

for Transplantation" (62 FR 40429, July 29, 1997). FDA announced a plan for a new approach to regulate cells and tissue-based products in February 1997 with two documents: "Reinventing the Regulation of Human Tissue" and "A Proposed Approach to the Regulation of Cellular and Tissue-Based Products." FDA requested written comments on the proposed approach and on March 17, 1997, held a public meeting to solicit information and views from the interested public (62 FR 9721, March 4, 1997). FDA is implementing its regulatory plan for human cellular and tissue-based products with publication of a series of proposed regulations. On May 14, 1998, FDA published a proposed regulation entitled "Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products" (63 FR 26744). On September 30, 1999, FDA published a proposed rule entitled "Suitability Determination for Donors of Human Cellular and Tissue-Based Products" (64 FR 52696). The comment period for the 1999 proposed rule was reopened on April 18, 2000 (65 FR 20774), and will close on July 17, 2000.

The proposed rule for establishment registration and listing also proposed criteria that human cellular and tissue-based products must meet for regulation solely under section 361 of the Public Health Service Act. One of the criteria is that these products be "minimally manipulated." "Minimal manipulation" is defined in proposed § 1271.3(g) for structural tissue, as processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement. Another criterion, "homologous use," is defined in proposed § 1271.3(d). "Homologous use" means the use of a cellular or tissue-based product for replacement or supplementation or for structural tissue-based products, used for the same basic function that it fulfills in its native state, in a location where such structural function normally occurs. FDA has received numerous comments to the dockets of both proposed rules (Docket Nos. 97N-484R and 97N-484S) about the application of the definitions for minimal manipulation and homologous use in the regulation of human allograft bone products. Many of these comments request that FDA clarify how these definitions will be applied to bone products that are preshaped for use in spinal fixation. Other comments cite the long history of safe use of bone products.

This public meeting is being organized by CBER and CDRH to provide stakeholders with the

opportunity to provide additional information to the agency. The agency is requesting information concerning the characteristics of various bone products as they relate to the agency's proposed definitions for "minimal manipulation" and "homologous use." Such information will be considered for future guidance to industry in conjunction with the regulations discussed above. Stakeholders are encouraged to provide information about the following issues:

1. Which processing procedures applied to human bone allograft fall within, or outside of, FDA's proposed definition for "minimal manipulation?"
2. Which uses of human bone allograft fall within, or outside of, FDA's proposed definition for "homologous use?"
3. What risks to health have been identified and characterized for human bone allograft products?
4. What controls have been identified to adequately address the risk to health of human bone allograft products?
5. What industry standards for bone allograft products are available, and what standards will be needed in the future?

## II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments by September 1, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the appropriate docket number found in brackets in the heading of this document. FDA is requesting that those persons making oral presentations at the public meeting also submit in writing comments based on their statements by September 1, 2000, to ensure their adequate consideration. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Registration and Requests for Oral Presentations

Those persons interested in attending the public meeting should fax or e-mail their registration information (including name, title, firm name, address, and telephone and fax numbers), a summary of their presentation, and a notice of intent to make an oral presentation, to Kathy Eberhart (address above) by Monday, July 24, 2000. Registration is not required for attendees not making a presentation. However, all interested persons are encouraged to preregister because space is limited. An announcement of the public meeting and the notice of intent to participate

may be accessed at <http://www.fda.gov/cber/scireg/htm>. FDA will post a draft agenda on this web site about a week before the meeting.

If time permits, those who did not submit a notice of participation will be given an opportunity to speak at the end of the meeting.

If you need special accommodations due to a disability, please contact Kathy Eberhart at least 7 days in advance.

## IV. Transcripts

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript will also be available at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: July 10, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 00-17942 Filed 7-17-00; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### 23 CFR Part 172

[FHWA Docket No. FHWA-98-4350]

RIN 2125-AE45

#### Administration of Engineering and Design Related Services Contracts

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM); request for comments.

**SUMMARY:** The FHWA proposes to revise its regulation on the administration of engineering and design related services contracts in order to establish procedures to be followed when using Federal-aid highway funds for the procurement of engineering and design related services, materials, equipment, or supplies. The proposed regulation describes procurement methods contracting agencies are to use when acquiring these services or related items. This proposed rule implements 23 U.S.C. 112(b), as amended by section 307 of the National Highway System Designation Act of 1995 (NHS Act) and section 1205(a) of the Transportation Equity Act for the 21st Century (TEA-21), by requiring States to award Federal-aid highway engineering and design service contracts: In accordance

with the provisions of title IX of the Federal Property and Administrative Services Act of 1949, or by use of equivalent State qualifications-based procedures unless a State has previously established by statute a formal procurement procedure for engineering and design related services.

**DATES:** Written comments are due on or before September 18, 2000. Comments received after that date will be considered to the extent practicable.

**ADDRESSES:** Signed written comments should refer to the docket number that appears at the top of this document and should be submitted to the Docket Clerk, U.S. DOT Dockets Room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001. All comments received will be available for examination at the above address between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notifications of receipt of comments must include a self-addressed, stamped envelope or postcard.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gary E. Moss, Office of Program Administration, (HIPA-10), (202)-366-4654, or Mr. Steven Rochlis, Office of the Chief Counsel, (HCC-30), (202)-366-1395, FHWA, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m. e.t., Monday through Friday, except Federal holidays.

#### **SUPPLEMENTARY INFORMATION:**

##### **Electronic Access**

Internet users may access all comments received by the U.S. DOT Dockets, Room PL-401, by using the universal resources locator (URL): <http://dms.dot.gov>. It is available 24 hours each day, 365 days each year. Please follow instructions online for more information and help.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may reach the Office of the Federal Register's home page at <http://www.nara.gov/fedreg> and at the Government Printing Office's web page at <http://www.access.gpo.gov/nara>.

##### **Background**

The FHWA's regulation on the administration of engineering and design related services contracts, 23 CFR part 172, draws its authority from 23 U.S.C. 112. Title 23, U.S.C., section 112 references the provisions of title IX of the Federal Property and Administrative Services Act of 1949

(Pub. L. 92-582, 86 Stat. 1278 (1972); 40 U.S.C. 541, *et seq.*) which provides the qualifications-based procedures to be followed for the selection of engineering and design related services. Section 307 of the NHS Act, Public Law 104-59, 109 Stat. 568, modified 23 U.S.C. 112 by requiring grantees of Federal highway funds to accept indirect cost rates for architectural and engineering firms which are established in accordance with the Federal Acquisition Regulations (FAR) and accepted by a cognizant Federal or State agency if such rates are not under dispute. The law also specifies that once a firm's indirect cost rate is accepted, the grantee shall apply those indirect cost rates for the purposes of contract estimation, negotiation, administration, reporting, and contract payment. The NHS Act also provided a period of time in which State Departments of Transportation (State DOTs) could adopt statutes to allow use of alternate State procedures other than those provided for in the NHS Act.

Section 1205 of TEA-21, Public Law 105-178, 112 Stat. 107 (1998), further modified 23 U.S.C. 112(b) by removing the provision allowing State DOTs to adopt alternate procedures for the procurement of design and engineering consultants.

The changes made to 23 U.S.C. 112(b) by these two laws, as well as provisions in 23 U.S.C. 106(c) relating to the assumption by the State of responsibilities of the Secretary for project design and construction, require the FHWA to modify 23 CFR part 172, subpart A—Procurement Procedures. In addition, the FHWA proposes to add several new terms to the definition section to clarify existing terms used in the regulation.

The small purchase procedures section would be revised by raising the maximum value for small purchases from \$25,000 to \$100,000.

The references to Certification Acceptance (CA), and § 172.15, Alternate Procedures, which were incorporated into 23 CFR part 172 to implement Certification Acceptance, would be removed since Certification Acceptance was repealed by section 1601 of the TEA-21.

Reference to the Secondary Road Plan (SRP) and the Combined Road Plan (CRP) demonstration project, would be removed since these programs are no longer being funded.

#### **Section-by-Section Analysis**

##### *Section 172.1 Purpose and Applicability*

The statement of purpose and applicability would be revised to remove the references to the Certification Acceptance Plans that were repealed by the TEA-21; to remove an obsolete reference to the Secondary Road Plans; and to remove the reference to Combined Road Plans because the Secondary and Combined Road programs are no longer being funded. Additionally, paragraph (b) would be revised to limit the use of State statutes for an alternate procedure to those enacted into law before June 9, 1998 (the date the TEA-21 was enacted) and redesignated as § 172.5(b).

##### *Section 172.3 Definitions*

The term "cognizant agency" would be added to the list of definitions to mean any Federal or State agency that has conducted and issued an audit report of the consultant's indirect cost rate that has been developed in accordance with the cost principles contained in the Federal Acquisition Regulations (title 48, Code of Federal Regulations). This term was used in section 307(a) of the NHS Act. The term "competitive negotiation" would be revised to prohibit the use of procurement procedures enacted into State law after the enactment of TEA-21 (June 9, 1998). The terms "contract modification," "extra work," "fixed fee," "prenegotiation audit," and "scope of work" would be removed since they would not be used in the new regulation.

##### *Section 172.5 General Principles*

This section, with the exception of paragraphs (b) and (e) would be removed. The material that was covered in § 172.5 is either covered by other regulations or is not required by law. The provisions of paragraph (a) need for consultant services in management roles are still required to be consistent with 49 CFR 18.36(a) which requires States to use the same procurement procedures as if they were procuring with State funds, except where such procedures are inconsistent with Federal statute requirements (see 49 CFR 18.4). In addition, States would still have to meet the provisions of 23 U.S.C. 112(b)(2) that require a State to award architectural and engineering contracts relating to highway construction in the same manner as a contract for architectural and engineering services is negotiated under the Brooks Architects-Engineering Act (title IX of the Federal Property and Administrative Services

Act of 1949, as amended; 40 U.S.C 541–544), or equivalent State based qualifications requirements. Alternatively, prior to TEA–21, the Congress authorized a State to adopt a formal procedure for procurement of architectural and engineering services adopted by State statute (23 U.S.C. 112(b)(2)(B)(ii)).

Paragraph (b), written procedures, would be redesignated as § 172.9(a).

The provisions of paragraph (c) are still required to be consistent with 49 CFR 18.36(a) which requires States to use the same procurement procedures as if they were procuring with State funds, except where such procedures are inconsistent with Federal statutory requirements (see 49 CFR 18.4).

The provisions of paragraph (d) are still required to be consistent with 49 CFR 18.36 and 18.37, except where such procedures are inconsistent with Federal statutory requirements (see 49 CFR 18.4). But, as stated in the comments for § 172.5(a), State and local agencies must meet the requirements of 23 U.S.C. 112(b)(2).

The requirements of paragraph (e), the Disadvantaged Business Enterprise program, are specified under 49 CFR part 26. Paragraph (e), is redesignated as paragraph (b).

The requirements of paragraph (f), Contractual responsibilities, are still required to be consistent with 49 CFR 18.36(a) which requires States to use the same procurement procedures as if they were procuring with State funds, except where such procedures are inconsistent with Federal statutory requirements (see 49 CFR 18.4). Because States would be responsible for approving contracts and settlements, provided such contracts and settlements follow the same policies and procedures as the State would follow using State funds, there would no longer be a requirement that such settlements be approved by the FHWA, except for settlements on contracts requiring approval under proposal § 172.9.

#### *Section 172.7 Methods of Procurement*

This section would be redesignated as § 172.5 and revised. This section generally covers the methods that can be used for procurement of design engineering services. Those same methods are still in the regulations, but have been simplified. The small purchase section would be revised by raising the maximum amount for procurement by small purchase procedures from \$25,000 to \$100,000 to conform to the simplified acquisition threshold set in 41 U.S.C. 403(11) and 49 CFR 18.36(d). The threshold has already been raised from \$25,000 to

\$100,000 by FHWA memorandum dated June 26, 1996, from the Director, Office of Engineering to the FHWA Regional Administrators to implement the change in the final rule published in the **Federal Register** of April 19, 1995 (60 FR 19646) concerning 49 CFR part 18 and the change to 41 U.S.C. 403(11), which defines the “simplified acquisition threshold” to mean \$100,000.

#### *Section 172.9 Compensation*

The information in paragraph (a) of this section would be transferred to a new paragraph (a) in § 172.7, Audit Principles, and revised to prohibit procedures enacted into State law after June 9, 1998 (TEA–21). Paragraphs (b), (c), and (d) would be removed.

#### *Section 172.11 Contract Modification*

This section would be removed to promote uniformity with the common grant rule, 49 CFR part 18. The requirements of this section would in general be addressed by 49 CFR 18.36 and 18.52.

#### *Section 172.13 Monitoring the Contract Work*

This section would be removed to promote uniformity with the common grant rule, 49 CFR part 18. The requirements of this section would be covered by 49 CFR 18.36 which generally involve State procedures.

#### *Section 172.15 Alternate Procedures*

This section would be removed as it implemented 23 U.S.C. 117, Certification Acceptance, which was repealed by section 1601 of the TEA–21 in 1998.

#### *Sections 172.21, 172.23, and 172.25 of Subpart B*

Subpart B, Private sector involvement program, would be removed. This section was developed to meet the requirements of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Public Law 102–240, 105 Stat. 1914, section 1060, Private sector involvement program, but has never been funded.

For ease of reference the following distribution table is provided:

Old section	New section
172.1(a) .....	172.1 Revised.
172.1(b) .....	172.1 Revised and 172.5(b) Revised.
172.3 .....	172.3 Revised.
Cognizant agency .....	Added.
Competitive negotiation.	Revised.
Contract modification	Removed.
Extra work .....	Removed.

Old section	New section
Fixed fee .....	Removed.
Pre negotiation audit ..	Removed.
Scope of work .....	Removed.
172.5(a) .....	Removed.
172.5(b) .....	172.9(a).
172.5(c) .....	Removed.
172.5(d) .....	Removed.
172.5(e) .....	172.5(b) Revised.
172.5(f) .....	Removed.
172.7 introductory paragraph.	172.5 introductory paragraph revised and 172.5(a)(1) Revised.
172.7(a) .....	172.5(a)(1) Revised.
172.7(a)(3)(ii)(B) .....	172.5(a)(2) Revised.
172.7(b) .....	172.5(a)(4) Revised.
172.7(c) .....	172.5(a)(3) Revised.
172.7(c)(1) .....	172.5(a)(3) Revised.
172.7(c)(1)(i) .....	172.5(a)(3)(i) Revised.
172.7(c)(1)(ii) .....	172.5(a)(3)(ii) Revised.
172.7(c)(1)(iii) .....	172.5(a)(3)(iii) Revised.
172.7(c)(2) .....	Removed.
None .....	172.7(b) Added.
None .....	172.7(c) Added.
None .....	172.7(d) Added.
72.9(a) .....	172.7(a) Revised.
172.9(b), (c), and (d)	Removed.
None .....	172.9(a), (b), (c) Added.
172.11 .....	Removed.
172.13 .....	Removed.
172.15 .....	Removed.
172 Subpart B .....	Removed.
172.21 .....	Removed.
172.23 .....	Removed.
172.25 .....	Removed.

#### **Rulemaking Analysis and Notices**

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable, but the FHWA may issue a final rule at any time after the close of the comment period. In addition to the late comments, the FHWA will also continue to file relevant information in the docket as it becomes available after the comment closing date, and interested persons should continue to examine the docket for new material.

#### **Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures**

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of the U.S. Department of Transportation's regulatory policies and procedures. This proposed action would

not adversely affect, in a material way, any sector of the economy. In addition, these proposed changes would not interfere with any action taken or planned by another agency and would not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. This rulemaking merely proposes to amend current regulations governing the administration of engineering and design related services contracts based on changes in law. It is not anticipated that these proposed changes would affect the total Federal funding available under the engineering and design related services contracts. Consequently, it is anticipated that the economic impact of this rulemaking would be minimal; therefore, a full regulatory evaluation is not required.

#### **Regulatory Flexibility Act**

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the anticipated effects of this proposed rule on small entities, such as local governments and businesses. Based on the evaluation, the FHWA hereby certifies that this proposed action would not have a significant economic impact on a substantial number of small entities.

Essentially, this rulemaking proposes to implement certain changes in 23 U.S.C. 112 as mandated by recent laws. The rulemaking would eliminate sections that were removed by the recent laws and other sections that were not required directly by law or that were outdated. Thus, the projected impact upon the small entities affected is expected to be negligible because the FHWA merely proposes to update, simplify, and clarify existing procedures. We specifically invite comments on the projected economic impact of this proposal and would consider such information before completing our Regulatory Flexibility Act analysis when adopting final rules.

#### **Unfunded Mandates Reform Act of 1995**

This proposed rule will not impose a Federal mandate resulting in the expenditure by State, Local, and tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (2 U.S.C. 1531 *et seq.*).

#### **Executive Order 13132 (Federalism)**

The proposed action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999, and it has been determined that this proposed action does not have a substantial direct effect or sufficient

federalism implications on States that would limit the policymaking discretion of the States. Nothing in this document directly preempts any State Law or regulation.

#### **Executive Order 12372 (Intergovernmental Review)**

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

#### **Paperwork Reduction Act**

This proposed action does not contain a collection of information requirement for the purpose of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

#### **National Environmental Policy Act**

The agency has analyzed this proposed action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) and has determined that this action would not have any effect on the quality of the environment.

#### **Executive Order 12630 (Taking of Private Property)**

This proposed rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

#### **Executive Order 12988 (Civil Justice Reform)**

This proposed action meets applicable standards in section 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

#### **Executive Order 13045 (Protection of Children)**

We have analyzed this proposed action under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

#### **Regulation Identification Number**

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory

Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

#### **List of Subjects in 23 CFR Part 172**

Government procurement, Grant programs—transportation, Highways and roads.

Issued on: June 26, 2000.

**Kenneth R. Wykle,**

*Federal Highway Administrator.*

In consideration of the foregoing, the FHWA proposes to revise part 172 of title 23, Code of Federal Regulations to read as set forth below:

### **PART 172—ADMINISTRATION OF ENGINEERING AND DESIGN RELATED SERVICE CONTRACTS**

Sec.

- 172.1 Purpose and applicability.
- 172.3 Definitions.
- 172.5 Methods of procurement.
- 172.7 Audit principles.
- 172.9 Approvals.

**Authority:** 23 U.S.C. 112, 114(a), 302, 315, and 402; 40 U.S.C. 541 *et seq.*; 41 U.S.C. 253 and 259; sec. 1205(a), Pub. L. 105–178, 112 Stat. 107 (1998); sec. 307, Pub. L. 104–59, 109 Stat. 568 (1995); sec. 1060, Pub. L. 102–240, 105 Stat. 1914, 2003 (1991); 48 CFR 12 and 31; 49 CFR 1.48(b) and 18.

#### **§ 172.1 Purpose and applicability.**

To prescribe policies and procedures for exceptions to the general contracting regulations under the common grant rule, 49 CFR part 18. It is not the intent of this regulation to release the grantee from the other requirements of the common rule. The exceptions involve federally funded contracts for engineering and design related services for projects subject to the provisions of 23 U.S.C. 112(a) and are issued to ensure that a qualified consultant is obtained through an equitable selection process, that prescribed work is properly accomplished in a timely manner, and at fair and reasonable cost.

#### **§ 172.3 Definitions.**

As used in this part:

*Cognizant agency* means any Federal or State agency that has conducted and issued an audit report of the consultant's indirect cost rate that has been developed in accordance with the cost principles contained in the Federal Acquisition Regulations (FAR).

*Competitive negotiation* means any form of negotiations that utilizes the following:

- (1) Qualifications-based procedures complying with title IX of the Federal Property and Administrative Services

Act of 1949 (Pub. L. 92-582, 86 Stat. 1278 (1972));

(2) Equivalent State qualifications-based procedures; or

(3) A formal procedure permitted by State statute that was enacted into State law prior to the enactment of Public Law 105-178 (TEA-21) on June 9, 1998.

*Consultant* means the individual or firm providing engineering and design related services as a party to the contract.

*Contracting agencies* means State Departments of Transportation (State DOTs) or local governmental agencies that are responsible for the procurement of engineering and design services.

*Engineering and design services* means program management, construction management, feasibility studies, preliminary engineering, design, engineering, surveying, mapping, or architectural related services with respect to a construction project subject to 23 U.S.C. 112(a).

*Private sector engineering and design firms* means any individual or private firm (including small business concerns and small businesses owned and controlled by socially and economically disadvantaged individuals as defined in 49 CFR part 26) contracting with a State to provide engineering and design services.

#### **§ 172.5 Methods of procurement.**

(a) *Procurement.* The procurement of Federal-aid highway contracts for program management, construction management, feasibility studies, preliminary engineering, design, engineering, surveying, mapping, and architectural related services as specified in 23 U.S.C. 112(b)(2) shall be evaluated and ranked by the contracting agency using one of the following procedures:

(1) *Competitive negotiation.* Contracting agencies shall use competitive negotiation for the procurement of engineering and design related services when Federal-aid highway funds are involved in the contract. These contracts shall use qualifications-based selection procedures in the same manner as a contract for architectural and engineering services is negotiated under title IX of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 541-544) or equivalent State qualifications-based requirements. The proposal solicitation (project, task, or service) process shall be by public announcement/advertisement or any other method that assures qualified in-State and out-of-State consultants/firms are given fair opportunity to be awarded the contract.

(2) *State statutory procedures.* States may procure engineering and design related services using a different selection procedure as long as these procedures are established in State statutes and the State statutes were enacted into law before June 9, 1998.

(3) *Noncompetitive negotiation.* Noncompetitive negotiation may be used to procure engineering and design related services on Federal-aid participating contracts when it is not feasible to award the contract using competitive negotiation or equivalent State qualifications-based procedures. Contracting agencies shall submit justification and receive approval from the FHWA before using this form of contracting. Circumstances under which a contract may be awarded by noncompetitive negotiation are limited to the following:

(i) The service is available only from a single source;

(ii) There is an emergency which will not permit the time necessary to conduct competitive negotiations; or

(iii) After solicitation of a number of sources responding is determined to be inadequate.

(4) *Small purchases.* Contracting agencies may use small purchase procedures for the procurement of engineering and design related services when the contract costs do not exceed \$100,000.

(b) *Disadvantaged Business Enterprise (DBE) program.* The contracting agency shall give consideration to DBE firms in the procurement of engineering and design related service contracts subject to 23 U.S.C. 112(b)(2) in accordance with 49 CFR part 26.

#### **§ 172.7 Audit principles.**

(a) *Performance of audits.* When contracts or subcontracts awarded in accordance with 23 U.S.C. 112(b)(2)(A) are audited, the audits shall comply with the cost principles contained in the Federal Acquisition Regulations provided at 48 CFR part 31. Other procedures may be used if permitted by State statutes that were enacted into law prior to June 9, 1998.

(b) *Audits for indirect cost rate.* Contracting agencies shall use the indirect cost rate established by a cognizant agency audit for the consultant, if such rates are not under dispute. The grantee shall apply these indirect cost rates for the purposes of contract estimation, negotiation, administration, reporting, and contract payment and the indirect cost rates shall not be limited by any administrative ceilings. The cost rates have a one-year applicability period. Other procedures may be used if permitted by State

statutes that were enacted into law prior to June 9, 1998.

(c) *Disputed audits.* When the indirect cost rate(s) as established by the cognizant audit in paragraph (b) of this section are in dispute, then the parties of any proposed new contract must negotiate a provisional indirect cost rate or perform an independent audit to establish a rate for the specific contract.

(d) *Prenotification; confidentiality of data.* Only the FHWA and recipients and sub-recipients of Federal-aid highway funds may share the audit information, provided that the firm is given notice of such use. Audit information shall not be provided to other firms or any other government agencies without the written permission of the affected firms, unless otherwise required by Federal law, regulation, or pursuant to court order.

#### **§ 172.9 Approvals.**

(a) *Written procedures.* The contracting agency shall prepare written procedures for each method of procurement it proposes to utilize. These procedures and all revisions shall be approved by the FHWA and describe, as appropriate to the particular method of procurement, each step used:

(1) In preparing a scope of work, evaluation factors and cost estimate for selecting a consultant,

(2) In soliciting proposals from prospective consultants,

(3) In the evaluation of proposals and the ranking/selection of a consultant,

(4) In negotiation of the reimbursement to be paid to the selected consultant,

(5) In monitoring the consultant's work and in preparing a consultant's performance evaluation when completed, and

(6) In determining the extent to which the consultant, who is responsible for the professional quality, technical accuracy, and coordination of services, may be reasonably liable for costs resulting from errors or deficiencies in design furnished under its contract.

(b) *Contracts.* Contracts and contract settlements involving design services for projects that have not been delegated to the State under 23 U.S.C. 106(c) or that do not fall under the small purchase procedures in § 172.5(a)(4) shall be submitted to the FHWA for approval.

(c) *Major projects.* Any contract, revision of a contract or settlement of a contract for design services for a project that is expected to fall under 23 U.S.C. 106(h) shall be submitted to the FHWA for approval.

[FR Doc. 00-17774 Filed 7-17-00; 8:45 am]

BILLING CODE 4910-22-P