards and modifications of proposed architect-engineer contracts expected to exceed $50,000 shall be reviewed and approved prior to award by the reviewing official designated in PHS 304.7101(c).

(c) Reviewing officials. For PHS agency contract awards expected to exceed the dollar amounts stated in this paragraph, the reviewing official indicated will personally approve the award. Other than these specified requirements for the designated reviewing official, PHS agencies may assign other review and approval responsibilities at their discretion. The following officials shall be responsible for preaward contract review and approval of all proposed contracts and modifications which are expected to exceed the dollar limits expressed below:
### Appendix A—Public Health Service

<table>
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<th>Reviewing official</th>
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</thead>
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<tr>
<td>$300,000 Administrative Services Center, Office of Management</td>
<td>Director, Administrative Services Center</td>
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#### Alcohol, Drug Abuse and Mental Health Administration

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<td>National Institute on Drug Abuse</td>
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<tr>
<td>300,000</td>
<td>National Institute on Alcohol Abuse and Alcoholism</td>
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<tr>
<td>300,000</td>
<td>National Institute of Mental Health</td>
<td>Director, Division of Grants and Contracts Management</td>
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<tr>
<td>300,000</td>
<td>St Elizabeths, Hospital, NIMH</td>
<td>Director, Division of Grants and Contracts Management</td>
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<tr>
<td>50,000</td>
<td>Addiction Research Center</td>
<td>Director, Division of Grants and Contracts Management</td>
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#### Centers for Disease Control

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<td>National Center for Toxicological Research</td>
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#### National Institutes of Health

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<tr>
<td>1,000,000</td>
<td>National Heart, Lung, and Blood Institute</td>
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#### National Institutes of Environmental Health Sciences

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<td>Other than research and development</td>
<td>Director, Division of Procurement</td>
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<td>750,000</td>
<td>National Institute of Child Health and Human Development</td>
<td>Director, Division of Grants and Contracts Management</td>
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<tr>
<td>750,000</td>
<td>National Institute of Allergy and Infectious Diseases</td>
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<tr>
<td>500,000</td>
<td>National Institute of Neurological and Communicative Disorders and Stroke</td>
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#### Health Resources and Services Administration

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<tr>
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<td>Awards made by other than Headquarters and the Indian Health Service</td>
<td>Director, Division of Grants and Procurement Management</td>
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</table>
PHS 304.7102 Conduct of the review.

(a) General. The reviewing official is not required to personally perform the review, but he or she is responsible for assuring that the reviewer is knowledgeable in the acquisition field and has sufficient expertise to perform a comprehensive review and to make cogent recommendations to the reviewing official for actions exceeding the dollar amounts stated in this subpart. The reviewing official shall approve each proposed contract award that is reviewed.
SUBCHAPTER B—ACQUISITION PLANNING

PART PHS 305—PUBLICIZING CONTRACT ACTIONS


Subpart PHS 305.2—Synopses of Proposed Contract Actions

PHS 305.202 Exceptions.

(b) A determination and finding has been executed by the Acting Assistant Secretary for Health after concurrence by the Administrator of the Office of Federal Procurement Policy and the Administrator of the Small Business Administration, which exempts for the period September 30, 1985 through September 29, 1988, certain acquisitions with the National Academy of Sciences (NAS) from the synopsis requirements set forth in FAR 5.201. This exemption is applicable only to acquisitions where NAS is the only source which can provide the measure of expertise, independence, objectivity, and audience acceptance necessary to meet the program requirements. To ensure that this exemption will be used only when appropriate, the agency competition advocate shall certify, prior to award, each acquisition with NAS which is not synopsized regardless of the dollar value. The certification must state that only NAS can provide the measure of expertise, independence, objectivity, and audience acceptance necessary to meet the program needs.

[51 FR 20487, June 5, 1986]

PART PHS 306—COMPETITION REQUIREMENTS

Subpart PHS 306.3—Other Than Full and Open Competition

Sec.

PHS 306.304 Approval of the justification.

PHS 306.502 Duties and responsibilities.


SOURCE: 51 FR 20487, June 5, 1986, unless otherwise noted.

Subpart PHS 306.5—Competition Advocates

PHS 306.502 Duties and responsibilities.

(a)(3) The Deputy Assistant Secretary for Health, Operations, PHS, is designated as the approving official referenced in FAR 6.304(a)(3) and 306.304(a)(3).

Subpart PHS 306.3—Other Than Full and Open Competition

PHS 306.304 Approval of the justification.

(a)(3) The Deputy Assistant Secretary for Health, Operations, PHS, is designated as the approving official referenced in FAR 6.304(a)(3) and 306.304(a)(3).

Subpart PHS 306.5—Competition Advocates

PHS 306.502 Duties and responsibilities.

(b) The competition advocates for the PHS activities shall coordinate their efforts with the PHS competition advocate, the Deputy Assistant Secretary for Health Operations.
SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

PART PHS 314—FORMAL ADVERTISING

Subpart PHS 314.4—Opening of Bids and Award of Contract

Sec. 314.406-3 Other mistakes disclosed before award.

PHS 314.406-4 Mistakes after award.


Subpart PHS 314.4—Opening of Bids and Award of Contract

PHS 314.406-3 Other mistakes disclosed before award.

(g)(3) In addition to the requirement in 314.406-3(g)(3), a copy of the data required by FAR 14.406-3(g)(3) shall be sent to the Office of General Counsel, Business and Administrative Law Division, Parklawn Building, Room 17A-32, 5600 Fishers Lane, Rockville, MD 20857. An information copy of the contracting officer's written statement of facts and circumstances shall be provided to the Contracts Management Branch, DGC/ORM/OM/PHS.

[51 FR 20488, June 5, 1986]

PHS 314.406-4 Mistakes after award.

(e)(2) The data shall be submitted as prescribed in PHS 314.406-3(g)(3).

[51 FR 20488, June 5, 1986]

PART PHS 315—CONTRACTING BY NEGOTIATION

Subpart PHS 315.4—Solicitation and Receipt of Proposals and Quotations


PHS 315.412 Late proposals and modifications.

(c)(1) When the principal official responsible for acquisition determines that certain classes of biomedical or behavioral research and development acquisitions should be subject to conditions other than those specified in FAR 52.215-10, Late Submissions, Modifications and Withdrawals of Proposals, he/she may authorize the use of the provision in PHS 352.215-10 in addition to the provision at FAR 52.215-10.

(2) When the provision in PHS 352.215-10 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 PHS 352.215-10 and, therefore, can be considered.

SUBCHAPTER D—SOCIOECONOMIC PROGRAMS

PART PHS 323—ENVIRONMENT, CONSERVATION, AND OCCUPATIONAL SAFETY

Subpart PHS 323.70—Safety and Health

Sec.
PHS 323.7000 Scope of subpart.
PHS 323.7001 General.
PHS 323.7002 Policy.
PHS 323.7003 Actions required.
PHS 323.7004 Contract clause.
PHS 323.7005 Solicitation notice—construction.

SOURCE: 51 FR 20488, June 5, 1986, unless otherwise noted.

Subpart PHS 323.70—Safety and Health

PHS 323.7000 Scope of subpart.

This subpart prescribes the use of a safety and health clause in contracts involving hazardous material or operations, and procedures for developing and administering safety and health provisions.

PHS 323.7001 General.

Various statutes and regulations (e.g., Walsh-Healey Act; Service Contract Act) require adherence to minimum safety and health standards by contractors engaged in potentially hazardous work. Positive action to reduce accidents and conditions hazardous to health under all contracts is in the Government’s interest since the cost of such accident and health hazards is borne by the Government through higher prices and sometimes by direct indemnification of contractors against liability claims.

PHS 323.7002 Policy.

(a) The guidance contained in FAR Subpart 23.3 shall be used for hazardous material as the primary reference. When that guidance is judged insufficient or does not meet the safety and health situation in the instant acquisition, this subpart shall be followed.

(b) Whenever the performance of a contract will require use of hazardous materials or operations, the contracting activity shall require the prime contractor and subcontractors to:
   (1) Provide protection for the life and health of PHS employees, contractor employees, other persons involved with work on PHS programs and projects, and the public;
   (2) Avoid accidental work interruptions which could delay progress of PHS programs and project;
   (3) Maintain controls for the prevention of damage and loss to property; and
   (4) Accumulate and provide data necessary for analysis of risk and loss factors relating to PHS programs and projects.

PHS 323.7003 Actions required.

(a) Contracting activities. Contracting activities shall use the clause set forth in PHS 352.223-70 as a guide in developing appropriate safety and health clauses for use in prospective contracts involving 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) Selecting or developing safety and health clause provisions for incorporation in a prospective contract,
   (3) Evaluating a prospective contractor’s safety and health programs; and
   (4) Conducting post-award review 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 RFP or IFB:
PHS 323.7004  Contract clause.
All contracts which require the use of hazardous materials or operations shall include a clause to provide adherence to minimum safety and health standards. The clause set forth in PHS 352.223-70 may be used or appropriately modified to meet the needs of the individual contract.

PHS 323.7005  Solicitation notice—construction.
The contracting officer shall include the clause in PHS 352.223-71 in all solicitations and resultant contracts for construction and construction services.

(i) Ensure that hazardous materials and operations to be utilized in the performance of the contract are clearly identified; and
(ii) Coordinate with the appropriate safety officer to ensure that all hazardous materials and operations are evaluated and that adequate safety requirements are established in the RFP or IFB.
(2) During the period of performance:
(i) Apprise the contracting officer of any noncompliance with safety and health provisions identified in the contract; and
(ii) Cooperate with the safety officer in conducting review and surveillance activities.
SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS

PART PHS 333—PROTESTS, DISPUTES, AND APPEALS

Subpart PHS 333.1—Protests

Sec.
PHS 333.102 General.
PHS 333.104 Protests to GAO.
PHS 333.105 Protests to GSBCA.

SOURCE: 51 FR 20488, June 5, 1986, unless otherwise noted.

Subpart PHS 333.1—Protests

PHS 333.102 General.

The Division of Grants and Contracts (DGC), ORM/OM/PHS, will participate directly in the resolution of protests against PHS agencies when the Office of the Secretary, HHS, requests DGC involvement, or when DGC considers a protest action to be sensitive or controversial, or otherwise has an interest in the protest. In cases where DGC will participate, the cognizant PHS contracting office shall be notified. In those instances, all file materials and written statements normally forwarded directly to the Departmental Protest Control Officer shall be forwarded to DGC, ORM/OM/PHS.

PHS 333.104 Protests to GAO.

(a) General. (2) A copy of the protest files shall be sent to the Office of General Counsel, Business and Administrative Law Division (OGC-BAL), Parklawn Building, Room 17A-32, 5600 Fishers Lane, Rockville, MD 20857. In addition, an information copy of the contracting officer’s statement of facts required by 333.104(a)(2)(i) shall be sent to the Contracts Management Branch, DGC/ORM/OM/PHS.

(b) Protests before award. (1) The head of the contracting activity authority to approve the written finding required by FAR 33.104(b)(1) to authorize a contract award while a protest is pending, may be delegated to an organizational level no lower than the Executive Officer of each PHS Agency.

(4) The data shall be submitted as prescribed in PHS 333.104(a)(2).

(c) Protests after award. (1) The data shall be submitted as prescribed in PHS 333.104(a)(2).

(2) The head of the contracting activity authority to authorize contract performance notwithstanding a protest as set forth in FAR 33.104(c)(2), may be delegated to an organizational level no lower than the Executive Officer of each PHS Agency.

PHS 333.105 Protests to GSBCA.

(b) The copy of the protest file to be sent to OGC-BAL shall be sent to OGC-BAL, Parklawn Building, Room 17A-32, 5600 Fishers Lane, Rockville, MD 20857. In addition, an information copy of the contracting officer’s statement of facts required by 333.105(b)(1) shall be sent to the Contracts Management Branch, DGC/ORM/OM/PHS.
SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING

PART PHS 335—RESEARCH AND DEVELOPMENT CONTRACTING


PHS 335.080 Special determinations and findings affecting research and development contracting.

The Assistant Secretary for Health 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).

[51 FR 20489, June 5, 1986]

PART PHS 336—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

Subpart PHS 336.6—Architect-Engineer Services

Sec.

PHS 336.680 Program of Requirements approval.

PHS 336.681 Funding.

PHS 336.681 Funding.

(a) The contracting officer shall ensure that the agency financial management officer has identified and certified that design funds have been appropriated and apportioned prior to the release of a synopsis or solicitation for architect-engineer services for the types of acquisitions specified in PHS 336.680. New facilities, replacement facilities, and building additions must only be acquired with funds appropriated for that specific project as evidenced by either (1) specific language in an appropriations act, or (2) Congressional appropriations intent as reflected in appropriations committee reports or Congressional budget justification.

(b) In the case of ADAMHA, FDA, HRSA, and NIH, the referenced agency financial management officer is the Director of the agency’s Division of Financial Management. In the case of CDC, this official is the Director of the Financial Management Office. Subject to HRSA concurrence, funding for projects of the Indian Health Service/HRSA may be certified by the designated financial management officer within the IHS Office of Administration.

(c) The funding source certification shall include identification of the title, appropriation symbol, and fiscal year of the appropriation plus any relevant project or activity description in the appropriation act or reports.

(d) In an unusual circumstance where time is critical, a synopsis or solicitation for architect-engineer services may be issued after the POR has been approved if the agency financial management officer certifies that appropriation and apportionment of proper funds as set forth in paragraph (a) above are expected within 60 days. In such cases, the synopsis or solicitation must specify that award is subject to the availability of funds. In these circumstances the contracting officer shall ensure that contract award is not made until the agency financial management officer has certified in writing...
that proper funds have been appropriated and apportioned. Other exceptions to the funding requirements set forth in paragraph (a) above, must be specifically approved in writing by the Office of the Assistant Secretary for Health prior to the release of a synopsis or solicitation for architect-engineer services for new facilities, replacement facilities, and building additions.
SUBCHAPTER H—CLAUSES AND FORMS

PART PHS 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Subpart PHS 352.2—Texts of Provisions and Clauses

Sec. 352.215-10 Late proposals, modifications of proposals, and withdrawals of proposals.

As prescribed in PHS 315.412, the following provision may be included in the solicitation when authorized by the principal official responsible for acquisition.

LATE PROPOSALS, MODIFICATIONS OF PROPOSALS, AND WITHDRAWALS OF PROPOSALS (NOV 1986)

Notwithstanding the procedures contained in the provision of this solicitation entitled Late Submissions, Modifications, and Withdrawals of Proposals, 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)

PHS 352.223-70 Safety and health.

The following clause is covered by the policy set forth in Subpart PHS 323.70 and is to be used in accordance with the instructions set forth in PHS 323.7002 and PHS 323.7003.

SAFETY AND HEALTH (APR 1994)

(a) In order to provide safety controls for protection to the life and health of employees and other persons; for prevention of damage to all property; and for avoidance of work interruptions in the performance of the contract; the Contractor will comply with the following standards: (Insert codes, standards, and criteria (including any applicable State and local requirements) prescribed by the Safety Officer.)

Further, the Contractor shall take or cause to be taken such additional safety measures as the Contracting Officer may determine to be reasonably necessary; provided, that, if compliance with such additional safety measures results in a material increase in the cost or time of performance of the contract, an equitable adjustment will be made in accordance with the clause of this contract entitled “Changes.”

(b) Prior to commencement of work, the Contractor will submit in writing its plan for complying with the safety and health provisions of this contract, and will meet with the Contracting Officer or his/her designated representative to discuss and develop a mutual understanding relative to administration of the overall safety program.

(c) During the performance of work under this contract, the Contractor shall comply with all procedures prescribed by the Contracting Officer for the control and safety of persons visiting the job site and will comply with such requirements to prevent accidents as may be prescribed by the Contracting Officer.

(d) The Contractor will maintain an accurate record of, and report to the Contracting Officer in such manner as the Contracting Officer may prescribe, all accidents and incidents resulting in death, traumatic injury, occupational disease, and/or damage to all property incident to work performed under the contract.
Appendix A—Public Health Service

(e) The Contracting Officer shall notify (if otherwise, confirm in writing) the Contractor of any noncompliance with the provisions of this clause and corrective action to be taken. After receipt of such notice, the Contractor shall immediately take such corrective action. (Such notice, when delivered to the Contractor or its representative at the site of the work, shall be deemed sufficient for the purpose.) If the Contractor fails or refuses to comply promptly, the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action has been taken. No part of the time lost due to any such stop order shall be the subject of claim for extension of time or for costs or damages by the Contractor.

(f) The Contractor shall insert the substance of this clause in each subcontract involving the use of hazardous materials or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

PHS 352.223–71 Safety and health—construction.

The following clause shall be included in all solicitations and resultant contracts for construction and construction services, as required by PHS 323.7005.

SAFETY AND HEALTH—CONSTRUCTION (APR 1984)

Your attention is invited to the regulations issued by the Secretary of Labor pursuant to section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) entitled “Safety and Health Regulations for Construction” (29 CFR part 1926). The Contractor is required to comply with the referenced regulations to the extent that the resultant contract involves construction.

(End of clause)

PHS 352.232–70 Additional payment provision.

The following clause shall be included in all solicitations and resultant contracts for construction which contain the “Payments Under Fixed-Price Construction Contracts” clause set forth in FAR 52.232-4:

ADDITIONAL PAYMENT PROVISION (APR 1984)

Unless otherwise stated in this contract, there will be taken into consideration in computing progress payments material that will be incorporated into the structure if such material is delivered at the site, or is delivered to the Contractor and properly stored by it in a suitable warehouse, storage yard, or similar place either within 25 miles of the site or as otherwise approved by the Contracting Officer. Before each payment is made, the Contractor shall furnish to the Contracting Officer such evidence as he/she may require of the quantity and value of such material and that it will be incorporated into the structure. If such material is stored off the site, the Contractor shall also furnish to the Contracting Officer, before payment, properly executed bills of sale to the Government for the delivered material upon which such payment is to be made.

(End of clause)

PHS 352.280–1 Protection of human subjects.

The policy and procedures to be followed whenever individuals may be involved as subjects in research activities supported or conducted by the Department under a contract are provided in Subpart PHS 380.1 and 45 CFR Part 46, Protection of Human Subjects.

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

NOTICE TO OFFERORS OF REQUIREMENTS OF 45 CFR PART 46, PROTECTION OF HUMAN SUBJECTS (SEP 1985)

(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 (1) data through intervention of interaction with the individual, or (2) 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 non-involvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Public Health Service 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 contracts involving human subjects:

PROTECTION OF HUMAN SUBJECTS (OCT 1986)

(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 for Research Risks, National Institutes of Health, Public Health Service. 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 agency 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 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) 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 such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete the 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 Department of Health and Human Services Human Subject Assurances.

(End of clause)

[51 FR 20490, June 5, 1986, as amended at 52 FR 9300, Mar. 24, 1987]

PHS 352.280–2 Care of laboratory animals.

The policies and procedures to be used when contracts involve live vertebrate animals are provided in Subpart PHS 380.2, and in the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions and accompanying implementation instructions published in a special edition of the NIH Guide for Grants and Contracts, Vol. 14, No. 8, June 25, 1985.
Appendix A—Public Health Service

PHS 352.280-3

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

**PHS 352.280-3 Maximum allowable cost for drugs.**

The following clause, or one reading substantially as follows, shall be included in all contracts subject to the provisions of the Maximum Allowable Cost (MAC) regulation and PHS 380.305.

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

**CARE OF LIVE VERTEBRATE ANIMALS (OCT 1986)**

(a) Before undertaking performance of any contract involving research on live vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2336 and 9 CFR 2.25-2.28. The Contractor shall furnish evidence of such 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 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 and Use of Laboratory Animals by Awardee Institutions, 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) and (c), above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects such 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 Public Health Service 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 Senior Staff Officer, Animal Care Staff, USDA/APHIS, Federal Center Building, Hyattsville, Maryland 20782.
Maximum Allowable Cost for Drugs (APR 1984)

(a) Reimbursement for drugs provided or used under this contract shall be in accordance with the Maximum Allowable Cost (MAC) regulation set forth in 45 CFR subtitle A, part 19. In accordance with 19.3 of the MAC regulation, the amount which is recognized for reimbursement or payment purposes for any drug purchased under the terms of the contract shall not exceed the lowest of:

1. The maximum allowable cost of the drug, if any, established in accordance with 19.5 of the MAC regulation plus a reasonable dispensing fee;
2. The acquisition cost of the drug plus a reasonable dispensing fee; or
3. The provider's usual and customary charge to the public for the drug.

Provided, That:

1. The maximum allowable cost established for any drug shall not apply to a brand of that drug prescribed for a patient which the prescriber has certified in his/her own handwriting is medically necessary for that patient; and Provided, further, That:
   i. When compensation for drug dispensing is included in some other amount payable to the provider by the reimbursing or payment program agency, a separate dispensing fee will not be recognized.
   (b) The Contractor agrees:
      1. To include the following solicitation notification in all applicable solicitations issued under this contract and to ensure that subcontractors include it in any subsequent applicable solicitation:
         This acquisition is subject to the Maximum Allowable Cost (MAC) regulation set forth in part 19 to subtitle A of title 45 of the Code of Federal Regulations.
      2. To include this clause, including this paragraph (b), in all applicable subcontracts, regardless of tier, awarded pursuant to this contract.
      3. To include the furnished MAC determination or acquisition cost data in all applicable solicitations issued under this contract and in all resultant subcontracts awarded pursuant to this contract.

(End of clause)

PHS 352.280-4 Contracts awarded under the Indian Self-Determination Act.

(a) Insert the following clauses in cost-reimbursement contracts awarded under the Indian Self-Determination Act as described in subpart PHS 380.4.
CLAUSE NO. 3–LIMITATION OF COST (JUN 1977)

(a) It is estimated that the total cost to the Government for the performance of this contract will not exceed the estimated cost set forth in this contract and the Contractor agrees to use its best efforts to perform all work and all obligations under this contract within such estimated costs. If at any time the Contractor has reason to believe that the costs which it expects to incur in the performance of this contract in the next succeeding sixty (60) days, when added to all costs previously incurred, will exceed seventy-five percent (75%) of the estimated cost set forth in the contract, or, if at any time the Contractor has reason to believe that the total cost to the Government, for the performance of this contract, will be substantially greater or less than the estimated cost thereof, the Contractor shall notify the Contracting Officer in writing to that effect, giving its revised estimate of such total cost for the performance of this contract.

(b) The Government shall not be obligated to reimburse the Contractor for costs incurred in excess of the estimated cost set forth in the contract and the Contractor shall not be obligated to continue performance under the contract or to incur costs in excess of such estimated cost unless and until the Contracting Officer shall have notified the Contractor in writing that such estimated cost has been increased and shall have specified in such notice a revised estimated cost which shall thereupon constitute the estimated cost of performance of this contract. When and to the extent that the estimated cost set forth in this contract has been increased by the Contracting Officer in writing, any costs incurred by the Contractor in excess of such estimated cost prior to the increase in estimated cost shall be allowable to the same extent as if such costs had been incurred after such increase in estimated cost.

CLAUSE NO. 4—ALLOWABLE COST (JUN 1977)

(a) Compensation for Contractor’s performance. Payment for the allowable cost, as herein defined and as actually incurred by the Contractor shall constitute full and complete compensation for the performance of the work under this contract.

(b) Allowable cost. The allowable cost of performing the work under this contract shall be the cost actually incurred by the Contractor, either directly incident or properly allocable to the contract, in the performance of this contract in accordance with its terms. The allowable cost, direct and indirect, including acceptability of cost allocation methods, shall be determined by the Contracting Officer in accordance with:

1. (i) “A Guide for Nonprofit Institutions Establishing Indirect Cost Rates for Research Grants and Contracts with the Department of Health and Human Services,” HHS Publication OASC-5,” or (ii) “A Guide for Hospitals, Grants and Contracts with the Department of Health and Human Services, HHS Publication OASC-3,” or (iii) Subpart 1-15.7 of the Federal Procurement Regulations (41 CFR subpart 1-15.7) if the contract is with a state or local government agency, or (iv) Subpart 1-15.4 of the Federal Procurement Regulations (41 CFR subpart 1-15.4) if the contract is for the procurement of construction or architect-engineer services.

2. The terms of the contract.

CLAUSE NO. 5—NEGOTIATED OVERHEAD RATES (JUN 1977)

(a) Notwithstanding the provisions of the clause of this contract entitled, “Allowable Cost,” the allowable indirect costs shall be obtained by applying negotiated overhead rates to bases agreed upon by the parties, as specified below.

(b) The Contractor, as soon as possible, but not later than six (6) months after the expiration of each of the Contractor’s financial years or such period as may mutually be agreed upon by the Government and the Contractor, shall submit to the Contracting Officer, with a copy to the cognizant audit agency, a proposed final overhead rate or rates for that period based on the Contractor’s cost experience during that period, together with supporting cost data. Negotiation of final overhead rates by the Contractor and the Contracting Officer shall be undertaken as promptly as practicable after receipt of the Contractor’s proposal.

(c) Allowability of costs and acceptability of cost allocation methods shall be determined in accordance with the applicable cost principles set forth in paragraph (b)(1) of Clause 4, as in effect on the date of this contract, and the same hereby incorporated herein by reference.

(d) The results of each negotiation shall be set forth in an amendment to this contract, which shall specify (1) the agreed final rate,
(2) the bases to which the rates apply, and (3) the periods for which the rates apply.

(e) Pending establishment of final overhead rates for any period, the Contractor shall be reimbursed either at negotiated provisional rates as provided in this contract or at billing rates acceptable to the Contracting Officer, subject to appropriate adjustment when the final rates for that period are established. To prevent substantial over or underpayment, the provisional or billing rates may, at the request of either party, be revised by mutual agreement, either retroactively or prospectively. Any such revision of negotiated provisional rates provided in this contract shall be set forth in an amendment to this contract.

(f) Any failure by the parties to agree on any final rate or rates under this clause shall be considered a dispute concerning a question of fact for decision by the Contracting Officer within the meaning of the clause of this contract entitled "Disputes."

(g) Submission of proposed provisional and/or final overhead rates, together with appropriate data in support thereof, to the Secretary or his/her duly authorized representative, and agreements on provisional and/or final overhead rates entered into between the Contractor and the Secretary or his/her duly authorized representative, as evidenced by Negotiated Overhead Rate Agreements signed by both parties, shall be deemed to satisfy the requirements of (b), (d) and (e) above.

(End of clause)

CLAUSE NO. 6—PAYMENT (JUN 1977)

(a) Payment on account of allowable cost. Once each month (or at more frequent intervals if approved by the Contracting Officer) the Contractor may submit to the Contracting Officer, in such form and reasonable detail as may be required, an invoice or voucher supported by a statement of costs incurred by the Contractor in the performance of this contract and claimed to constitute allowable costs. Promptly after receipt of each invoice or voucher, the Government shall, subject to the provisions of (b) below, make payment thereon as approved by the Contracting Officer.

(b) Audit Adjustments. At any time or times prior to settlement under this contract the Contracting Officer may have invoices or vouchers and statements of cost audited. Each payment theretofore made shall be subject to reduction for amounts included in the related invoice or voucher which are found by the Contracting Officer, on the basis of such audit, not to constitute allowable cost. Any payment may be reduced for overpayment, or increased for underpayments on preceding invoices or vouchers.

(c) Completion voucher. On receipt and approval of the invoice or voucher designated by the Contractor as the "completion invoice" or "Completion Voucher" and upon compliance by the Contractor with all the provisions of this contract (including without limitation, the provisions relating to patents and provisions of (d) below) the Government shall promptly pay to the Contractor any balance of allowable cost. The completion invoice or voucher shall be submitted by the Contractor promptly following completion of the work under this contract but in no event later than 6 months (or such longer period as the Contracting Officer may in his/her discretion approve in writing) from the date of such completion.

(d) Applicable credits. The Contractor agrees that any refunds, rebates, credits, or other amounts (including any interest thereon) accruing to or received by the Contractor or any assignee under this contract shall be paid by the Contractor to the Government, to the extent that they are properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract. Reasonable expenses incurred by the Contractor for the purpose of securing such refunds, rebates, credits, or other amounts shall be allowable cost hereunder when approved by the Contracting Officer.

(e) Financial settlement. Prior to final payment under this contract, the Contractor and each assignee under this contract whose assignment is in effect at the time of final payment under this contract shall execute and deliver:

(1) An assignment to the Government in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including any interest thereon) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract, and

(2) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, subject only to the following exceptions:

(i) Specified claims in stated amounts or in estimated amounts where the amounts are susceptible to exact statement by the Contractor;

(ii) Claims, together with reasonable expenses incidental thereto, based upon liabilities of the Contractor to third parties arising out of the performance of this contract; Provided, That such claims are not known to the Contractor on the date of the execution of the release; And provided further, That the Contractor gives notice of such claims in writing to the Contracting Officer not more than 6 years after the date of the release or the date of any notice to the Contractor that the Government is prepared to make final payment, whichever is earlier; and

(iii) Claims for reimbursement of costs (other than expenses of the Contractor by...
reason of its indemnification of the Government against patent liability, including reasonable expenses incidental thereto, incurred by the Contractor under the provisions of this contract relating to patents.

(End of clause)

CLAUSE NO. 7—ADVANCE PAYMENTS (JUN 1977)

(a) Amount of Advance. At the request of the Contractor, and subject to the conditions herein set forth, the Government shall make an advance payment, or advance payments from time to time, to the Contractor. No advance payment shall be made (1) without the approval of the office administering advance payments (hereinafter called the "Administering Office" and designated in paragraph (k)(4) as with all advance payments theretofore made, shall exceed the amount stated in paragraph (k)(1) hereof; and (3) without a properly certified invoice or invoice.

(b) Special Bank Account. Until all advance payments made hereunder are liquidated and the Administering Office approves in writing the release of any funds due and payable to the Contractor, all advance payments and all other payments under the contract shall be made by check payable to the Contractor, and be marked for deposit only in a Special Bank Account with the bank designated in paragraph (k)(2) hereof. No part of the funds in the Special Bank Account shall be mingled with other funds of the Contractor prior to withdrawal therefrom from the Special Bank Account as hereinafter provided. Except as hereinafter provided, each withdrawal shall be made only by check of the Contractor countersigned on behalf of the Government by the Contracting Officer or such other person or persons as he/she may designate in writing (hereinafter called the "Countersigning Agent"). Until otherwise determined by the Administering Office, countersignature on behalf of the Government will not be required.

(c) Use of Funds. The funds in the Special Bank Account may be withdrawn by the Contractor solely for the purposes of making payments for items of allowable cost or to reimburse the Contractor for such items of allowable cost, and for such other purposes as the Administering Office may approve in writing. An interpretation required as to the proper use of funds shall be made in writing by the Administering Office.

(d) Return of Funds. The Contractor may at any time repay all or any part of the funds advanced hereunder. Whenever so requested in writing by the Administering Office, the Contractor shall repay to the Government such part of the unliquidated balance of advance payments as shall in the opinion of the Administering Office be in excess of current requirements, or (when added to total advance previously made and liquidated) in excess of the amount specified in paragraph (k)(1) hereof. In the event the Contractor fails to repay such part of the unliquidated balance of advance payments when requested by the Administering Office, all or any part thereof may be withdrawn from the Special Bank Account by checks payable to the Treasurer of the United States alone by the Countersigning Agent and applied in reduction of advance payments then outstanding hereunder.

(e) Liquidation. If not otherwise liquidated, the advance payments made hereunder shall be liquidated as herein provided. When the sum of all payments under this contract, other than advance payments, plus the unliquidated amount of advance payments are equal to the total estimated cost for the work under this contract or such lesser amount to which the total estimated cost under this contract may have been reduced, plus increases, if any, in this total estimated cost not exceeding, in the aggregate (including, without limitation, reimbursable costs incident to termination for cause and retrocession as estimated by the Contracting Officer), the Government shall thereafter withhold further payments to the Contractor and apply the amounts withheld against the Contractor's obligation to repay such advance payments until such advances payments shall have been fully liquidated. If upon completion, termination, or retrocession of the contract all advance payments have not been fully liquidated, the balances therefor shall be deducted from any sums otherwise due or which may become due to the Contractor from the Government, and any deficiency shall be paid by the Contractor to the Government upon demand.

(f) Bank Agreement. Before an advance payment is made hereunder, the Contractor shall transmit to the Administering Office, in the form prescribed by such office, an Agreement in triplicate from the bank in which the Special Bank Account is established, clearly setting forth the special character of the account and the responsibilities of the bank thereunder. Wherever possible, such bank shall be a member bank of the Federal Reserve System, or an "insured" bank within the meaning of the Act creating the Federal Deposit Insurance Corporation Act of August 23, 1935, 49 Stat. 685, as amended (12 U.S.C. 264).

(g) Lien on Special Bank Account. The Government shall have a lien upon any balance in the Special Bank Account pursuant to any and all other liens, which lien shall secure the repayment of any advance payments made hereunder.

(h) Lien on Property Under Contract. Any and all advance payments made under this contract shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, upon the supplies or other...

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things covered by this contract and on all material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other provision of this contract, or otherwise, shall have valid title to such supplies, materials, or other property as against other creditors of the Contractor. The Contractor shall identify, by marking or segregation, all property which is subject to a lien in favor of the Government by virtue of any provision of this contract in such a way as to indicate that it is subject to such lien and that it has been acquired for or allocated to the performance of this contract. If for any reason such supplies, materials, or other property are not identified by marking or segregation, the Government shall be deemed to have a lien to the extent of the Government's interest under this contract on any mass of property with which such supplies, materials, or other property are commingled. The Contractor shall maintain adequate accounting control over such property on its books and records. If at any time during the progress of the work on the contract it becomes necessary to deliver any item or items and materials upon which the Government has a lien as aforesaid to a third person, the Contractor shall notify such third person of the lien herein provided and shall obtain from such third person a receipt, in duplicate, acknowledging, inter alia, the existence of such lien. A copy of each receipt shall be delivered by the Contractor to the Contracting Officer. If this contract is terminated in whole or in part and the Contractor is authorized to sell or retain termination inventory acquired for or allocated to this contract, such sale or retention shall be made only if approved by the Contracting Officer, which approval shall constitute a release to the Government's lien hereunder to the extent that such termination inventory is sold or retained, and to the extent that the proceeds of the sale, or the credit allowed for such retention on the Contractor's termination claim, is applied in reduction of advance payments then outstanding hereunder.

(a) This clause is applicable if the amount of this contract exceeds $2,500 and was entered into by means of negotiation including small business restricted advertising, but is not applicable if this contract was entered into by means of formal advertising.

(b) The Contractor agrees that the Controller General of the United States and the Secretary, or any of their duly authorized representatives, shall until expiration of 3 years after final payment under this contract or of the time period for the particular records in Part 1-20 of the Federal Procurement Regulations (48 CFR part 1-20) whichever expires earlier, have access to and the

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right to examine any directly pertinent books, documents, papers, and records of the Contractor involving transactions related to this contract.

(c) The Contractor further agrees to include in all its subcontracts hereunder a provision to the effect that the subcontractor agrees that the Comptroller General of the United States, or his/her duly authorized representatives, shall, until expiration of 3 years after final payment under the subcontract or of the time periods for the particular records specified in Part 1-20 of the Federal Procurement Regulations (41 CFR part 1-20) whichever expires earlier, have access to and the right to examine any directly pertinent books, documents, papers, and records of such subcontractor, involving transactions related to the subcontract. The term "subcontract" as used in this clause excludes (1) purchases orders not exceeding $2,500 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public.

(d) The periods of access and examination described in (b) and (c) above, for records which relate to (1) appeals under the "Disputes" clause of this contract, (2) litigation or the settlement of claims arising out of the performance of this contract, or (3) costs and expenses of this contract as to which exception has been taken by the Comptroller General or any of his/her duly authorized representatives, shall continue until such appeals, litigation, claims, or exceptions have been disposed of.

(End of clause)

CLAUSE NO. 9—INSPECTION AND REPORTS (JUN 1977)

(a) Inspection of work. The Government shall have the right to inspect the work and activities under this contract, including without limitation, premises where any Government property may be located at such reasonable times and in such manner as it may deem appropriate and the Contractor shall afford Government proper facilities and assistance for such inspection.

(b) Reports. The Contractor shall furnish such progress reports, schedules, financial and cost reports, and other reports, concerning the work under this contract as specified elsewhere in this contract. Cost and other financial data and projections furnished pursuant to this paragraph (b) shall not relieve the Contractor of the requirements for furnishing notice specified in the clause of this contract entitled "Limitation of Cost."

(c) In addition, where Federal financial assistance is involved in the contract effort, the following clause will apply:

Reports to the Indian People

The contractor, as a recipient of Federal financial assistance, shall make reports and information available to the Indian people served or represented by the contractor. Such reports will reflect how the Federal assistance funds were utilized to the benefit of the Indian people served or represented as follows: (specific reporting requirements, formats and methods of distribution to the Indian people will be prescribed in the scope of the contract.)

(d) Annual Reporting.

(1) For each fiscal year during which a tribal organization receives or expends funds pursuant to a contract under this Part, the tribe which requested the contract must submit a report to the Contracting Officer. The report shall include, but not be limited to, an accounting of the amounts and purposes for which the contract funds were expended and information on the conduct of the program or services involved. The reports shall include any other information requested by the Contracting Officer and may be submitted as follows:

(i) When the contract is with the governing body of an Indian tribe, the tribe shall submit the report to the Contracting Officer.

(ii) When the contract is with a tribal organization other than the governing body of the tribe, the tribe has the option of having the tribal organization prepare the report and submit it to the tribe for review and approval before the tribe submits it to the Contracting Officer.

(iii) When the contract benefits more than one tribe, the tribal organization shall prepare and submit the report to each of the tribes benefiting under the contract. Each tribe shall endorse the report before submitting it to the Contracting Officer.

(2) The annual report shall be submitted to the Contracting Officer within 90 days of the end of the fiscal year in which the contract was performed. However, the period for submitting the report may be extended if there is just cause for such extension.

(3) In addition to the yearly reporting requirement given in paragraphs (a) and (b) of this section, the tribal contractor shall furnish other reports when and as required by the Secretary.

(End of clause)

CLAUSE NO. 10—SUBCONTRACTING (JUN 1977)

(a) Prior approval required. Except as provided in (c) below, the Contractor shall not enter into any subcontract or purchase order not otherwise expressly authorized elsewhere in this contract without the prior written approval of the Contracting Officer and subject to such conditions as the Contracting Officer may require.

(b) Records of such subcontractor, involving transactions related to this contract. The Government shall have the right to inspect the work and activities under this contract, including without limitation, premises where any Government property may be located at such reasonable times and in such manner as it may deem appropriate and the Contractor shall afford the Government proper facilities and assistance for such inspection.

(c) In addition, where Federal financial assistance is involved in the contract effort, the following clause will apply:

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(b) Request for approval. The Contractor's request for approval to enter into a subcontract pursuant to this clause shall include: (1) A description of the supplies or services to be called for by the subcontract; (2) identification of the proposed subcontractor and an explanation of why and how the proposed subcontractor was selected, including the degree of competition obtained; (3) the proposed subcontract price, together with the Contractor's cost or price analysis thereof; (4) identification of the type of subcontract to be used; (5) a copy or draft of the proposed subcontract, if available; and (6) any other information which the Contracting Officer may require.

(c) Certain purchases of property and services. Prior written approval shall not be required for firm fixed-price subcontracts for the purchase or rental of items of personal property having a unit acquisition cost of less than $200 or for subcontracts in a total amount less than $1,000 unless otherwise specified elsewhere in this contract. Provided, however, that advance notification shall be given by the Contractor of any subcontract which exceeds in dollar amount 5 percentum of the total estimated cost of this contract.

(d) Contractor's procurement system. The contractor shall use methods, practices or procedures in subcontracting or purchasing (hereinafter referred to as the Contractor's "procurement system") acceptable to the Contracting Officer. The Contracting Officer may, at any time during the performance of this contract, require the Contractor to provide information concerning its procurement system.

(e) Effect of subcontracting. Subcontracts shall be made in the name of the Contractor and shall not bind nor purport to bind the Government. The making of subcontracts hereunder shall not relieve the Contractor of any requirement under this contract (including, but not limited to, the duty to properly supervise and coordinate the work of subcontracts, and the duty to maintain and account for property pursuant to the clause of this contract entitled "Government Property"), or approval of the provisions of any subcontract by the Contracting Officer shall not be construed to constitute a determination of the allowability of any cost under this contract, unless such approval specifically provides that it constitutes a determination of the allowability of such cost. In no event shall approval of any subcontract by the Contracting Officer be construed as effecting any increase in the estimated cost set forth in this contract. No subcontract placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis.

(f) Procurements from contractor-controlled sources. Procurement or transfer of equipment, materials, supplies, or services from contractor-controlled source (any division or other organizational component of the prime contractor, exclusive of the contracting component, and any subsidiary or affiliate of the Contractor under a common control) shall be considered a subcontract for the purpose of this clause.

(End of clause)
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(CLAUSE NO. 12—GOVERNMENT PROPERTY (JUN 1977))

(a) Government furnished property. (1) The Government reserves the right to furnish any property or services required for the performance of the work under this contract.

(2) The Government shall deliver to the Contractor, for use in connection with and under the terms of this contract, the property described elsewhere in this contract, together with such related data and information as the Contractor may request and as may reasonably be required for the intended use of such property (such property to be referred to as "Government furnished property").

In the event that Government furnished property is not delivered to the contractor by the time or times as stated, or if not stated, in sufficient time to enable the Contractor to meet such delivery or performance dates under this contract, the Contracting Officer shall, upon timely written request made by the Contractor, make a determination of the delay occasioned the Contractor and make appropriate equitable adjustments to any contractual provisions affected by any such delay in accordance with the provisions of the clause of this contract entitled "Changes."

In the event that Government furnished property is received by the Contractor in a condition not suitable for the intended use, the Contractor shall, immediately upon receipt thereof, notify the Contracting Officer of such fact, and, as directed by the Contracting Officer either (i) return or otherwise dispose of such property, or (ii) effect repairs or modifications thereon. Upon completion of (i) or (ii) above, the Contracting Officer, upon timely written request of the Contractor, shall make appropriate equitable adjustments to any contractual provisions affected thereby in accordance with the provisions of the clause of this contract entitled "Changes."

The foregoing provisions for adjustment are exclusive and the Government shall not be liable to suit for breach of contract by reason of any delay in delivery of Government furnished property or delivery of such property in a condition not suitable for its intended use.

(b) Title. (1) Title to all property furnished by the Government shall remain in the Government. Title to all property purchased by the Contractor, the cost of which the Contractor is entitled to be reimbursed as a direct item of cost under this contract, shall pass to and vest in the Government upon delivery of such property by the vendor. Title to other property, the cost of which is reimbursable to the Contractor under this contract, shall pass and vest in the Government upon issuance for use of such property in the performance of this contract, or (ii) commencement of processing or use of such property in the performance of this contract, or (iii) reimbursement of the cost thereof by the Government in which ever first occurs. All Government furnished property, together with all property acquired by the Contractor, title to which vests in the Government under this paragraph, are subject to the provisions of this clause and are hereinafter collectively referred to as "Government property."

(2) Title to the Government property shall not be affected by the incorporation or attachment thereof to any property now owned by the Government, nor shall such Government property, or any part thereof, become a fixture or lose its identity or personality by reason of affixation to any realty.

(c) Use of Government property. Government property shall, unless otherwise provided herein or approved by the Contracting Officer, be used only for the performance of this contract.

(d) Property management and control. The Contractor shall maintain and administer in accordance with sound business practice a program for the maintenance repair, protection, and preservation of Government property, so as to assure its full availability and usefulness for the performance of this contract. The Contractor shall comply with Federal, State, and local laws, codes, ordinances, regulations, and orders pertaining to standards of construction, safety, environment quality, energy conservation, historic site preservation, facilities for the handicapped, emergency preparedness, and other requirements that are applicable to the physical characteristics, operation, and maintenance of Government property. The Contractor agrees to promptly receipt for all Government property in a form and manner as prescribed by the Contracting Officer. The Contractor further agrees to take all reasonable steps to comply with all directions or instructions which the Contracting Officer may prescribe regarding the management and control of Government property.

(e) Risk or loss. (1) The Contractor shall not be liable for any loss of or damage to Government property, or for expenses incidental to such loss or damage, except that the Contractor shall be responsible for any such loss or damage (including expenses incidental thereto);

(i) Which results from willful misconduct or lack of good faith on the part of any of the Contractor’s directors or officers, or on the part of any of its managers, superintendents, or other equivalent representatives, who have supervision or direction of

(A) all or substantially all of the Contractor’s operations at any one plant, laboratory or separate location in which this contract is being performed
(B) a separate and complete major organization, industrial or otherwise in connection with the performance of this contract; (ii) Which results from a failure on the part of the Contractor, or its agents, to exercise all due care, or from the willful misconduct or lack of good faith on the part of any of its directors, officers, or other representatives mentioned in subparagraph (i) above, (A) to maintain and administer, in accordance with sound business practice, the program for maintenance, repair, protection, and preservation of Government property as required by paragraph (d) hereof, or (B) to take all reasonable steps to comply with any appropriate written directions of the Contracting Officer under paragraph (h) hereof; (iii) For which the Contractor is otherwise responsible under the express terms of this contract; (iv) Which results from a risk expressly required to be insured under this contract, but only to the extent of the insurance so required to be procured and maintained, or to the extent of insurance actually procured and maintained, whichever is greater; or (v) Which results from a risk which is in fact covered by insurance or for which the Contractor is otherwise reimbursed, but only to the extent of such insurance or reimbursement; Provided That, if more than one of the above exceptions shall be applicable in any case, the Contractor's liability under any one exception shall not be limited by any other exception.

(2) If the Contractor transfers Government property to the possession and control of a subcontractor the transfer shall not affect the liability of the Contractor for loss or destruction of or damage to Government property as set forth in (1) above. The Contractor shall require the subcontractor to assume the risk of and be responsible for any loss or destruction of or damage to Government property while in the latter's possession or control, and the subcontract shall contain appropriate provisions requiring the return of all Government property in a good condition as when received (except for reasonable wear and tear or for the utilization of the property in accordance with the provisions of this contract). Provided, however, That the subcontractor may be relieved from such liability only to the extent that the subcontract, with the prior approval of the Contracting Officer, so provides.

(3) The Contractor shall not be reimbursed for, and shall not include as an item of overhead, the cost of insurance, or any provisions for a reserve, covering the risk of loss or damage to the Government property, except to the extent that the Government may have required the Contractor to carry such insurance under any other provision of this contract.

(4) Upon the happening of loss or destruction of or damage to the Government property, the Contractor shall notify the Contracting Officer thereof, and shall take all reasonable steps to protect the Government property from further damage, separate the damaged and undamaged Government property, put all the Government property in the best order, and furnish to the Contracting Officer a statement of: (i) The lost, destroyed, and damaged Government property; (ii) The time and origin of the loss, destruction or damage; (iii) All known interests in commingled property of which the Government property is a part; and (iv) The insurance, if any, covering any part of or interest in such commingled property.

The Contractor shall make repairs and renovation of the damaged Government property, or take such other actions as the Contracting Officer directs.

(5) In the event the Contractor is indemnified, reimbursed, or otherwise compensated for any loss or destruction of or damage to the Government property, it shall use the proceeds to repair, renovate, or replace the Government property involved, or shall credit such proceeds against the cost of the work covered by the contract, or shall otherwise reimburse the Government, as directed by the Contracting Officer. The loss, destruction or damage and, upon the request of the Contracting Officer, shall, at the Government's expense, furnish to the Government all reasonable assistance and cooperation (including assistance in the prosecution of suit and the execution of instruments of assignment in favor of the Government) in obtaining recovery. In addition, where a subcontractor has not been relieved from liability for any loss or destruction of or damage to Government property, the Contractor shall enforce the liability of the subcontractor for such loss or destruction of or damage to the Government property for the benefit of the Government.

(f) Disposition of Government property.

(1) During the period of performance of this contract, the Contractor shall promptly and regularly report to the Contracting Officer, in such form and manner as the Contracting Officer may direct, concerning the status of Government property under the contract, including all Government property in the Contractor's possession which is not in use or which is excess to the needs of the contract. The Contractor shall make such disposition of Government property as the Contracting Officer may direct. The Contractor shall in no way be relieved of responsibility for Government property without the prior written approval of the Contracting Officer.

(2) Upon completion or expiration of this contract, or at such earlier date as may be fixed by the Contracting Officer, the Contractor shall render an accounting, as prescribed by the Contracting Officer, of all
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Government property which had come into the possession or custody of the Contractor under this contract. Such accounting shall include inventory schedules covering all items of Government property not consumed in the performance of this contract, or not theretofore delivered to the Government, or for which the Contractor has not otherwise been relieved of responsibility. The Contractor shall deliver or make such other disposition of Government property covered in such inventory schedules as the Contracting Officer may direct.

(3) The net proceeds of any disposition of Government property, in accordance with (1) and (2) above, shall be credited to the cost of the work covered by the contract or shall be paid in such manner as the Contracting Officer may direct.

(g) Restoration of premises. Unless otherwise provided herein, the Government shall not be under any duty or obligation to restore or rehabilitate, or to pay the costs of the restoration or rehabilitation of the Contractor’s facility or any portion thereof which is affected by removal of any Government property.

(End of clause)

CLAUSE NO. 13—Changes (JUN 1977)

The Contracting Officer may at any time, with the consent of the Contractor, by a written order, and without notice to the sureties, if any, make changes, within the general scope of this contract, in any one or more of the following: (a) Drawings, designs, or specifications; (b) method of shipment or packing; (c) place of inspection, delivery, or acceptance; and (d) the amount of Government furnished property. If any such change causes an increase or decrease in the estimated cost of, or the time required for performance of this contract, or otherwise affects any other provisions of this contract, whether changed or not by any such order, an equitable adjustment shall be made (a) in the estimated cost or delivery schedule, or both, and (b) in such other provisions of the contract as may be so affected, and the contract shall be modified in writing accordingly. Any claim by the Contractor for adjustment under this clause must be asserted within thirty (30) days from the date of receipt by the Contractor of the notification of change: Provided, however, that the Contracting Officer, if he/she decides that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. Where the cost of property made obsolete or excess as a result of a change is included in the Contractor’s claim for adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of such property. Failure to agree to any adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled “Disputes.” However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(End of clause)

CLAUSE NO. 14—Notice to the Government of Delays (JUN 1977)

Whenever the Contractor has knowledge that any actual or potential situation, including, but not limited to, labor disputes, is delaying or threatens to delay the timely performance of the work under this contract, the Contractor shall immediately give written notice thereof, including all relevant information with respect thereto, to the Contracting Officer.

(End of clause)

CLAUSE NO. 15—Retrocession (JUN 1977)

(a) The Indian Tribe that initially requested this contract may also request its retrocession, notwithstanding the fact that the Contractor may be a tribal organization other than the Tribe.

(b) Should the Tribe request retrocession of the contract and the Contractor is other than the Tribe, the Contracting Officer will notify the Contractor of the request and in consultation with the Tribe and the Contractor establish the effective date of the retrocession. The retrocession will become effective no later than 120 days after the Contracting Officer receives the Tribe’s request unless the Tribe and the Contracting Officer mutually agree on a later date.

(c) Immediately after receipt of the request for retrocession and where applicable notifying the Contractor, the Contracting Officer will meet with the Contractor and, where applicable, the tribal governing body or bodies, mutually agree to:

(1) A plan for the orderly transfer of responsibilities;

(2) A plan for inventorying materials and supplies on hand;

(3) An accounting for funds, including but not limited to current and anticipated obligations;

(4) The cost of operation until retrocession; and,

(5) The identification of all records relating to the contract and the contracted function.

(End of clause)

CLAUSE NO. 16—Assumption and Reassumption of Contract Programs (JUN 1977)

(a) When the Director or his/her delegate determines that the performance of a Contractor under these regulations involves (J)
the violation of the rights or endangerment of the health, safety, or welfare of any persons, or (2) gross negligence or the mismanagement in the handling or use of funds under the contract, he/she will, in writing, notify the contractor of such determinations and will request that the contractor take such corrective action within such period of time as the Director or his/her delegate may prescribe.

(b) When the Director or his/her delegate determines that a contractor has not taken corrective action (as prescribed by him/her under paragraph (a) of this section) to his/her satisfaction, he/she may, after the contractor has been provided an opportunity for a hearing in accordance with paragraph (c) of this section, rescind the contract in whole or in part and, if he/she deems it appropriate, assume or resume control or operation of the program, activity, or service involved.

(c)1 When the Director or his/her delegate has made a determination described in paragraph (b) of this section, he/she shall in writing notify the contractor of such determination and of the contractor's right to request a review of such determination and of the determination described in paragraph (a) of this section. Such notification by the Director or his/her delegate shall set forth the reasons for the determination in sufficient detail to enable the contractor to respond and shall inform the contractor of its right to a hearing on the record before a Contract Appeals Board established pursuant to paragraph (d) of this section. Upon the request of the contractor for a hearing, the board, established pursuant to paragraph (d) of this section, shall in writing within 10 days of the establishment notify the contractor of the time, place and date of the hearing which will be held not later than 45 days after the request for a hearing.

(2) Where the Director or his/her delegate determines that a contractor's performance under a contract awarded under this subpart poses an immediate threat to the safety of any person, he/she may immediately rescind the contract in whole or in part and, if he/she deems it appropriate, assume or resume control or operation of the program, activity, or service involved. Upon such a decision he/she will immediately notify the contractor of such action and the basis therefor, and offer the contractor an opportunity for a hearing on the record before the Contract Appeals Board established pursuant to paragraph (d) of this section to be held within 10 days of such action.

(d) The Contract Appeals Board shall be composed of 3 persons appointed by the Director, Indian Health Service. Such persons may not be selected from the immediate office of any person participating in the determination at issue. The Board shall afford the contractor the right:

(i) To notice of the issues to be considered;

(ii) To be represented by counsel;

(iii) To present witnesses on contractor's behalf;

(iv) To cross-examine other witnesses either orally or through written interrogatories; and

(v) To compel the appearance of Indian Health Service personnel or to take depositions of such persons at reasonable times and places.

(2) The Contract Appeals Board shall make an initial written decision which shall become final within 20 days unless the Director, Indian Health Service or his/her representative modifies or reverses the decision. Any such decision by the Director of the Indian Health Service or his/her representative shall be in writing, shall be specific as to the reasons for such decision, and shall be considered final.

(3) Where the Board is considering issues arising under paragraph (2) of this section, the Board shall within 25 days after the conclusion of the hearing, notify all parties in writing of its decision.

(c) In any case where the officer has rescinded a contract under paragraph (b) or (c) of this section, he/she may decline to enter into a new contract agreement with the contractor until such time as he/she is satisfied that the basis for the rescission has been corrected.


(End of clause)

CLAUSE NO. 17—KEY PERSONNEL (JUN 1977)

Where “key personnel” have been identified in this contract, it has been determined that such named personnel are necessary for the successful performance of the work under this contract; and the contractor agrees to assign such personnel to the performance of the work under this contract, and shall not reassign or remove any of them without the consent of the Contracting Officer. Whenever, for any reason, one or more of the aforementioned personnel is unavailable for assignment for work under the contract, the Contractor shall immediately notify the Contracting Officer to that effect and shall, subject to the approval of the Contracting Officer without formal modification to the contract, replace such personnel with personnel of substantially equal ability and qualifications.

(End of clause)

CLAUSE NO. 18—LITIGATION AND CLAIMS (JUN 1977)

The Contractor shall give the Contracting Officer immediate notice in writing of (a)
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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 (b) any claim against the Contractor the cost and expense of which is allowable under the clause entitled “Allowable Cost,” 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 (a) 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 (b) 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 cost 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)

CLAUSE NO. 19—INDEMNITY AND INSURANCE
(JUN 1977)

(a) The Contractor shall indemnify and save and keep harmless the Government against any or all loss, cost, damage, claim, expense or liability whatsoever, because of accident or injury to persons or property or others occurring in connection with any program included as a part of this contract, by providing where applicable, the insurance described below:

(b) The Contractor shall secure, pay the premium for, and keep in force until the expiration of this contract, or any renewal period thereof, insurance as provided below. Such insurance policies shall specifically include a provision stating the liability assumed by the Contractor under this contract.

(3) Workman’s compensation insurance as required by laws of the state.

(2) Owner’s, landlord’s, and tenant’s bodily injury liability insurance with limits of not less than $50,000 for each person and $500,000 for each accident.

(3) Property damage liability insurance with limits of not less than $25,000 for each accident.

(4) Automobile bodily injury liability insurance with limits of not less than $50,000 for each person, and $500,000 for each accident.

(5) Food products liability insurance with limits of not less than $50,000 for each person and $500,000 for each accident.

(6) Professional malpractice insurance where medical, dental and other health professional services are involved.

(7) Other liability insurance not specifically mentioned when required.

(c) Each policy of insurance shall contain an endorsement providing that cancellation by the insurance company shall not be effective unless a copy of the cancellation is mailed (registered) to the Contracting Officer 30 days prior to the effective date of cancellation.

(d) A certificate of each policy of insurance, and any change therein, shall be furnished to the Contracting Officer immediately upon receipt from the insurance company.

(e) Insurance companies of the Contractor shall be satisfactory to the Contracting Officer. When in his/her opinion an insurance company is not satisfactory for reasons that will be stated, the Contractor shall provide insurance through companies that are satisfactory to the Contracting Officer.

(f) Each policy of insurance shall contain a provision that the insurance carrier waives any rights it may have to raise as a defense the tribe’s sovereign immunity from suit, but such waivers shall extend only to claims the amount and nature of which are within the coverage and limits of the policy of insurance. The policy shall contain no provision, either expressed or implied, that will serve to authorize or empower the insurance carrier to waive or otherwise limit the tribe’s sovereign immunity outside or beyond the coverage and limits of the policy insurance.
Clause No. 20—Overtime (JUN 1977)

Except as provided in this contract, the Contractor shall not perform overtime work under or in connection with this contract for which premium compensation is required to be paid, without specific written approval from the Contracting Officer.

Clause No. 21—Foreign Travel (JUN 1977)

Foreign travel shall not be performed without prior written approval of the Contracting Officer. As used in this clause “Foreign Travel” means travel outside the United States, its Territories and Possessions, and Canada.

Clause No. 22—Questionnaire and Surveys (JUN 1977)

In the event the performance of this contract involves the collection of information upon identical items from 10 or more persons, other than Federal employees, the Contractor shall obtain written approval from the Contracting Officer, prior to the use thereof, of any forms, schedules, questionnaires, survey plans or other documents, and any revisions thereto, intended to be used in such collection.

Clause No. 23—Printing (JUN 1977)

Unless otherwise specified in this contract, the Contractor shall not engage in, nor subcontract for, any printing (as that term is defined in Title I of the Government Printing and Binding Regulations in effect on the effective date of this contract) in connection with the performance of work under this contract; Provided, however, That performance of a requirement under this contract involving the reproduction of less than 5,000 production units of any one page or less than 25,000 production units in the aggregate of multiple pages, will not be deemed to be printing. A production unit is defined as one sheet, size 8 by 10 and 1/2 inches, one side only, one color.

Clause No. 24—Services of Consultants (JUN 1977)

Except as otherwise expressly provided elsewhere in this contract, and notwithstanding the provisions of the clause of this contract entitled “Subcontracting,” the prior written approval of the Contracting Officer shall be required:

(a) Whenever any employee of the Contractor is to be reimbursed as a “consultant” under this contract; and

(b) For the utilization of the services of any consultant under this contract exceeding the daily rate set forth elsewhere in this contract or, if no amount is set forth, $100, exclusive of travel costs or where the services of any consultant under this contract will exceed 10 days in any calendar year. Whenever Contracting Officer approval is required, the Contractor will obtain and furnish to the Contracting Officer information concerning the need for such consultant services and the reasonableness of the fees to be paid, including but not limited to, whether fees to be paid to any consultant exceed the lowest fee charged by such consultant to others for performing consultant services of a similar nature.

Clause No. 25—Assignment of Claims (JUN 1977)

(a) Pursuant to the provisions of the Assignment of Claims Act of 1940, as amended (31 U.S.C. 203, 41 U.S.C. 15), if this contract provides for payments aggregating $1,000 or more, claims for money due or to become due the Contractor from the Government under this contract may be assigned to a bank, trust company, or other financing institution, including any Federal lending agency, and may thereafter be further assigned and reassigned to any such institution. Any such assignment or reassignment shall cover all amounts payable under this contract and not already paid, and shall not be made to more than one party, except that any such assignment or reassignment may be made to one party as agent or trustee for two or more parties participating in such financing. Unless otherwise provided in this contract, payment to assignee of any moneys due or to become due under this contract shall not, to the extent provided in said Act, as amended, be subject to reduction or setoff. (The preceding sentence applies only if this contract is made in time of war or national emergency as defined in said Act and is with the Department of Defense, the General Services Administration, the Atomic Energy Commission, the National Aeronautics and Space Administration, the Federal Aviation Agency or any other department or agency of the United States designated by the President pursuant to Clause 4 of the proviso of section 1 of the Assignment of Claims Act of 1940, as amended by the Act of May 15, 1951, 65 Stat. 41.)

(b) In no event shall copies of this contract or of any plans, specifications, or other similar documents relating to work under this contract, if marked “Top Secret,” “Secret,”
or "Confidential," be furnished to any assignee of any claim arising under this contract or to any other person not entitled to receive the same. However, a copy of any part or all of this contract so marked may be furnished, or any information contained therein may be disclosed, to such assignee upon the prior written authorization of the Contracting Officer.

(End of clause)

CLAUSE NO. 26—CONTRACT WORK HOURS AND SAFETY STANDARD ACT—OVERTIME COMPENSATION (JUN 1977)

This contract, to the extent that it is of a character specified in the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-330), is subject to the following provisions and to all other applicable provisions and exceptions of such Act and the regulations of the Secretary of Labor thereunder.

(a) Overtime requirements. No Contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers or mechanics shall require or permit any laborer or mechanic in any workweek in which he/she is employed on such work to work in excess of eight hours in any calendar day or in excess of forty hours in such workweek on work subject to the provisions of the Contract Work Hours Standards Act unless such laborer or mechanic receives compensation at a rate not less than one and one-half times his/her basic rate of pay for all such hours worked in excess of eight hours in any calendar day or in excess of forty hours in such workweek, whichever is the greater number of overtime hours.

(b) Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the provisions of paragraph (a), the Contractor and any subcontractor responsible therefor shall be liable to any affected employee for his/her unpaid wages. In addition, such Contractor and subcontractor shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic employed in violation of the provisions of paragraph (a) in the sum of $10 for each calendar day on which such employee was required or permitted to be employed on such work in excess of eight hours or in excess of the standard workweek of forty hours without payment of the overtime wages required by paragraph (a).

(c) Withholding for unpaid wages and liquidated damages. The Contracting Officer may withhold from the Government Prime Contractor any monies payable on account of work performed by the Contractor or subcontractor, such sums as may administratively be determined to be necessary to satisfy any liabilities of such Contractor or subcontractor for unpaid wages and liquidated damages as provided in the provisions of paragraph (b).

(d) Subcontracts. The Contractor shall insert paragraphs (a) through (d) of this clause in all subcontracts, and shall require their inclusion in all subcontracts for any tier.

(e) Records. The Contractor shall maintain payroll records containing the information specified in 29 CFR 516.2(a). Such records shall be preserved for three years from the completion of the contract. This requirement does not apply where the tribal contractor is the governing body of the tribe and the work is being performed by the tribal contractor or the tribe with its regular employees.

(End of clause)

CLAUSE NO. 27—WALSH-HEALEY PUBLIC CONTRACTS ACT (JUN 1977)

If this contract is for the manufacture or furnishing of materials, supplies, articles, or equipment in an amount which exceeds or may exceed $10,000 and is otherwise subject to the Walsh-Healey Public Contracts Act, as amended (41 U.S. Code 35-45), there are hereby incorporated by reference all representations and stipulations being subject to all applicable rulings and interpretations of the Secretary of Labor which are now or may hereafter be in effect. This requirement does not apply where the tribal contractor is the governing body of the tribe and the work is being performed by the tribal contractor or the tribe with its regular employees.

(End of clause)

CLAUSE NO. 28—EQUAL OPPORTUNITY (JUN 1977)

Subject to the Indian preference in training and employment of Clause 29 during the performance of this contract, the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, creed, color, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, creed, color, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or re-recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be

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provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, creed, color, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which it has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or workers' representative of the Contractor's commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, and the rules, regulations, and orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and accounts by the contracting agency and the Secretary of Labor for purposes of investigating to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor's noncompliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, or orders, this contract may be cancelled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: Provided, however, That in the event the Contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

(End of clause)

CLAUSE NO. 29—INDIAN PREFERENCE IN TRAINING AND EMPLOYMENT (JUN 1977)

(a) The Contractor shall give preference in employment for all work performed under the contract, including subcontracts thereunder, to qualified Indians regardless of age, religion, or sex, and to the extent feasible consistent with the efficient performance of the contract, provide employment and training opportunities to Indians, regardless of age, religion, or sex, that are not fully qualified to perform under the contract. The Contractor shall comply with any Indian preference requirements established by the Tribe receiving services under the contract to the extent that such requirements are consistent with the purpose and intent of this paragraph.

(b) If the Contractor or any of its subcontractors is unable to fill its employment openings after giving full consideration to Indians as required in paragraph (a) above, these employment openings may then be filled by other than Indians under the conditions set forth in the Equal Opportunity clause of this contract.

(c) The Contractor agrees to include this clause or one similar thereto in all subcontracts issued under the contract.

(End of clause)

CLAUSE NO. 30—CERTIFICATE OF NONSEGREGATED FACILITIES (JUN 1977)

By signing the contract the Contractor certifies that it does not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. It certifies further that it will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it will not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. The Contractor agrees that a breach of this certification is a violation of the Equal Opportunity clause in this contract. As used in this certification, the term "segregated facilities" means any waiting rooms, work areas, rest rooms, and wash rooms, restaurants and other eating areas, time clocks, locker rooms, and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees which are segregated.
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by explicit directive or are in fact segregated on the basis of race, color, religion, or national origin, because of habit, local custom or otherwise. It further agrees that (except where it has obtained identical certifications from proposed subcontractors for specific time periods) it will obtain identical certifications from proposed subcontractors prior to the award of subcontracts exceeding $10,000 which are not exempt from the provisions of the Equal Opportunity clause; that it will retain such certifications in its files; and that it will forward the following notice to such proposed subcontractors (except where the proposed subcontractors have submitted identical certifications for specific time periods):

Notice to prospective subcontractors of requirement for certifications of nonsegregated facilities. A certificate of Nonsegregated Facilities must be submitted prior to the award of a subcontract exceeding $10,000 which is not exempt from the provisions of the Equal Opportunity clause. The certification may be submitted either for each subcontract or for all subcontracts during a period (i.e., quarterly, semiannually, or annually).

(End of clause)

CLAUSE NO. 31—CONVICT LABOR (JUN 1977)

In connection with the performance of work under this contract, the Contractor agrees not to employ any person undergoing sentence of imprisonment at hard labor, except as provided by Public Law 89-176, September 10, 1965 (18 U.S.C. 4082(c)(2)), and Executive Order No. 11755, December 29, 1973.

(End of clause)

CLAUSE NO. 32—OFFICIALS NOT TO BENEFIT (JUN 1977)

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this contract, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this contract if made with a corporation for its general benefit.

(End of clause)

CLAUSE NO. 33—BUY AMERICAN ACT FOR SUPPLY AND SERVICE CONTRACTS (JUN 1977)

(a) In acquiring end products, the Buy American Act (41 U.S.C. 10a–d) provides that the Government give preference to domestic source end products. For the purpose of this clause:

(i) “Components” means those articles, materials, and supplies which are directly incorporated in the end products;

(ii) “End products” means those articles, materials, and supplies which are to be acquired under this contract for public use; and

(iii) A “domestic source end product” means (A) an unmanufactured end product which has been mined or produced in the United States and (B) an end product manufactured in the United States if the cost of the components thereof which are mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. For the purpose of this (a)(iii) (B), components of foreign origin of the same type or kind as the products referred to in (b) (ii) or (iii) of this clause shall be treated as components mined, produced or manufactured in the United States.

(b) The Contractor agrees that there will be delivered under this contract only domestic source end products, except end products:

(i) Which are for use outside the United States;

(ii) Which the Government determines are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality;

(iii) As to which the Secretary determines the domestic preference to be inconsistent with the public interest; or

(iv) As to which the Secretary determines the cost to the Government to be unreasonable.

(The foregoing requirements are administered in accordance with Executive Order No. 10582, dated December 17, 1954).

(End of clause)

CLAUSE NO. 34—ANTI-KICKBACK ACT (JUN 1977)

(a) Public Law 86-695, September 2, 1960 (41 U.S.C. 51-54) among other things prohibits the payment, directly or indirectly, by or on behalf of a subcontractor in any tier under any Government negotiated contract of any fee, gift or gratuity to the prime contractor or any higher tier subcontractor or any officer, agent, partner or employee thereof, as an inducement or acknowledgment for the award of a subcontract or order.

(b) The provisions of Public Law 86-695 are applicable to this contract and any subcontracts entered into under the contract.

(End of clause)

CLAUSE NO. 35—USE OF INDIAN BUSINESS CONCERNS (JUN 1977)

(a) As used in this clause, the term “Indian business concern” means Indian organizations or an Indian-owned economic enterprise as defined in 42 FR 36,204(i).

(b) The contractor agrees to give preference to qualified Indian business concerns in the awarding of any subcontracts entered
into under the contract consistent with the efficient performance of the contract. The contractor shall comply with any preference requirements regarding Indian business concerns established by the Tribes(s) receiving services under the contract to the extent that such requirements are consistent with the purpose and intent of this paragraph.

(c) If no Indian business concerns are available under the conditions in paragraph (b) above, the Contractor agrees to accomplish the maximum amount of subcontracting, as the Contractor determines is consistent with its efficient performance of the contract, with small business concerns, labor surplus area concerns or minority business enterprises, the definitions for which are contained in Subparts 1–1.7, 1–1.8, and 1–1.13 of the Federal Procurement Regulations. The Contractor is not, however, required to establish a small business, labor surplus, or minority business subcontracting program as described in sections 1–1.710–3(b), 1–1.805–3(b), and 1–1.1310–2(b), respectively, of the Federal Procurement Regulations (41 CFR chapter 1).

(End of clause)

CLAUSE NO. 36—PAYMENT OF INTEREST ON CONTRACTOR'S CLAIMS (JUN 1977)

(a) If an appeal is filed by the Contractor from a final decision of the Contracting Officer under the Disputes clause of this contract, denying a claim arising under the contract, simple interest on the amount of the claim finally determined owed by the Government shall be payable to the Contractor. Such interest shall be at the rate determined by the Secretary of the Treasury pursuant to P.L. 92–41, 85 Stat. 97, from the date the Contractor furnished to the Contracting Officer his written appeal under the Disputes clause of this contract, to the date of (1) a final judgment by a court of competent jurisdiction, or (2) mailing to the Contractor of a supplemental agreement for execution either confirming completed negotiations between the parties or carrying out a decision of a board of contract appeals.

(b) Notwithstanding (a), above, (1) interest shall be applied only from the date payment was due, if such date is later than the filing of appeals, and (2) interest shall not be paid for any period of time that the Contracting Officer determines the Contractor has unduly delayed in pursuing its remedies before a board of contract appeals or a court of competent jurisdiction.

The Contractor further agrees to comply with any rules, regulations and reporting requirements which may be imposed by the HHS Office for Civil Rights for purposes of insuring the proper exercise of this authority. The Contractor agrees to insert this clause in all subcontract(s) under this contract.

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CLAUSE NO. 37—FAIR AND EQUAL TREATMENT OF INDIAN PEOPLE (JUN 1977)

(a) The Contractor agrees consistent with medical needs to make no discriminatory distinctions among Indian patients or beneficiaries of this contract. For the purpose of this contract discriminatory distinctions include but are not limited to the following: (i) denying a patient access to any service or benefit; (ii) providing any service or benefit to a patient which is different, or is provided in a different manner or at a different time from that provided to other patients under this contract; subjecting a patient to segregation or separate treatment in any manner related to his/her receipt of any service; restricting a patient in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service or benefit; treating a patient differently from others in determining whether he/she satisfies any admission, enrollment, quota, eligibility membership, or other requirements of condition which individuals must meet in order to be provided any service or benefit; the assignment of times or places for the provision of services on the basis of discriminatory distinctions which may be made of the patients to be served.

(b) The Government reserves the right to reassert this contract in whole or in part whenever the Contractor fails to comply with the requirements of this clause.

(End of clause)

CLAUSE NO. 38—PRICE REDUCTION FOR DEFECTIVE COST OR PRICING DATA

The following clause applies to all contracts where cost and pricing data is required in accordance with P.L. 87–653.

Price Reduction for Defective Cost or Pricing Data (JUN 1977)

(a) If the Contracting Officer determines that any price negotiated in connection with this contract or any cost reimbursable under this contract was increased by any significant sums because the Contractor, or any subcontractor pursuant to the Clause of this contract entitled "Subcontractor Cost or Pricing Data" or "Subcontractor Cost or Pricing Data-Price Adjustments," or any subcontract clause therein required, furnished incomplete or inaccurate cost or pricing data or data not current as certified in its Contractor's Certificate of Current Cost or Pricing Data, then such price or cost shall be reduced accordingly and the contract shall be modified in writing to reflect such reduction.
(b) Failure to agree on a reduction shall be a dispute concerning a question of fact within the meaning of the "Disputes" clause of this contract.

NOTE: Since this contract is subject to reduction under this clause by reason of defective cost or pricing data submitted in connection with certain subcontracts, it is expected that the Contractor may wish to include a clause in each such subcontract requiring the subcontractor to appropriately indemnify the Contractor. It is also expected that any subcontractor subject to such indemnification will generally require substantively similar indemnification for defective cost or pricing data required to be submitted by its lower tier subcontractors.

(End of clause)

Clause No. 39—Subcontractor Cost and Pricing Data

The following clauses should be included in all contracts, when the subcontracts of the type and size described therein are contemplated.

Subcontractor Cost and Pricing Data (JUN 1977)

(a) The Contractor shall require subcontractors hereunder to submit in writing cost or pricing data under the following circumstances:

(1) Prior to award of any cost-reimbursable type, time and material, labor-hour, incentive, or price redeterminable subcontract the price of which is expected to exceed $100,000; and

(2) Prior to the award of any other subcontract, the price of which is expected to exceed $100,000, or to the pricing of any subcontract change or other modification of which the price adjustment is expected to exceed $100,000, where the price or price adjustment is not based on adequate price competition, established catalog or market price of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(b) The Contractor shall require subcontractors to certify, substantially the same form as that used in the Certificate by the Prime Contractor to the Government, that, to the best of their knowledge and belief, the cost and pricing data submitted under (a) above are accurate, complete, and current as of the date of the execution, which date shall be as close as possible to the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(c) The Contractor shall insert the substance of this clause including this paragraph (c) in each of its cost-reimbursable type, time and material, labor-hour, price redeterminable, or incentive subcontract hereunder, and in any other subcontract hereunder which exceeds $100,000 unless the price thereof is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation. In each such expected subcontract hereunder which exceeds $100,000, the Contractor shall insert the substance of the following clauses:

Subcontractor Cost and Pricing Data—Price Adjustments

(a) Paragraphs (b) and (c) of this clause shall become operative only with respect to any change or other modification made pursuant to one or more provisions of this contract which involves a price adjustment in excess of $100,000. The requirements of this clause shall be limited to such price adjustments.

(b) The Contractor shall require subcontractors hereunder to submit cost or pricing data under the following circumstances:

(1) Prior to award of any cost-reimbursable type, time and material, labor-hour, incentive, or price redeterminable subcontract, the price of which is expected to exceed $100,000; and

(2) Prior to award of any other subcontract, the price of which is expected to exceed $100,000, or to the pricing of any subcontract change or other modification for which the price adjustment is expected to exceed $100,000, where the price or price adjustment is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(c) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the Certificate by the Prime Contractor to the Government, that, to the best of their knowledge and belief, the cost and pricing data submitted under (b) above are accurate, complete, and current as of the date of the execution, which date shall be as close as possible to the date of agreement on the negotiated price of the contract modification.

(d) The Contractor shall insert the substance of this clause including this paragraph (d) in each subcontract hereunder which exceeds $100,000.

(End of clause)

Clause No. 40—Penalties (JUN 1977)

(a) Any officer, director, agent, employee or such other person connected in any capacity with this contract or any subcontract hereunder that embezzles, willfully misapplies, steals or obtains by fraud any of the money, funds, assets or property provided through the contract shall be fined not
more than $10,000 or imprisoned for more than two years, or both; Provided, That if the amount embezzled, misapplied, stolen, or obtained by fraud does not exceed $100, such person shall be fined not more than $1,000 or imprisoned not more than one year, or both.

(b) The Contractor agrees to insert the clause in all subcontracts.

(End of clause)

CLAUSE NO. 41—EFFECT ON EXISTING RIGHTS (JUN 1977)

(a) Nothing in this contract shall be construed as:
(1) Affecting, modifying, diminishing, or otherwise impairing the sovereign immunity of the United States with respect to the Indian nation of any existing trust responsibility of a suit enjoyed by an Indian tribe; or,
(2) Authorizing or requiring the termination of any existing trust responsibility of the United States with respect to the Indian people.

(End of clause)

CLAUSE NO. 42—GENERAL SERVICES ADMINISTRATION (GSA) SUPPLY SOURCES

Indian tribal organizations which are awarded cost-reimbursement type contracts under the Indian Self-Determination Act, may be authorized to utilize GSA supply sources. The following clause will be inserted in all cost-reimbursement type contracts under which the Contractor may be authorized to acquire items for the account of the Government from GSA supply sources:

General Services Administration Supply Sources (June 1977)

The Contracting Officer may issue the Contractor an authorization to utilize General Services Administration supply sources for property to be used in the performance of this contract. Title to all property acquired by the Contractor under such an authorization shall vest in the Government, (1) unless otherwise specifically provided in the contract, (2) unless otherwise provided in the Government Property clause of this contract, or (3) in the absence of both the conditions in (1) and (2) of the clause. However, such property shall not be considered to be “Government-furnished property.”

(End of clause)

(b) Insert the following clauses in fixed price contracts awarded under the Indian Self-Determination Act as described in Subpart PHS 380.4:

CLAUSE NO. 1—DEFINITIONS (JUN 1977)

As used throughout this contract, the following terms shall have the meanings set forth below:

(a) The term “Secretary” means the Secretary, the Under Secretary, or any Assistant Secretary of the Department of Health and Human Services and the term “his/her duly authorized representative” means any person or persons or board (other than the Contracting Officer) authorized to act for the Secretary.

(b) The term “Contracting Officer” means the person executing this contract on behalf of the Government, and any other officer or employee who is properly designated Contracting Officer, and the term includes, except as otherwise provided in this contract, the authorized representative of the Contracting Officer acting within the limits of his/her authority.

(c) The term “Department” means the Department of Health and Human Services (HHS).

(d) The term “constituent agency” means the agency of the Department responsible for the administration of this contract.

(e) Except as otherwise provided in this contract, the term “subcontract” includes purchase orders under this contract.

(f) The term “Project Officer” means the person representing the Government for the purpose of technical direction of contract performance. The Project Officer is not authorized to issue any instructions or directions which effect any increase or decrease in the cost of this contract or which change the period of this contract.

(End of clause)

CLAUSE NO. 2—DISPUTES (JUN 1977)

(a) Except as otherwise provided in this contract, any dispute concerning a question of fact arising under this contract which is not disposed of by agreement shall be decided by the Contracting Officer, who shall reduce his/her decision to writing and mail or otherwise furnish a copy thereof to the Contractor. The decision of the Contracting Officer shall be final and conclusive unless, within 30 days from the date of receipt of such copy, the Contractor mails or otherwise furnishes to the Contracting Officer a written appeal addressed to the Secretary. The decision of the Secretary or his/her duly authorized representative for the determination of such appeals shall be final and conclusive unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with any appeal proceeding under this clause, the Contractor shall be afforded an opportunity to be heard and to offer evidence in support of its appeal. Pending final decision of a dispute hereunder, the Contractor shall proceed diligently with the performance of the contract and in accordance with the Contracting Officer’s decision.
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(b) This “Disputes” clause does not preclude consideration of law questions in connection with decisions provided for in paragraph (a) above. Provided, That nothing in this contract shall be construed as making final the decision of any administrative official, representative, or board on a question of law.

(End of clause)

CLAUSE NO. 3—CONTRACT WORK HOURS AND SAFETY STANDARD ACT—OVERTIME COMPENSATION (JUN 1977)

This contract, to the extent it is of a character specified in the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-330), is subject to the following provisions and exceptions of such Act and the regulations of the Secretary of Labor thereunder.

(a) Overtime requirements. No Contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers or mechanics shall require or permit any laborer or mechanic in any workweek in which he/she is employed on such work to work in excess of eight hours in any calendar day or in excess of forty hours in such workweek. The Contractor and any subcontractor responsible therefor shall be liable to the United States for liquidated damages at a rate not less than one and one-half times his/her basic rate of pay for all such hours worked in excess of eight hours in any calendar day or in excess of forty hours in such workweek, whichever is the greater number of overtime hours.

(b) Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the provisions of paragraph (a), the Contractor and any subcontractor responsible therefor shall be liable to any affected employee for his/her unpaid wages. In addition, such Contractor and subcontractor shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic employed in violation of the provisions of paragraph (a) at the sum of $10 for each calendar day on which such employee was required or permitted to be employed on such work in excess of eight hours or in excess of the standard workweek of forty hours without payment of the overtime wages required by paragraph (a).

(c) Withholding for unpaid wages and liquidated damages. The Contracting Officer may withhold from the Government Prime Contractor, from any moneys payable on account of work performed by the Contractor or subcontractor, such sums as may administratively be determined to be necessary to satisfy any liabilities of such Contractor or subcontractor for unpaid wages and liquidated damages as provided in the provisions of paragraph (b).

(d) Subcontracts. The Contractor shall insert paragraphs (a) through (d) of this clause in all subcontracts, and shall require their inclusion in all subcontracts of subcontractors contracting for any part of the contract work which may require or involve the employment of laborers or mechanics.

(e) Records. The Contractor shall maintain payroll records containing the information specified in 29 CFR 516.2(a). Such records shall be preserved for three years from the completion of the contract. This requirement does not apply where the tribal contractor is the governing body of the Tribe and the work is being performed by the tribal organization or Tribe with its own regular employees.

(End of clause)

CLAUSE NO. 4—WALSH-HEALEY PUBLIC CONTRACTS ACT (JUN 1977)

If this contract is for the manufacture or furnishing of materials, supplies, articles, or equipment in an amount which exceeds or may exceed $10,000 and is otherwise subject to the Walsh-Healey Public Contracts Act, as amended (41 U.S. Code 34-45), there are hereby incorporated by reference all representations and stipulations required by the Secretary of Labor, such representations and stipulations being subject to all applicable rulings and interpretations of the Secretary of Labor which are now or may hereafter be in effect. This requirement does not apply where the tribal contractor is the governing body of the Tribe and the work is being performed by the tribal organization or Tribe with its own regular employees.

(End of clause)

CLAUSE NO. 5—CONVICT LABOR (JUN 1977)

In connection with the performance of work under this contract, the Contractor agrees not to employ any person undergoing sentence of imprisonment at hard labor except as provided by Public Law 89-176, September 10, 1965 (18 U.S.C. 4082(c)(2) and Executive Order No. 11755, December 29, 1973.

(End of clause)

CLAUSE NO. 6—NOTICE TO THE GOVERNMENT OF DELAYS (JUN 1977)

Whenever the Contractor has knowledge that any actual or potential situation is delaying or threatens to delay the timely performance of this contract, the Contractor shall within ten days give notice thereof, including all relevant information with respect thereto, to the Contracting Officer.
CLAUSE NO. 7—ASSIGNMENT OF CLAIMS (JUN 1977)

(a) Pursuant to the provisions of the Assignment of Claims Act of 1940, as amended (31 U.S.C. 203, 41 U.S.C. 15), if this contract provides for payment aggregating $1,000 or more, claims for moneys due or to become due the Contractor from the Government under this contract may be assigned to a bank, trust company, or other financing institution, including any Federal lending agency, and may thereafter be further assigned and reassigned to any such institution. Any such assignment or reassignment shall cover all amounts payable under this contract and not already paid, and shall not be made to more than one party, except that any such assignment or reassignment may be made to one party as agent or trustee for two or more parties participating in such financing. Unless otherwise provided in this contract payments to assignee of any moneys due or due to become due under this contract shall not, to the extent provided in said Act, as amended, be subject to reduction or setoff. (The preceding sentence applies only if this contract is made in time of war or national emergency as defined in said Act and is with the Department of Defense, the General Services Administration, the Atomic Energy Commission, the National Aeronautics and Space Administration, the Federal Aviation Agency, or any other department or agency of the United States designated by the President pursuant to Clause 4 of the proviso of section 1 of the Assignment of Claims Act of 1940, as amended by the Act of May 15, 1951, 65 Stat. 41.)

(b) In no event shall copies of this contract or any plans, specifications, or other similar documents relating to work under this contract, if marked “Top Secret,” “Secret,” or “Confidential,” be furnished to any assignee of any claim arising under this contract or to any other person not entitled to receive the same. However, a copy of any part or all of this contract so marked may be furnished, or any information contained therein may be disclosed, to such assignee upon the prior written authorization of the Contracting Officer.

CLAUSE NO. 8—OFFICIALS NOT TO BENEFIT (JUN 1977)

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this contract, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this contract if made with a corporation for its general benefit.

CLAUSE NO. 9—ANTI-KICKBACK ACT (JUN 1977)

(a) Pursuant to Public Law 86-695, September 2, 1960 (41 U.S.C. 51-54) among other things, prohibits the payment, directly or indirectly, by or on behalf of a subcontractor in any tier under any Government negotiated contract of any fee, gift, or gratuity to the prime contractor or any officer, agent, partner or employee thereof, as an inducement or acknowledgement for the award of a subcontract or order.

(b) The provisions of Public Law 86-695 are applicable this contract and any subcontracts entered into under the contract.

CLAUSE NO. 10—BUY AMERICAN ACT (JUN 1977)

(a) In acquiring end products, the Buy American Act (41 U.S.C. 10a-d) provides that the Government give preference to domestic source end products. For the purpose of this clause:

(i) “Components” means those articles, materials, and supplies, which are directly incorporated in the end products;

(ii) “End products” means those articles, materials, and supplies, which are to be acquired under this contract for public use; and

(iii) “A domestic source end product” means (A) an unmanufactured end product which has been mined or produced in the United States and (B) an end product manufactured in the United States if the cost of the components thereof which are mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. For the purposes of this (a)(iii)(B), components of foreign origin of the same type or kind as the products referred to in (b) (i) or (iii) of this clause shall be treated as components mined, produced, or manufactured in the United States.
(b) The Contractor agrees that there will be delivered under this contract only domestic source end products, except end products:

(i) Which are for use outside the United States;

(ii) Which the Government determines are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality;

(iii) As to which the Secretary determines the domestic preference to be inconsistent with the public interest; or

(iv) As to which the Secretary determines the cost to the Government to be unreasonable. (The foregoing requirements are administered in accordance with Executive Order No. 10582, dated December 17, 1954).

(End of clause)

CLAUSE NO. 12—EQUAL OPPORTUNITY (JUN 1977)

Subject to the Indian preference requirements of Clause 17, during the performance of this contract the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, creed, color, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, creed, color, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or reemployment advertising; layoff or termination, rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisement for employees placed by or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, creed, color, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which it has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or workers representative of the Contractor's commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, and of the rules, regulations and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by executive Order No. 11246 of September 24, 1965, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to its books, records, and accounts by the contracting agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor's non-compliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, or orders, this contract may be cancelled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: Provided, however, That in the event the Contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

(End of clause)

CLAUSE NO. 13—CERTIFICATE OF NONSEGREGATED FACILITIES (JUN 1977)

By signing the contract the Contractor certifies that it does not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. It certifies further that it will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it will not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. The Contractor agrees that a...
breach of this certification is a violation of the Equal Opportunity clause in this contract. As used in this certification, the term "Segregated facilities" means any waiting rooms, work areas, rest rooms and wash rooms, restaurants and other eating areas, time clocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees which are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, or national origin, because of habit, local custom, or otherwise. It further agrees that (except where it has obtained identical certification from proposed subcontractors for specific time periods) it will obtain identical certifications from proposed subcontractors prior to the award of subcontracts exceeding $10,000 which are not exempt from the provisions of the Equal Opportunity clause; that it will retain such certifications in its files; and that it will forward the following notice to such proposed subcontractors (except where the proposed subcontractors have submitted identical certifications for specific time periods):

Notice to prospective subcontractors of requirement for certifications of nonsegregated facilities. A certification of Nonsegregated Facilities must be submitted prior to the award of a subcontract exceeding $10,000 which is not exempt from the provisions of the Equal Opportunity clause. The certification may be submitted either for such proposed subcontractors (except where it has obtained identical certification as described in sections 1-1.710-3(b), 1-1.805-3(b), and 1-1.13 of the Federal Procurement Regulations. The Contractor determines is consistent with the purpose and intent of this paragraph.

(a) As used in this clause, the term, "Indian business concern" means Indian organizations or an Indian-owned economic enterprise as defined in 42 CFR 36.204(i).
(b) The Contractor agrees to give preference to qualified Indian business concerns in the awarding of any subcontracts entered into under the contract consistent with efficient performance of the contract. The Contractor shall comply with any preference requirements regarding Indian business concerns established by the tribe(s) receiving contract price.
(c) If no Indian business concerns are available under the conditions in paragraph (b) above, the Contractor agrees to accomplish the maximum amount of subcontracting, as the Contractor determines is consistent with its efficient performance of the contract, with small business concerns, labor surplus area concerns or minority business enterprises, the definitions for which are contained in Subparts 1-1.7, 1-1.8, and 1-1.13 of the Federal Procurement Regulations. The Contractor is not, however, required to establish a small business, labor surplus, or minority business subcontracting program as described in sections 1-1.710-3(b), 1-1.805-3(b), and 1-1.1310-2(b), respectively of the Federal Procurement Regulations (41 CFR chapter 1).

(End of clause)
Appendix A—Public Health Service

age, religion, or sex, that are not fully qualified to perform under the contract. The Contractor shall comply with any Indian preference requirements established by the tribe receiving services under the contract to the extent that such requirements are consistent with the purpose and intent of this paragraph.

(b) If the Contractor or any of its subcontractors is unable to fill its employment openings after giving full consideration to Indians as required in paragraph (a), the openings may then be filled by other than Indians under the conditions set forth in the Equal Opportunity clause of this contract.

(c) The Contractor agrees to include this clause or one similar thereto in all subcontracts issued under this contract.

(End of clause)

CLAUSE NO. 18—INSPECTION (JUN 1977)

The Government, through any authorized representatives, has the right, at all reasonable times, to inspect, or otherwise evaluate the work performed or being performed hereunder and the premises in which it is being performed. If any inspection, or evaluation is made by the Government on the premises of the Contractor or a subcontractor, the Contractor shall provide and shall require its subcontractors to provide all reasonable facilities and assistance for the safety and convenience of the Government representatives in the performance of their duties. All inspections and evaluations shall be performed in such a manner as will not unduly delay the work.

(End of clause)

CLAUSE NO. 19—CHANGES (JUN 1977)

The Contracting Officer may at any time, with the consent of the Contractor, by a written order, and without notice to the sureties, if any, make changes, within the general scope of this contract, in any one or more of the following: (i) drawings, designs, or specifications, (ii) place of inspection, delivery, or acceptance, and (iii) the amount of Government-furnished property. If any such change causes an increase or decrease in the cost of, or the time required for performance of, this contract, or otherwise affects an equitable adjustment shall be made in the contract price or time of performance, or both, and (ii) in such provisions of the contract as may be so affected, and the contract shall be modified in writing accordingly. Any claim by the Contractor for adjustment under this clause must be asserted within thirty (30) days from the date of receipt by the Contractor of the notification of change.

Provided, however, that the Contracting Officer, if he/she decides that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. Where the cost of property made obsolete or excess as a result of a change is included in the Contractor's claim for adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of such property. Failure to agree to any adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(End of clause)

CLAUSE NO. 20—RETRCESSION (JUN 1977)

(a) The Indian tribe that initially requested this contract may also request its retrocession, notwithstanding the fact that the Contractor or a tribal organization other than the Tribe.

(b) Should the Tribe request retrocession of the contract and the Contractor is other than the Tribe, the Contracting Officer will notify the Contractor of the request and in consultation with the Tribe and the Contractor establish the effective date of the retrocession. The retrocession will become effective no later than 120 days after the Contracting Officer receives the Tribe's request unless the Tribe and the Contracting Officer mutually agree on a later date.

(c) Immediately after receipt of the request for retrocession and where applicable, notifying the Contractor, the Contracting Officer will meet with the Contractor and, where applicable, the tribal governing body or bodies mutually agree to:

(1) A plan for the orderly transfer of responsibilities;
(2) A plan for inventorying materials and supplies on hand;
(3) An accounting for funds, including but not limited to current and anticipated obligations;
(4) The cost of operation until retrocession;
and,
(5) The identification of all records relating to the contract and the contracted function.

(End of clause)

CLAUSE NO. 21—ASSUMPTION AND REASSUMPTION OF CONTRACT PROGRAMS (JUN 1977)

(a) When the Contracting Officer determines that the performance of a Contractor under these regulations involves (1) the violation of the rights or endangerment of the health, safety, or welfare of any person, or
(2) gross negligence or the mismanagement

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in the handling or use of funds under the contract, the Contracting Officer will, in writing, notify the Contractor of such determination and request that the Contractor take corrective action before the end of such period of time as the Secretary may prescribe.

(b) When the Director or his/her delegate determines that a Contractor has not taken corrective action (as prescribed by him/her under paragraph (a) of this section) to his/her satisfaction, he/she may, after the Contractor has been provided an opportunity for a hearing in accordance with paragraph (c) of this section, rescind the contract in whole or in part and, if he/she deems it appropriate, assume or resume control or operation of the program, activity, or service involved.

(c)(1) When the Director or his/her delegate has made a determination described in paragraph (b) of this section, he/she shall in writing notify the Contractor of such determination and of the Contractor’s right to request a review of such determination and of the determination described in paragraph (a) of this section. Such notification by the Director or his/her delegate shall set forth the reasons for the determination in sufficient detail to enable the Contractor to respond and shall inform the Contractor of its rights to a hearing on the record before a Contract Appeals Board described in paragraph (d) of this section. Upon the request of the Contractor for a hearing, the Board, established pursuant to paragraph (d) of this section, shall in writing within 10 days of the establishment notify the Contractor of the time, place and date of the hearing which will be held not later than 45 days after the request for a hearing.

(2) Where the Director or his/her delegate determines that a Contractor’s performance under a contract awarded under this subpart poses an immediate threat to the safety of any person, he/she may immediately rescind the contract in whole or in part and, if he/she deems it appropriate, assume or resume control or operation of the program, activity, or service involved. Upon such a decision he/she will immediately notify the Contractor of such action and the basis therefor; and offer the Contractor an opportunity for a hearing on the record before the Contract Appeals Board established pursuant to paragraph (d) of this section to be held within 10 days of each action.

(d)(1) The Contract Appeals Board shall be composed of 3 persons appointed by the Director, Indian Health Service. Such persons may not be selected from the immediate office of any person participating in the determinations at issue. The Board shall afford the Contractor the right:

(i) To notice of the issues to be considered;

(ii) To be represented by counsel;

(iii) To present witnesses on contractor’s behalf;

(iv) To cross-examine other witnesses either orally through written interrogations; and

(v) To compel the appearance of Indian Health Service personnel or to take depositions of such persons at reasonable times and places.

(2) The Contract Appeals Board shall make an initial written decision which shall become final within 20 days unless the Director, Indian Health Service or his/her representative modifies or reverses the decision. Any such decision by the Director of the Indian Health Service or his/her representative shall be in writing, shall be specific as to the reasons for such decision, and shall be considered final.

(3) Where Board is considering issues arising under paragraph (2) of this section, the Board shall within 25 days after the conclusion of the hearing, notify all parties in writing of its decision.

(e) In any case where the officer has rescinded a contract under paragraphs (b) or (c) of this section, he/she may decline to enter into a new contract agreement with the Contractor until such time as he/she is satisfied that the basis for the rescission has been corrected.


(End of clause)

CLAUSE NO. 22—PAYMENT OF INTEREST ON CONTRACTORS’ CLAIMS (JUN 1977)

(a) If an appeal is filed by the Contractor from a final decision of the Contracting Officer under the Disputes clause of this contract, denying a claim arising under the contract, simple interest on the amount of the claim shall be payable to the Contractor. Such interest shall be at the rate determined by the Secretary of the Treasury pursuant to Public Law 92÷41, 85 Stat. 97, from the date the Contractor furnished to the Contracting Officer his written appeal under the Disputes clause of this contract, to the date of (1) a final judgment by a court of competent jurisdiction, or (2) mailing to the Contractor of a supplemental agreement for execution either confirming completed negotiations between the parties or carrying out a decision of a board of contract appeals.

(b) Notwithstanding (a), above, (1) interest shall be applied only from the date payment was due, if such date is later than the filing of appeal, and (2) interest shall not be paid for any period of time that the Contracting Officer determines the Contractor has unduly delayed in pursuing its remedies before a board of contract appeals or a court of competent jurisdiction.
(a) The Government shall deliver to the Contractor, for use in connection with and under the terms of this contract, the property described elsewhere in this contract, together with such related data and information as the Contractor may request and as may reasonably be required for the intended use of such property (hereinafter referred to as "Government-Furnished Property"). The delivery or performance dates for the supplies or services to be furnished by the Contractor under this contract are based upon the expectation that Government-Furnished Property suitable for use will be delivered to the Contractor at the times stated elsewhere in this contract or, if not so stated, in sufficient time to enable the Contractor by such time or times, to meet such delivery or performance dates. In the event that Government-Furnished Property is not delivered to the Contractor to meet such delivery or performance dates, the Contracting Officer shall, upon timely written request made by the Contractor, make a determination of the delay occasioned the Contractor and shall equitably adjust the delivery or performance dates, or the contract price, or both, and any other contractual provision affected by the delay. In the event that Government-Furnished Property is received by the Contractor in a condition not suitable for its intended use, the Contractor shall, upon receipt thereof, notify the Contracting Officer of such fact and, as directed by the Contracting Officer, either (1) return such property at the Government's expense or otherwise dispose of such property, or (2) effect repairs or modifications. Upon completion of (1) or (2) above, the Contracting Officer upon timely written request of the Contractor shall equitably adjust the delivery or performance dates of the contract price, or both, and any other contractual provision affected by the return, disposition, repair, or modification. The foregoing provisions for adjustment are exclusive and the Government shall not be liable to suit for breach of contract by reason of any delay in delivery of Government-Furnished Property or delivery of such property in a condition not suitable for its intended use.

(b) By notice in writing the Contracting Officer may decrease the property furnished or to be furnished by the Government under this contract. In any such case, the Contracting Officer upon timely written request of the Contractor shall equitably adjust the delivery or performance date or the contract price, or both, and any other contractual provisions affected by the decrease.

(c) Title to the Government-Furnished Property shall remain in the Government. Title to Government-Furnished Property shall not be affected by the incorporation or attachment thereof to any property not owned by the Government, nor shall such Government-Furnished Property, or any part thereof, be or become a fixture or lose its identity as personality by reason of affixation to any realty.

(d) The Government-Furnished Property, unless otherwise specifically provided herein, and except as otherwise approved or directed by the Contracting Officer in writing, shall be used exclusively for the performance of this contract.

(e) The Contractor shall maintain and administer, in accordance with sound business practice, a program for the maintenance, repair, protection and preservation of Government-Furnished Property, until disposed of by the Government-Furnished Property at the Government's expense or otherwise disposed of such property, or (2) effect repairs or modifications. Upon completion of (1) or (2) above, the Contracting Officer shall replace such items or the Contractor shall make such repair of the property, as the Government directs; Provided, however, That if the Contractor cannot effect such repair within the required, the Contractor may reject such property. The contract price includes no compensation to the Contractor for the performance of any repair or replacement for which the Government is responsible; and an equitable adjustment will be made in the contract price for any such repair or replacement of Government-Furnished Property made at the direction of the Government. Any repair or replacement for which the Contractor is responsible under the provisions of this contract shall be accomplished by the Contractor at its own expense.

(f) The Contractor also agrees to maintain and administer, in accordance with sound business practice, a property control system which will provide the following: Contract number; nomenclature of item; quantity received; issued; and balance on hand; posting reference to include date received, issued unit price and location; marking or identification of item; adequate maintenance, storage, and security of Government-Furnished Property, until disposed of by the Contractor in accordance with this clause.

The Contractor further agrees to receipt promptly for all Government property in a form and manner as prescribed by the Contracting Officer.

(g) The Contractor agrees to make available to authorized representatives of the Contracting Officer at all reasonable times at the office of the Contractor all of its property records under this contract, and access to any premises where any of the Government-Furnished Property is located.

(h) (i) The Contractor shall not be liable for any loss or damage to the Government-
Furnished Property, or for expenses incidental to such loss or damage except that the Contractor shall be liable for any such loss or damage (including expenses incidental thereto):

(A) Which results from willful misconduct, lack of good faith on the part of any of the Contractor's directors or officers, or on the part of any of its managers, superintendents, or other equivalent representatives who have supervision or direction of all or substantially all of the Contractor's business, or all or substantially all of the Contractor's operations, or the Government-Furnished Property from further damage, separate the damaged and undamaged Government-Furnished Property in the best possible order, and furnish to the Contracting Officer a statement of:

(A) The lost, destroyed and damaged Government-Furnished Property;
(B) The time and origin of the loss, destruction or damage;
(C) All known interest in commingled property of which the Government-Furnished Property is a part; and
(D) The insurance, if any, covering any part of or interest in such commingled property.

The Contractor shall be reimbursed for the expenditures made by it in performing its obligations under the subparagraph (iii), to the extent approved by the Contracting Officer and set forth in a supplemental agreement or amendment to this contract.

(iv) With the prior written approval of the Contracting Officer, after loss or destruction of or damage to Government-Furnished Property, and subject to such conditions and limitations as may be imposed by the Contracting Officer, the Contractor may, in order to minimize the loss to the Government or in order to permit resumption of business or the like, sell for the account of the Government any item of Government-Furnished Property which has been damaged beyond practicable repair, or which is so commingled or combined with property of other, including the Contractor, that separation is impracticable.

(v) Except to the extent of any loss or destruction of or damage to Government-Furnished Property for which the Contractor is relieved of liability under the foregoing provisions of this clause, and except for reasonable wear and tear or depreciation, or the utilization of the Government-Furnished Property in accordance with the provisions of this contract, the Government-Furnished Property (other than property permitted to be sold) shall be returned to the Government in as good condition as when received by the Contractor in connection with this contract, or as repaired under paragraph (e) above.

(vi) In the event the Contractor is reimbursed or compensated for any loss or destruction of or damage to the Government-Furnished Property, it shall equitably reimburse the Government. The Contractor shall do nothing to prejudice the Government's rights to recover against third parties for any such loss, destruction or damage and, upon the request of the Contracting Officer shall at the Government's expense, furnish to the Government all reasonable assistance and cooperation (including assistance in the prosecution of suit and the execution of instruments of assignment in favor of the Government) in obtaining recovery.

(i) Upon completion or expiration of this contract, any Government property which has not been consumed in the performance of this contract or which has not been previously disposed of in accordance with the
provisions of this clause, or for which the Contractor has not otherwise been relieved of responsibility, shall be disposed of as the Contracting Officer may direct. The Contractor shall in no way be relieved of responsibility for Government property without the prior written approval of the Contracting Officer.

(i) If the Contracting Officer determines that the interests of the Government require removal of any Government-Furnished Property, or if the Contractor determines any Government-Furnished Property to be in excess of its need under this contract such Government-Furnished Property shall be disposed of in the same manner as covered by paragraph (i) above. In the event that the Contracting Officer requires the removal of any Government-Furnished Property under this paragraph (j) or paragraph (i) above, upon timely written request of the Contractor, an equitable adjustment shall be made in the contract price to cover the direct cost to the Contractor of such removal and of any property damage occasioned thereby.

(End of clause)

CLAUSE NO. 24—EXAMINATION OF RECORDS BY THE COMPTROLLER GENERAL (JUN 1977)

(a) The Contractor agrees that the Comptroller General of the United States or any of his/her duly authorized representatives shall, until expiration of 3 years after final payment under this contract, or of the time periods for the particular records specified in Part 1-20 of the Federal Procurement Regulations (41 CFR part 1-20), whichever expires earlier, have access to and the right to examine any directly pertinent books, documents, papers, and records of the Contractor involving transactions related to this contract.

(b) The Contractor further agrees to include in all its subcontracts hereunder a provision to the effect that the subcontractor agrees that the Comptroller General of the United States or any of his/her duly authorized representatives shall, until expiration of 3 years after final payment under the subcontract, or of the time periods for the particular records specified in Part 1-20 of the Federal Procurement Regulations (41 CFR part 1-20), whichever expires earlier, have access to and the right to examine any directly pertinent books, documents, papers, and records of such subcontractor, involving transactions related to the subcontract. The term “subcontract” as used in this clause excludes (1) purchase orders not exceeding $2,500 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public.

CLAUSE NO. 25—INDEMNITY AND INSURANCE (JUN 1977)

(a) The Contractor shall indemnify and save and keep harmless the Government against any or all loss, cost, damage, claim, expense or liability whatsoever, because of accident or injury to persons or property or others occurring in connection with any program including as a part of this contract, by providing where applicable, the insurance described below:

(b) The Contractor shall secure, pay the premium for, and keep in force until the expiration of this contract, or any renewal period thereof, insurance as provided below. Such insurance policies shall specifically include a provision stating the liability assumed by the Contractor under this contract.

(1) Workman’s compensation insurance as required by laws of the state.

(2) Owner’s, landlord’s, and tenant’s bodily injury liability insurance with limits of not less than $50,000 for each person and $500,000 for each accident.

(3) Property damage liability insurance with limits of not less than $25,000 for each accident.

(4) Automobile bodily injury liability insurance with limits of not less than $50,000 for each person, and $500,000 for each accident and property damage liability insurance with a limit of not less than $5,000 for each accident.

(5) Food products liability insurance with limits of not less than $50,000 for each person and $500,000 for each accident.

(6) Professional malpractice insurance where medical, dental, or other health professional services are involved.

(7) Other liability insurance not specifically mentioned when required.

(c) Each policy of insurance shall contain an endorsement providing that cancellation by the insurance company shall not be effective unless a copy of the cancellation is mailed (registered) to the Contracting Officer 30 days prior to the effective date of cancellation.

(d) A certificate of each policy of insurance, and any change therein, shall be furnished to the Contracting Officer immediately upon receipt from the insurance company.

(e) Insurance companies of the Contractor shall be satisfactory to the Contracting Officer. When in his/her opinion an insurance company is not satisfactory for reasons that will be stated, the Contractor shall provide insurance through companies that are satisfactory to the Contracting Officer.

(f) Each policy of insurance shall contain a provision that the insurance carrier waives any rights it may have to raise as a defense
the tribe's sovereign immunity from suit, but such waiver shall extend only to claims the amount and nature of which are within the coverage and limits of the policy of insurance. The policy shall contain no provis-
on, either expressed or implied, that will serve to authorize or empower the insurance carrier to waive or otherwise limit the tribe's sovereign immunity outside or beyond the coverage and limits of the policy or insurance.

(End of clause)

CLAUSE NO. 26—FAIR AND EQUAL TREATMENT OF INDIAN PEOPLE (JUN 1977)

(a) The Contractor agrees to make no discriminating distinctions among Indian pa-
tients or beneficiaries of this contract. For the purpose of this contract discriminatory distinctions include but are not limited to the following:

(i) Denying a patient any service or benefit or availability of a facility;

(ii) Providing any service or benefit to a patient which is different, or is provided in a different manner or at a different time from that provided to other patients under this contract; subjecting a patient to segregation or separate treatment in any manner related to his/her receipt of any service; restricting a patient in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service or benefit; treating a patient differently from others in determining whether he/she satisfies any admission, enrollment, quota, eligibility membership, or other requirements or conditions which individuals must meet in order to be provided any service or benefit; the assignment of times or places for the provision of services on the basis of discriminatory distinctions which may be made of the patients to be served.

(b) The Government reserves the right to terminate this contract in whole or in part whenever the Contractor fails to comply with the requirements of this clause.

(End of clause)

CLAUSE NO. 27—REPORTS TO THE INDIAN PEOPLE AND ANNUAL REPORTS (JUN 1977)

(a) The Contractor, as a recipient of Federal financial assistance, shall make reports and information available to the Indian people serviced or represented by the Contractor. Such reports will reflect how the Federal assistance funds were utilized to the benefit of the Indian people served or represented as follows: (specific reporting requirements, formats and methods of distribution to the Indian people will be prescribed in the scope of the contract.)

(b) Annual reports.

(1) For each fiscal year during which a tribal organization receives or expends funds pursuant to the contract under this part, the tribe which requested the contract must submit a report to the Contracting Officer. The report shall include, but not be limited to, an accounting of the amounts and purposes for which the contract funds were expended and information on the conduct of the program or services involved. The report shall include any other information requested by the Contracting Officer and may be submitted as follows:

(i) When the contract is with the governing body of an Indian tribe, the tribe shall submit the reports to the Contracting Officer.

(ii) When the contract is with a tribal organization other than the governing body of the tribe, the tribe has the option of having the tribal organization prepare the report and submit it to the tribe for review and approval before the tribe submits it to the Contracting Officer.

(iii) When the contract benefits more than one tribe, the tribal organization shall prepare and submit the report to each of the tribes benefiting under the contract. Each tribe shall endorse the report before submitting it to the Contracting Officer.

(2) The annual report shall be submitted to the Contracting Officer within 90 days of the end of the fiscal year in which the contract was performed. However, the period for submitting the report may be extended if there is just cause for such extension.

(3) In addition to the yearly reporting requirement given in paragraphs (a) and (b) of this section, the tribal contractor shall furnish other reports when and as required by the Secretary.

(End of clause)

CLAUSE NO. 28—QUESTIONNAIRES AND SURVEYS (JUN 1977)

In the event the performance of this contract involves the collection of information upon identical items from 10 or more persons, other than Federal employees, the Contractor shall obtain written approval from the Contracting Officer, prior to the use thereof, of any forms, schedules, questionnaires, survey plans or other documents, and any revisions thereto, intended to be used in such collection.

(End of clause)

CLAUSE NO. 29—PRINTING (JUN 1977)

Unless otherwise specified in this contract, the Contractor shall not engage in, nor sub-contract for, any printing (as that term is defined in Title 1 of the Government Printing and Binding Regulations in effect on the effective date of this contract) in connection with the performance of work under this

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Appendix A—Public Health Service

CLAUSE NO. 30—PRICE REDUCTION FOR DEFECTIVE COST OR PRICING

The following clause applies to all contracts where cost and pricing data is required in accordance with P.L. 87-653.

Price Reduction for Defective Cost or Pricing Data (June 1977)

(a) If the Contracting Officer determines that any price negotiated in connection with this contract or any cost reimbursable under this contract was increased by any significant sums because the Contractor, or any subcontractor pursuant to the clause of this contract entitled “Subcontractor Cost or Pricing Data,” or any subcontract clause therein required, furnished incomplete or inaccurate cost or pricing data or data not current as certified in its Contractor’s Certificate of Current Cost or Pricing Data, then such price or cost shall be reduced accordingly and the contract shall be modified in writing to reflect such reduction.

(b) Failure to agree on a reduction shall be a dispute concerning a question of fact within the meaning of the “Disputes” clause of this contract.

NOTE: Since the contract is subject to reduction under this clause by reason of defective cost or pricing data submitted in connection with certain subcontracts, it is expected that the Contractor may wish to include a clause in each such subcontract requiring the subcontractor to appropriately indemnify the Contractor. It is also expected that any subcontractor subject to such indemnification will generally require substantially similar indemnification for defective cost or pricing data required to be submitted by its lower tier subcontractors.

CLAUSE NO. 31—SUBCONTRACTOR COST AND PRICING DATA

The following clause should be included in all contracts when the subcontracts of the type and size described therein are contemplated.

Subcontractor Cost and Pricing Data (JUN 1977)

(a) The Contractor shall require subcontractors hereunder to submit in writing cost or pricing data under the following circumstances:

(1) Prior to award of any cost-reimbursed type, time and material, labor-hour, incentive, or price redeterminable subcontract the price of which is expected to exceed $100,000; and

(2) Prior to the award of any other subcontract, the price of which is expected to exceed $100,000, or to the pricing of any subcontract change or other modification for which the price adjustment is expected to exceed $100,000, where the price or price adjustment is not based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(b) The Contractor shall require subcontractors to certify, substantially the same form as that used in the certificate by the Prime Contractor to the Government, that, to the best of their knowledge and belief, the cost and pricing data submitted under (a) above are accurate, complete, and current as of the date of the execution, which date shall be as close as possible to the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(c) The contractor shall insert the substance of this clause including this paragraph (c) in each of its cost-reimbursable type, time and material, labor-hour, price redeterminable, or incentive subcontract hereunder, and in any other subcontract hereunder which exceeds $200,000 unless the price thereof is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation. In each such excepted subcontract hereunder which exceeds $100,000, the Contractor shall insert the substance of the following clause:

Subcontractor Cost and Pricing Data—Price Adjustment

(a) Paragraphs (b) and (c) of this clause shall become operative only with respect to any change or other modification made pursuant to one or more provisions of this contract which involves a price adjustment in excess of $100,000. The requirements of this clause shall be limited to such price adjustments.

(b) The Contractor shall require subcontractors hereunder to submit cost or pricing data under the following circumstances:

(1) Prior to award of any cost-reimbursement type, time and material, labor-hour,
incentive, or price redeterminable subcontract, the price of which is expected to exceed $100,000; and

(2) Prior to award of any other subcontract, the price of which is expected to exceed $100,000, or to the pricing of any subcontract change or other modification for which the price adjustment is expected to exceed $100,000, where the price or price adjustment is not based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(c) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the Certificate by the Prime Contractor to the Government, that, to the best of their knowledge and belief, the cost and pricing data submitted under (b) above are accurate, complete, and current as of the date of the execution, which date shall be as close as possible to the date of agreement on the negotiated price of the contract modification.

(d) The Contractor shall insert the substance of this clause including this paragraph (d) in each subcontract hereunder which exceeds $100,000.

(End of clause)

Clause No. 32—Advance Payment (JUN 1977)

(a) Amount of Advance. At the request of the Contractor, and subject to the conditions hereinafter set forth, the Government shall make an advance payment, or advance payments from time to time, to the Contractor. No advance payment shall be made (1) without the approval of the office administering advance payments (hereinafter called the “Administering Office” and designated in paragraph (k)(4) hereof) as with all advance payments theretofore made, shall exceed the amount stated in paragraph (k)(1) hereof; and (3) without a properly certified invoice or invoices.

(b) Special Bank Account. Until all advance payments made hereunder are liquidated and the Administering Office approves in writing the release of any funds due and payable to the Contractor, all advance payments and all other payments under the contract shall be made by check payable to the Contractor, and be marked for deposit only in a Special Bank Account with the bank designated in paragraph (k)(2) hereof. No part of the funds in the Special Bank Account shall be mingled with other funds of the Contractor prior to withdrawal thereof from the Special Bank Account as hereinafter provided. Except as hereinafter provided, each withdrawal shall be made only by check of the Contractor countersigned on behalf of the Government by the Contracting Officer or such other person or persons as he/she may designate in writing (hereinafter called the “Countersigning Agent”). Until otherwise determined by the Administering Office, countersignature on behalf of the Government will not be required.

(c) Use of Funds. The funds in the Special Bank Account may be withdrawn by the Contractor solely for the purpose of making payments for items of allowable cost or to reimburse the Contractor for such items of allowable cost, and or such other purposes as the Administering Office may approve in writing. Any interpretation required as to the proper use of funds shall be made in writing by the Administering Office.

(d) Return of Funds. The Contractor may at any time repay all or any part of the funds advanced hereunder. Whenever so requested in writing by the Administering Office, the Contractor shall repay to the Government such part of the unliquidated balance of advance payments as shall in the opinion of the Administering Office be in excess of current requirements, or (when added to total advance previously made and liquidated) in excess of the amount specified in paragraph (k)(1) hereof. In the event the Contractor fails to repay such part of the unliquidated balance of advance payments when so requested by the Administering Office, all or any part thereof may be withdrawn from the Special Bank Account by checks payable to the Treasurer of the United States signed solely by the Countersigning Agent and applied in reduction of advance payments then outstanding hereunder.

(e) Liquidation. If not otherwise liquidated, the advance payments made hereunder shall be liquidated as herein provided. When the sum of all payments under this contract, other than advance payments, plus the unliquidated amount of advance payments are equal to the total estimated cost for the work under this contract or such lesser amount to which the total estimated cost under this contract may have been reduced, plus increases, if any, in this total estimated cost not exceeding, in the aggregate (including, without limitation, reimbursable costs incident to termination for cause and retrogression as estimated by the Contracting Officer), the Government shall thereafter withhold further payments to the Contractor and apply the amounts withheld against the Contractor’s obligation to repay such advance payments until such advance payments shall have been fully liquidated. If upon completion, termination, or retrogression of the contract all advance payments made under this contract have not been fully liquidated, the balances thereon shall be deducted from any sums otherwise due or which may become due to the Contractor from the Government, and any deficiency shall be paid by the Contractor to the government upon demand.

(f) Bank Agreement. Before an advance payment is made hereunder, the Contractor shall transmit to the Administering Office,
in the form prescribed by such office, an Agreement in triplicate from the bank in which the Special Bank Account is established, clearly setting forth the special character and responsibilities of the bank thereunder. Wherever possible, such bank shall be a member bank of the Federal Reserve System, or an "insured" bank within the meaning of the Act creating the Federal Deposit Insurance Corporation Act of August 23, 1935, 49 Stat. 685, as amended (12 U.S.C. 264).

(g) Lien on Special Bank Account. The Government shall have a lien upon any balance in the Special Bank Account paramount to all other liens, which lien shall secure the repayment or any advance payments made hereunder.

(h) Lien on Property under Contract. Any and all advance payments made under this contract shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, upon the supplies or other things covered by this contract and on all material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other provision of this contract, or otherwise, shall have valid title to such supplies, materials, or other property against other creditors of the Contractor. The Contractor shall identify, by marking or segregation, all property which is subject to a lien in favor of the Government by virtue of any provision of this contract in such a way as to indicate that it is subject to such lien and that it has been acquired for or allocated to the performance of this contract, if for any reason such supplies, materials, or other property are not identified by marking or segregation, the Government shall be deemed to have a lien to the extent of the Government’s interest under this contract on any mass of property with which such supplies, materials, or other property are commingled. The Contractor shall maintain adequate accounting control over such property on its books and records. If at any time during the progress of the work on the contract it becomes necessary to deliver any item or items and materials upon which the Government has a lien as aforesaid to a third party, the Contractor shall notify such third person of the lien therein provided and shall obtain from such third person a receipt, in duplicate, acknowledging, inter alia the existence of such lien. A copy of each receipt shall be delivered by the Contractor to the Contracting Officer. If this contract is terminated in whole or in part and the Contractor is authorized to sell or retain termination inventory acquired for or allocated to this contract, such sale or retention shall be made only if approved by the Contracting Officer, which approval shall constitute a release of the Government’s lien hereunder to the extent that such termination inventory is sold or retained, and to the extent that the proceeds of the sale, or the credit allowed for such retention on the Contractor’s termination claim, is applied in reduction of advance payments then outstanding hereunder.

(i) Insurance. The Contractor agrees that, until work under this contract has been completed and all advance payments made hereunder have been liquidated, it will maintain such insurance; (ii) maintain adequate insurance upon any materials, parts, assemblies, subassemblies, supplies, equipment and other property acquired for or allocable to this contract and subject to the Government lien hereunder; and (iii) furnish such certificates with respect to its insurance as the Administering Office may from time to time require.

(j) Prohibition against Assignment. Notwithstanding any other provision of this contract, the Contractor shall not transfer, pledge, or otherwise assign this contract, or any interest therein, or any claim arising thereunder, to any party or parties, bank, trust company, or other financing institution.

(k) Designations and Determinations. (1) Amount. The amount of advance payments at any time outstanding hereunder shall not exceed $.

(2) Depositary. The bank designated for the deposit of payments made hereunder shall be:

(3) Interest Charge. No interest shall be charged for advance payments made hereunder. The Contractor shall charge interest at the rate of 6 percent per annum on subadvances or down payments to subcontractors, and such interest will be credited to the account of the Government. However, interest need not be charged on subadvances on nonprofit subcontracts with nonprofit educational or research institutions for experimental, research or development work.

(4) Administering Office. The office administering advance payments shall be the office designated as having responsibility for awarding the contract.

(l) Other Security. The terms of this contract shall be considered adequate security for advance payments hereunder, except that if at any time the administering office deems the security furnished by the Contractor to be inadequate, the Contractor shall furnish
such additional security as may be satisfactory to the administering office, to the extent that such additional security is available.

(End of clause)

CLAUSE NO. 33—EFFECT ON EXISTING RIGHTS
(1977)
(a) Nothing in this contract shall be construed as:
(1) Affecting, modifying, diminishing, or otherwise impairing the sovereign immunity for suit enjoyed by an Indian tribe; or
(2) Authorizing or requiring the termination of any existing trust responsibility of the United States with respect to the Indian people.

(End of clause)

CLAUSE NO. 34—FEDERAL, STATE, AND LOCAL TAXES
(1977)
(a) Except as may be otherwise provided in this contract, the contract price includes all applicable Federal, State, and local taxes and duties.
(b) Nevertheless, with respect to any Federal excise tax or duty on the transactions or property covered by this contract, if a statute, court decision, written ruling, or regulation takes effect after the contract date, and
(1) Results in the Contractor being required to pay or bear the burden of any such Federal excise tax or duty or increase in the rate thereof which would not otherwise have been payable on such transactions or property, the contract price shall be increased by the amount of such tax or duty or rate increase; Provided, That the Contractor if requested by the Contracting Officer in accordance with trade custom), shall have their offers increased for
(2) Results in the Contractor not being required to pay or bear the burden of, or in its obtaining a refund or drawback of, any such Federal excise tax or duty which would otherwise have been payable on such transactions or property or which was the basis of an increase in the contract price, the contract price shall be decreased by the amount of the relief, refund, or drawback, or the amount shall be paid to the Government, as directed by the Contracting Officer. The contract price shall be similarly decreased if the Contractor, through its fault or negligence or its failure to follow instructions of the Contracting Officer, is required to pay or bear the burden of, or does not obtain, a refund or drawback of, any such Federal excise tax or duty.
(c) No adjustment pursuant to paragraph (b) above will be made under this contract unless the aggregate amount thereof is or may reasonably be expected to be over $100.
(d) As used in paragraph (b) above, the term "contract date" means the date set for the bid opening, or if this is a negotiated contract, the date of this contract. As to additional supplies or services procured by modification to this contract, the term "contract date" means the date of such modification.
(e) Unless there does not exist any reasonable basis to sustain an exemption, the Government, upon request of the Contractor, without further liability, agrees, except as otherwise provided in this contract, to furnish evidence appropriate to establish exemption from any tax which the Contractor warrants in writing was excluded from the contract price. In addition, the Contracting Officer may furnish evidence to establish exemption from any tax that may, pursuant to this clause, give rise to either an increase or decrease in the contract price. Except as otherwise provided in this contract, evidence appropriate to establish exemption from duties will be furnished only at the direction of the Contracting Officer.
(f) The Contractor shall promptly notify the Contracting Officer of matters which will result in either an increase or decrease in the contract price, and shall take action with respect thereto as directed by the Contracting Officer.

(End of clause)


PHS 352.280-6 Demurrage charge provisions for reusable cylinders and containers.

The clause set forth below shall be inserted in solicitations and resultant contracts when delivery of the items may be in contractor-furnished reusable gas cylinders or other containers.

DEMMURAGE CHARGE PROVISIONS FOR REUSABLE CYLINDERS AND CONTAINERS (APR 1984)

(a) Reusable gas cylinders or other containers identified below by offerees shall remain the property of the Contractor (except as provided in (c) below), and will be loaned without charge to the Government for the period stipulated below. In computing the period involved, such free loan period shall commence on the first day after date of delivery of each container to the herein specified f.o.b. point(s). Offerees who specify less than 30 days (to be determined by the Contracting Officer in accordance with trade custom), shall have their offers increased for

(End of clause)

[48 CFR Ch. 3 (10-1-00 Edition)]
Appendix A—Public Health Service

Contract clauses for contracts awarded under the Indian Self-Determination Act.

(a) PHS Acquisition Regulations (PHSAR) Clauses for Cost-Reimbursement Contracts Awarded under the Indian Self-Determination Act.

(b) PHSAR Clauses for Cost-Reimbursement Contracts Awarded under the Indian Self-Determination Act.

1. 352.280-4(a)(1) Definitions. (June 1977)
2. 352.280-4(a)(2) Disputes. (June 1977)
4. 352.280-4(a)(4) Allowable Cost. (June 1977)
5. 352.280-4(a)(5) Negotiated Overhead Rates. (June 1977)
6. 352.280-4(a)(6) Payment. (June 1977)
7. 352.280-4(a)(7) Advance Payment. (June 1977)
8. 352.280-4(a)(8) Examination of Records. (June 1977)
9. 352.280-4(a)(9) Inspection and Reports. (June 1977)
10. 352.280-4(a)(10) Subcontracting. (June 1977)
15. 352.280-4(a)(15) Retrocession. (June 1977)
16. 352.280-4(a)(16) Reassumption of Programs. (June 1977)
17. 352.280-4(a)(17) Key Personnel. (June 1977)
18. 352.280-4(a)(18) Litigation and Claims. (June 1977)
19. 352.280-4(a)(19) Indemnity and Insurance. (June 1977)
20. 352.280-4(a)(20) Overtime. (June 1977)
21. 352.280-4(a)(21) Foreign Travel. (June 1977)
22. 352.280-4(a)(22) Questionnaires and Surveys. (June 1977)
23. 352.280-4(a)(23) Printing. (June 1977)
24. 352.280-4(a)(24) Services of Consultants. (June 1977)
29. 352.280-4(a)(29) Indian Preference in Training and Employment. (June 1977)
32. 352.280-4(a)(32) Officials not to Benefit. (June 1977)
33. 352.280-4(a)(33) Buy American Act Supply and Service contracts. (June 1977)
34. 352.280-4(a)(34) Anti-Kickback Act. (June 1977)
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PHS 380.505 Responsibility determinations.
SOURCE: 49 FR 36263, Sept. 14, 1984, unless otherwise noted.

Subpart PHS 380.1—Acquisitions Involving Human Subjects

SOURCE: 51 FR 20491, June 5, 1986, unless otherwise noted.

PHS 380.101 Applicability.
This subpart applies to all research and development contracts involving human subjects except those that are exempt by Secretarial waiver under 45 CFR 46.101(e) or exempt under 45 CFR 46.101(b).

PHS 380.102 Policy.
(a) Safeguarding the rights and welfare of human subjects in activities under Public Health Service (PHS) research and development contracts is the responsibility of each institution that receives or is accountable to PHS for funds awarded for the conduct of that activity. To assure that this institutional responsibility is met, PHS shall not permit a nonexempt research activity involving human subjects to be undertaken unless the institution has an assurance on file with the Office for Protection from Research Risks (OPRR), NIH/PHS, and has filed a certification that an institutional review board (IRB) has reviewed and approved
PHS 380.103 Assurances.

In accordance with 45 CFR 46.103, OPRR is responsible for negotiation of assurances covering all PHS-supported research activities involving human subjects. Consultation with OPRR (telephone: 301-496-7041) is recommended on issues regarding assurances, certification of IRB review and approval, and interpretation of the regulations for the protection of human subjects in 45 CFR Part 46.

PHS 380.104 Notice to offerors.

Solicitations shall contain the notice to offerors set forth in PHS 352.280-1(a) whenever contract performance is expected to involve human subjects.

PHS 380.105 Contract clause.

The clause set forth in PHS 352.280-1(b) shall be inserted in all contracts involving human subjects.

Subpart PHS 380.2—Acquisitions Involving the Use of Laboratory Animals

SOURCE: 51 FR 20492, June 5, 1986, unless otherwise noted.

PHS 380.201 Scope of subpart.

This subpart describes Public Health Service (PHS) contracts for projects or activities involving animals, and the responsibilities of the PHS agencies and subordinate elements for implementing policies and procedures described herein.

PHS 380.202 Definitions.

(a) Animal. Any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes.

(b) Animal facility. Any building, room, area, enclosure, or vehicle, including satellite facility, used for animal confinement, transport, maintenance, breeding or experiments of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.


(d) Animal Welfare Assurance or Assurance. The documentation from an awardee or a prospective awardee institution assuring institutional compliance with this policy.


(f) Institution. Any public or private organization, business, or agency (including components of Federal, State and local governments).

(g) Institutional official. An individual who has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirement of this subpart will be met.

(h) Public Health Service. The Public Health Service includes the Office of the Assistant Secretary for Health; the Alcohol, Drug Abuse, and Mental Health Administration; the Centers for Disease Control; the Food and Drug Administration; the Health Resources and Services Administration; and the National Institutes of Health.

(i) Quorum. A majority of the members of the Institutional Animal Care and Use Committee.

PHS 380.203 Policy.

It is the policy of PHS to require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training and biological testing (hereinafter referred to as activities) supported by PHS. PHS endorses the “U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in
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Testing, Research and Training” developed by the Interagency Research Animal Committee (IRAC). This policy is intended to implement and supplement those Principles.

PHS 380.204 Applicability.

(a) This policy is applicable to all PHS-supported activities involving animals, whether the activities are performed at an awardee institution, or any other institution, in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States. Institutions in foreign countries receiving PHS support for activities involving animals shall comply with this policy, or provide evidence to PHS that acceptable standards for the humane care and use of the animals in PHS-supported activities will be met.

(b) No PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with this policy for PHS-supported activities, or unless the individual makes other arrangements with PHS.

(c) This policy does not supersede or preempt applicable State or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act, and other Federal statutes and regulations relating to animals.

PHS 380.205 Contractor implementation.

(a) Animal Welfare Assurance. No activity involving animals will be supported by PHS until the institution conducting the activity has provided a written Assurance acceptable to PHS, setting forth compliance with the policy in this subpart for PHS-supported activities. Assurances shall be submitted to OPRR, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 4B09, Bethesda, Maryland 20892. The Assurance shall be typed on the institution’s letterhead and signed by an institutional official. OPRR will provide the applicant institution with necessary instructions and an example of an acceptable Assurance. All Assurances submitted to PHS in accordance with the policy will be evaluated by OPRR to determine the adequacy of the institution’s proposed program for the care and use of animals in PHS-supported activities. On the basis of this evaluation, OPRR may approve or disapprove the Assurance, or negotiate an acceptable Assurance with the institution. Approval of an Assurance will be for a specified period of time (no longer than five years) after which time the institution must submit a new Assurance to OPRR. OPRR may limit the period during which any particular approved Assurance shall remain effective or otherwise condition, restrict, or withdraw approval. Without an applicable PHS approved Assurance, no PHS-supported activity involving animals at the institution will be permitted to continue.

(i) Institutional program for animal care and use. The Assurance shall fully describe the institution’s program for the care and use of animals in PHS-supported activities. PHS requires institutions to use the Guide for the Care and Use of Laboratory Animals (Guide) as a basis for developing and implementing an institutional program for activities involving animals. The program description must include the following:

   (i) A list of every branch and major component of the institution, as well as a list of every branch and major component of any institution which is to be included under the Assurance;

   (ii) The lines of authority and responsibility for administering the program and ensuring compliance with this policy;

   (iii) The qualifications, authority and responsibility of the veterinarian(s) who will participate in the program;

   (iv) The membership list of the Institutional Animal Care and Use Committee(s) (IACUC)\(^1\) established in accordance with the requirements set forth in this subpart;

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\(^1\)The name Institutional Animal Care and Use Committee (IACUC) as used in this policy is intended as a generic term for a committee whose function is to ensure that the
The care and use of animals in PHS-supported activities is appropriate and humane in accordance with this policy. However, each institution may identify the committee by whatever name it chooses. Membership and responsibilities of the IACUC are set forth in PHS 380.205(d).

As of the issuance date of this policy the only accrediting body recognized by PHS is the American Association for Accreditation of Laboratory Animal Care (AAALAC).

The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution’s programs and facilities. The IACUC may invite ad hoc consultants to conduct or assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report of the IACUC evaluation shall be maintained by the institution and made available to OPRR upon request. The report must contain a description of the nature and extent of the institution’s adherence to the Guide and this policy. The report must identify specifically any departures from provisions of the Guide and this policy, and state the reasons for each departure. If program or facility deficiencies are noted, the report must contain a reasonable and specific plan and schedule for correcting each deficiency. The report must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, in the judgment of the IACUC and the institutional official, is or may be a threat to the health or safety of the animals. Failure of the IACUC to conduct an annual evaluation and submit the required report to the institutional official may result in PHS withdrawal of its approval of the Assurance.

(3) Institutional Animal Care and Use Committee (IACUC). (i) Each institution shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through experience and expertise of its members, to oversee the institution’s animal program, facilities and procedures.

(ii) The Assurance must include the names, position titles and credentials of the IACUC chairperson and the members. The committee shall consist of not less than five members, and shall include at least:

(A) One Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the institution;

(B) One practicing scientist experienced in research involving animals;

(C) One member whose primary concern is in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and

(D) One individual who is not affiliated with the institution in any way.

If some of the institution’s facilities are accredited by AAALAC or other accrediting body recognized by PHS, the report should identify those facilities and need not contain any further information about evaluation of those facilities.
other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.

(iii) An individual who meets the requirements of more than one of the categories detailed in PHS 380.205(d)(2)(i)-(iv) above, may fulfill more than one requirement. However, no committee may consist of less than five members.

(b) Functions of the Institutional Animal Care and Use Committee. As an agent of the institution, the IACUC shall, will respect to PHS-supported activities:

(1) Review at least annually the institution’s program for humane care and use of animals;
(2) Inspect at least annually all of the institution’s animal facilities, including satellite facilities;
(3) Review concerns involving the care and use of animals at the institution;
(4) Make recommendations to the institutional official regarding any aspect of the institution’s animal program, facilities or personnel training;
(5) Review and approve, require modifications in (to secure approval), or withhold approval of those sections of PHS applications or proposals related to the care and use of animals, as specified in PHS 380.205(f) of this subpart;
(6) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities; and
(7) Be authorized to suspend an activity involving animals in accord with specifications set forth in this subpart.

(c) Review of applications and proposals. In order to approve applications and proposals or proposed changes in ongoing activities, the IACUC shall conduct a review of those sections related to the care and use of animals and determine that the proposed activities are in accordance with this policy. In making this determination, the IACUC shall confirm that the activity will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the activity is consistent with the Guide, unless the IACUC determines that acceptable justification for a departure is presented. Furthermore, the IACUC shall determine that the activity conforms with the institution’s Assurance and meets the following requirements:

(1) Procedures with animals will avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design.
(2) Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
(3) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly sacrificed at the end of the procedure or, if appropriate, during the procedure.
(4) The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and nonmedical care of the animals will be directed by a veterinarian or a scientist trained and experienced in the proper care, handling and use of the species being maintained or studied.
(5) Medical care for animals will be available and provided as necessary by a qualified veterinarian.
(6) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
(7) Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel of Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

PHS 380.206 Public Health Service implementation.

(a) Responsibility of the Office for Protection from Research Risks (OPRR). OPRR is responsible for the general administration and coordination of this policy and will:

(1) Request and negotiate, approve or disapprove, and, as necessary, withdraw approval of Assurances;
(2) Distribute to executive secretaries of initial review and technical evaluation groups, and to PHS contracting offices, lists of institutions that have an approved Assurance;

(3) Advise contracting offices and awardee institutions concerning the implementation of this policy;

(4) Evaluate allegations of noncompliance with this subpart;

(5) Have the authority to review and approve or disapprove waivers of this subpart (see paragraph (d) of this section); and

(6) With other PHS officials, conduct site visits to selected institutions.

(b) Responsibilities of PHS contracting offices. PHS contracting offices shall not make an award for an activity involving animals unless the institution submitting the application or proposal is on the list of institutions that have an approved Assurance of file with OPRR, and the institutional official has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals. If an institution is not listed, the contracting office shall ask OPRR to negotiate an Assurance with the institution before an award is made. No award shall be made until the Assurance has been submitted by the institution, approved by OPRR, and the institution has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals in PHS-supported activities.

(c) Conduct of special reviews/site visits. Each awardee institution is subject to review at any time by PHS staff and advisors, which may include a site visit, to assess the adequacy of the institution’s compliance with this policy.

(d) Waiver. Institutions may request a waiver of a provision of this policy by submitting a request to OPRR. No waiver will be granted unless sufficient justification is provided, and the waiver is approved in writing by OPRR.

Subpart PHS 380.3—Acquisition of Drugs and Medical Supplies

PHS 380.301 Scope of subpart.

This subpart provides policies and procedures pertaining to the acquisition of drug products and medical supplies by PHS or PHS’s contractors.

PHS 380.302 Acquisition of drugs.

PHS 380.302-1 Policy.

(a) Drugs shall be acquired at the lowest possible price consistent with acceptable standards of identity, strength, quality, purity, safety and effectiveness, and with due regard for the welfare of the patient and the professional judgment of the prescriber.

(b) Contracting activities shall ensure that drugs are acquired by generic name on a competitive basis whenever it is possible to obtain therapeutically effective drugs of established quality. However, the professional judgment of the prescriber to request drugs by brand name or house designation must be recognized when the best interest of the patient requires it. Similarly, scientific investigators have the prerogative to request drugs having end-product characteristics considered necessary for the conduct of research or investigations.

(c) Prior to taking any acquisition action, the contracting officer shall ensure that the requested drug products are not available from mandatory sources such as Federal Supply Schedules. Part 103-26 of the HHS Material Management Manual describes sources of supply for drugs.

PHS 380.302-2 Solicitation and contract requirements.

The contracting officer should consider including statements similar to the following in solicitations and resultant contracts pertaining to drug products:

(a) The offeror (contractor) guarantees that all requirements established by the Food and Drug Administration, HHS, have been met. These requirements include: plant sanitation, manufacturing, packaging, labeling, identification, strength, quality, purity, safety, and effectiveness.

NOTE: The contracting officer may want to cite the applicable reference(s) pertaining to the FDA requirements.
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(b) The offeror (contractor), by signing this document, guarantees/warrants that any applicable shelf-life requirements have been met and the furnished drugs are free from defects.

c) The Government reserves the right to inspect the manufacturer’s plant and premises during normal operating hours.

NOTE: FDA will normally conduct the inspection when requested, but may request to be reimbursed for the services.

d) The offeror (contractor) agrees to submit either a comprehensive, certified analysis on each lot of drugs at the time of delivery of the drugs, or a comprehensive list of specifications met by the drugs along with a certificate of analysis, or other suitable documentation, verifying that the drugs meet the appropriate standards.

e) The offeror (contractor) claims it is not currently listed as a disqualified bidder or offeror for drugs by any Federal agency or department.

(f) The offeror must set forth full, accurate, and complete information as required by this solicitation (including attachments). The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

(g) If the offeror (prime contractor) plans to use (or uses) a subcontractor or secondary manufacturer for the furnishing of any or all the drug products under the resultant contract, the name and address of the subcontractor or secondary manufacturer is to be furnished the contracting officer, along with the drug lots affected. The prime contractor shall ensure that the subcontractor or secondary manufacturer complies with the above stated requirements.

PHS 380.303 Acquisition of controlled drugs.

(a) Controlled drugs include narcotics and dangerous drugs identified by the Drug Enforcement Administration (DEA), Department of Justice, in the regulations implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Title 21 CFR Chapter II).

(b) The DEA issues a Controlled Substances Inventory List which provides general information pertaining to the ordering of controlled drug products and the use of specific order forms. The local DEA regional office should be contacted to receive the list and instructions regarding registering and ordering forms, as well as other matters concerning the handling and processing of controlled drugs. Sections 103-27.6204(a)(2) and 103-27.6302(b) of the HHS Material Management Manual provide information on issuing, shipping, and safeguarding controlled drugs.

(c) Contracting officers shall ensure that requests for contracts or purchase requests are supported by the required DEA form prior to initiation of any action.

PHS 380.304 Effectiveness of drug products.

PHS 380.304-1 General.

(a) The National Academy of Sciences National Research Council (NAS-NRC) has established effectiveness classifications for the indication of drug products, based upon the following criteria:

(1) Factual information that is freely available in scientific literature;

(2) Factual information that is available from the Food and Drug Administration, the manufacturer, or other sources; and

(3) Experience and informed judgment of the members of NAS-NRC panels.

(b) The indications mentioned in the following categories refer to “the effect the drug purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.” That is, the indications are the claims noted in the labeling of a given drug product.

(1) Category A—Effective. For the presented indication, the drug is effective on the basis of the criteria cited in PHS 380.304-1(a) above.

(2) Category B—Probably Effective. For the indication presented, effectiveness of the drug is probable on the basis of the criteria cited in PHS 380.304-1(a) but additional evidence is required before it can be assigned to Category A.

(3) Category C—Possibly Effective. In relation to the indication in question, there is little evidence of effectiveness under any of the criteria cited in PHS
380.304-1(a). The possibility that additional supporting evidence might be developed should not be ruled out, however.

(4) Category D—ineffective. In relation to the indication in question, there is no acceptable evidence under any of the criteria cited in PHS 380.304-1(a) to support a claim of effectiveness.

PHS 380.304-2 Policy.

(a) It is PHS policy to not acquire drug products classified "ineffective" or "possibly effective" for use in its direct care programs. However, there are two exceptions to this policy:

(1) Drug products categorized as "ineffective" and "possibly effective" may be acquired for use in the pursuit of approved clinical research products.

(2) Drug products categorized as "possibly effective" may be acquired when no alternate means of therapy with drug products in the "probably effective" or "effective" categories are available.

(b) This policy applies to similar drug products marketed by the same or other firms.

PHS 380.304-3 Procedures.

(a) The contracting officer, prior to initiating action on a purchase request or request for contract for drug products, shall ensure that the items are screened against current lists of products identified by the Pharmacy Liaison Officer, Public Health Service, to determine whether acquisition of the items is prohibited, and that the individual actually performing the screening has annotated and initialed the request.

(b) When the request is received for a drug product which is allowable under the exceptions stated in PHS 380.304-2, the contracting officer shall ensure that the appropriate justification is provided, that it is signed by the responsible program official, and that it is included in the contract or purchase request file.

(c) When the request for a restricted drug product cannot be resolved by the substitution of another item, the contracting officer shall consider the request as a deviation and process it in accordance with Subpart 301.4.

PHS 380.304-4 Distribution of information.

(a) The Pharmacy Liaison Officer, Public Health Service, has responsibility for distributing information on the effectiveness of drug products to the principal official responsible for acquisition. The principal official responsible for acquisition will be advised by telephone of drug products classified as "ineffective" or "possibly effective" prior to publication in the FEDERAL REGISTER, and will be provided a monthly list of these drug products following publication in the FEDERAL REGISTER.

(b) The principal official responsible for acquisition shall establish procedures for the distribution of information on the effectiveness of drug products and implement other controls necessary to assure compliance with the policy set forth in PHS 380.304-2.

PHS 380.305 Maximum allowable cost for drugs.

PHS 380.305-1 General.

(a) The regulation entitled "Limitation on Payment or Reimbursement for Drugs," also known as the Maximum Allowable Cost or MAC regulation, is set forth in Part 19 to Subtitle A of Title 45 of the Code of Federal Regulations.

(b) The MAC regulation established departmental policies and procedures for determining allowable drug costs and, where applicable, dispensing fees to be used to establish:

(1) Reimbursement to providers and health maintenance organizations under the Medicare program;

(2) Reimbursement to States under State administered health, welfare, and social service programs; and

(3) Allowable costs under projects for health services.

PHS 380.305-2 Applicability.

(a) This regulation implements the MAC regulation by establishing acquisition procedures consistent with the purpose and intent of the MAC regulation.

(b) This regulation applies to the direct acquisition of drugs by PHS and the acquisition or supply of drugs by PHS contractors.
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(c) This regulation does not apply to the acquisition of drugs for research programs made by PHS and its contractors.

PHS 380.305–3 Responsibilities.

(a) The program office which initiates the requirement is responsible for advising the contracting office as to the applicability of the MAC regulation to the proposed acquisition.

(b) The Pharmacy Liaison Officer, PHS, is responsible for distributing to the principal official responsible for acquisition of the MAC determination or data concerning the acquisition cost of drugs. The MAC determination should be furnished within thirty days after publication as a final rule in the Federal Register. Acquisition cost data should be furnished within thirty days after the effective date.

(c) The principal official responsible for acquisition shall establish procedures for disseminating MAC determinations and acquisition cost data and may initiate other actions necessary to ensure compliance with the requirements of this regulation.

PHS 380.305–4 Solicitation notification.

(a) The contracting officer shall ensure that all requests for proposals and invitations for bids which are subject to the provisions of the MAC regulation contain a notice worded substantially as follows:

This acquisition is subject to the Maximum Allowable Cost (MAC) regulation set forth in part 19 to subtitle A of title 45 of the Code of Federal Regulations.

(b) The contracting officer shall include the applicable MAC determination or acquisition cost data in the RFP or IFB.

(c) The referenced solicitation notice, or a notice worded similarly to it, is required to be included in all applicable solicitations issued by the contractor or its subcontractors.

PHS 380.305–5 Contract requirements.

(a) The contracting officer shall include a clause entitled “Maximum Allowable Cost for Drugs,” reading substantially as the clause cited in PHS 352.280–3, in all contracts subject to the provisions of the MAC regulation.

(b) The contracting officer shall incorporate in all contracts subject to the provisions of the MAC regulation the applicable MAC determination or acquisition cost data furnished in the solicitation.

(c) The clause cited in PHS 352.280–3, or a clause worded substantially as that clause, is required to be included in all applicable contracts awarded by the contractor or its subcontractors.

PHS 380.306 Acquisition of tax free and specially denatured alcohol.

(a) All orders for tax free and specially denatured alcohol shall be placed with the HRSA Supply Service Center, Perry Point, MD. Orders shall be placed in accordance with the ordering instructions contained in the HRSA Medical Supply Catalog.

Subpart PHS 380.4—Contracts Under the Indian Self-Determination Act

PHS 380.400 Scope of subpart.

This subpart prescribes procedures for contracting by the Public Health Service (PHS) under the Indian Self-Determination Act (25 U.S.C. 450f).

PHS 380.401 Applicability of regulations.

Contracts with tribal organizations resulting from the submission of Indian Self-Determination Contract Proposals as authorized in Public Law 93–638 shall be in accordance with 41 CFR Chapters 1 and 3, except as otherwise provided herein. If this subpart conflicts with any of the other provisions of 41 CFR Chapters 1 or 3, the provisions of this subpart govern.

PHS 380.402 Waivers.

(a) The Secretary of Health and Human Services (HHS) waives Federal contract clauses that are normally contained in the General provisions of a contract to the extent that they are omitted from the General provisions prescribed for such contracts in this subpart.

(b) The Secretary may waive for the purpose of a specific contract other provisions of Federal contracting laws.
or regulations as determined not appropriate in view of, or are inconsistent with, the provisions of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.). Requests for such waivers shall be in accordance with 42 CFR 36.216.

(c) Although it is PHS’s policy to obtain competition whenever possible, any contract award to a tribal organization resulting from the submission of an Indian Self-Determination Contract Proposal will be effected without competition.

(d) Proposed contracts under section 103 of the Indian Self-Determination Act are exempted from the synopsis requirements of 41 CFR 1–1.1003. Although subcontracts are subject under section 7(b) of that act to a preference to Indian organizations and to Indian-owned economic enterprises, opportunities to so subcontract may be published by contracting officers as provided for in 41 CFR 1–1.1003–4.

PHS 380.403 Negotiating authority.

Contracts entered into pursuant to section 103 of the Indian Self-Determination Act (25 U.S.C. 450g) will cite as the negotiating authority 41 U.S.C. 252(c)(15) and 25 U.S.C. 450g.

PHS 380.404 Definitions.

The definitions prescribed in 42 CFR 36.204 are applicable to this subpart.

PHS 380.405 Types of contracts.

(a) Cost-reimbursement contracts will be used for all contracts made pursuant to this subpart between PHS and an Indian tribe or tribal organization. In addition to other provisions as the Secretary may from time to time require, the cost-reimbursement contracts shall contain the terms set out in PHS 352.280–4(a).

(b) Fixed-price contracts may be used in only those instances where costs can be precisely established. In addition to other provisions as the Secretary may from time to time require, the fixed-price contracts shall contain the terms set out in PHS 352.280–4(b).

(c) Cost sharing contracts may be used where the tribe contributes to the cost of a program and may specify a percentage of cost or fixed amount to be funded by the Government.

PHS 380.406 Term of contract.

(a) The term of contracts awarded under the Act shall not exceed one year except that contracts may be made for a longer term up to three years subject to the availability of appropriations under the following circumstances:

(1) The services provided under the contract can reasonably be expected to be continuing in nature and, as a result, a longer contract term would be advantageous.

(2) The Indian tribe or tribes to be served by the contract request that the term be more than one year. The tribal organizational will indicate the desired term of the contract in the Self-Determination Contract Proposal.

(b) Contract made for a term of more than one year may be renegotiated annually to reflect factors which include, but need not be limited to, cost increases beyond the control of the tribal contractor. Proposed changes in the services provided under the contract which reflect changes in program emphasis may be considered during the annual renegotiation if the changes fall within the general scope of the contract.

PHS 380.407 Exemption from bonds.

A tribal organization is not required to furnish performance and payment bonds before carrying out a contract under this subpart for the construction of public buildings or works as required by the Miller Act of August 24, 1935 (49 Stat. 793), as amended. However, the tribal organization shall require each of its subcontractors other than tribal organizations, to furnish both performance and payment bonds as follows:

(a) A performance bond with a surety or sureties satisfactory to the approving official, and in an amount he/she deems adequate, for the protection of the United States.

(b) A payment bond with a surety or sureties satisfactory to the approving official for the protection of all persons supplying labor and material in the prosecution of the work provided for in the contract. Whenever the total amount payable by the terms of the contract is not more than $1,000,000, the payment bond shall be one-half the total amount payable by the terms of the contract. Whenever the total
amount payable by the terms of the contract is more than $1,000,000 but not more than $5,000,000, the payment bond shall be 40 percent of the total amount payable by the terms of the contract. Whenever the total amount payable by the terms of the contract is more than $5,000,000, the payment bond shall be $2,500,000.

PHS 380.408 Acquisition of construction and architect-engineering service contracts.

(a) This section sets forth procedures and requirements peculiar to construction and architect-engineering service contracts. The terms and conditions of these contracts when negotiated with an Indian tribe or tribal organization pursuant to the Act shall, to the extent applicable, be in accordance with the requirements set forth in 41 CFR Part 1-18 and Subpart 1-4.10. However, if there is a conflict between 41 CFR Part 1-18 and Subpart 1-4.10, and any provision of the Act or 42 CFR Part 36, the Act or 42 CFR Part 36 shall govern. In addition these contracts shall include the special provisions identified in PHS 380.410.

(b) Exceptions. (1) Subpart 1-18.10 of this title is not applicable.

(2) The contract clauses required by 1-18.703-1 of this title shall be inserted in construction contracts with an Indian tribe or tribal organization which serves as a governmental instrumentality of an Indian tribe, but shall be prefaced by the provision contained in 1-18.702-3 of this title.

(3) In all cases, the contracting officer shall obtain and insert the Wage Determination Decision issued by the Secretary of Labor in the contract prior to award of any contract for construction that falls within the purview of the Davis-Bacon Act. The Wage Determination Decision should be furnished sufficiently in advance of the contract award date to permit full consideration by the tribal organization and any prospective subcontractors.

PHS 380.409 Performance of personal services.

Any contract made under this subpart may include provisions for the performance of personal services which would otherwise be performed by Federal employees. Such services include, but are not limited to, performing the following functions in connection with the contract and applicable rules and regulations:

(a) Determining the eligibility of applicants for assistance, benefits, or services.

(b) Determining the extent or amount of assistance, benefits, or services to be provided.

(c) Providing such assistance, benefits, or services.

PHS 380.410 Special provisions of Indian Self-Determination contracts.

Contracts entered into pursuant to Section 103 of the Indian Self-Determination Act must incorporate special clauses which are consistent with those prescribed in Subpart I of Part 36 of 42 CFR on the following subjects:

(a) Fair and equal treatment of Indian people.

(b) Use of Indian business concerns.

(c) Indian preference in training and employment.

(d) Indemnity and insurance.

(e) Reports to the Indian people.

(f) Penalties.

(g) Retrocession.

(h) Assumption and reassertion of contract programs.

PHS 380.411 General provisions.

General provisions are published in these regulations (see PHS 352.280-4 for text of clauses) in order to respond to the expressed desire of the Indian people, to have published in one place, all of the terms and conditions applicable to contracts awarded under the Act. These general provisions incorporate the special clauses whose titles are listed in PHS 380.410, above, as well as applicable standard contract clauses.

Subpart PHS 380.5—Acquisitions Under the Buy Indian Act

PHS 380.500 Scope of subpart.

This subpart sets forth the policy on preferential acquisition from Indians under the negotiation authority of the Bay 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.
PHS 380.501 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 was enacted as a proviso to Section 23 of the Act of June 25, 1910, Chapter 431, Pub. L. 313, 61st Congress, 36 Stat. 861, and 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 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 were transferred to the Secretary of Health, Education, and Welfare, on July 1, 1955 by Pub. L. 568, 83rd Congress, 42 U.S.C. 2001 et seq. 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 Pub. L. 94-437 and Pub. L. 96-537.

PHS 380.502 Definitions.

PHS 380.502-1 Indian.

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 such determinations may take into account the determination of the tribe with which affiliation is claimed.

PHS 380.502-2 Indian firm.

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 Pub. L. 94-437, former or currently federally recognized Indian tribes in the State of New York) or by an Indian firm; or a non-profit firm organized for the benefit of Indians and controlled by Indians (see PHS 380.503(a)).

PHS 380.502-3 Product of Indian industry.

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.

PHS 380.502-4 Buy Indian contract.

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)(15) and 25 U.S.C. 47 between an Indian firm and a contracting officer representing the Indian Health Service.

PHS 380.502-5 Buy Indian restricted advertising.

Buy Indian restricted advertising is a special method of negotiated acquisition conducted in the same manner as a formally advertised acquisition, except that competition and award are restricted to Indian firms (see FAR 19.101). Thus, a Buy Indian acquisition may be considered an acquisition set-aside for Indian firms in the manner that some acquisitions are set-aside for small business concerns (see FAR 19.101). Set-aside acquisitions are, technically, negotiated acquisitions but should be conducted as if they were formally advertised acquisitions in instances where the formal advertising method would be used if the set-aside was not in effect.
Appendix A—Public Health Service

PHS 380.503 Requirements.

(a) Indian ownership. The degree of ownership that is called for by PHS 380.502-2 shall be 100 percent during the period covered by a Buy Indian contract unless a deviation from that 100 percent requirement is approved on an individual basis by the cognizant Area or Program Office Director of the Indian Health Service. Such a deviation, which may be to not less than 51 percent, must be accompanied by an appropriate justification for the deviation.

(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) and Part 28 of the Federal Acquisition Regulation (48 CFR Ch. 1). 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 (Pub. L. 93-383), which requires that preference be given to Indians in employment, training, and subcontracting. Subpart 370.2 and the contract clauses in 352.270-2 and 352.270-3 represent the Department’s implementation of section 7(b). 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-5) 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 members 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.

PHS 380.504 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, pursuant to FAR 14.101 and FAR 15.105. When competition is determined not to be practicable, a justification for Noncompetitive Acquisition shall be prepared in accordance with 315.7105 and subsequently retained in the contract file.

(b) Notwithstanding the provisions of Subpart 315.71, a request for approval of noncompetitive acquisitions to be negotiated under the Buy Indian Act may, if $25,000 or less, be approved by
PHS 380.505  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 such a contract and that the project or function is likely to be properly completed or maintained under that contract.

(b) The determination called for by paragraph (a), 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 F.A.R. 9.104-1, 309.104-1 of this chapter and PHS 380.502-2.

(c) Solicitations must be synopsized and publicized in the Commerce Business Daily (see F.A.R. 5.2 and Subpart 305.2) 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.