

additive regulations to provide for the safe use of D&C Black No. 3 (bone black, subject to FDA batch certification) as a color additive in the following cosmetics: Eyeliner, eye shadow, mascara, and face powder.

DATES: Effective date confirmed: July 20, 2007.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1071.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of June 19, 2007 (72 FR 33664), FDA amended the color additive regulations to add § 74.2053 (21 CFR 74.2053) to provide for the safe use of D&C Black No. 3 as a color additive in the following cosmetics: Eyeliner, eye shadow, mascara, and face powder.

FDA gave interested persons until July 19, 2007, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the *Federal Register* of June 19, 2007, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (1410.10 of the FDA Staff Manual Guide), notice is given that no objections or requests for a hearing were filed in response to the June 19, 2007, final rule. Accordingly, the amendments issued thereby became effective July 20, 2007.

Dated: August 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 630, 635, and 636

[FHWA Docket No. FHWA-2006-22477]

RIN 2125-AF12

Design-Build Contracting

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is amending its regulations for design-build contracting as mandated by section 1503 of the "Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users" (SAFETEA-LU). This rule will allow State transportation departments or local transportation agencies to issue request-for-proposal documents, award contracts, and issue notices-to-proceed for preliminary design work prior to the conclusion of the National Environmental Policy Act (NEPA) process.

EFFECTIVE DATE: September 13, 2007.

FOR FURTHER INFORMATION CONTACT: For technical information: Mr. Gerald Yakowenko, Office of Program Administration (HIPA), (202) 366-1562. For legal information: Mr. Michael Harkins, Office of the Chief Counsel (HCC-30), (202) 366-4928, Federal Highway Administration, 1200 New Jersey Avenue, SE., 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

This document and all comments received by the DOT Dockets, Room PL-401, may be viewed through the Docket Management System (DMS) at <http://dms.dot.gov>. It is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of this Web site.

An electronic copy of this document may be downloaded from the *Federal Register's* home page at <http://www.archives.gov> and the Government Printing Office's Web page at <http://www.access.gpo.gov/nara>.

Background

Section 1503 of the SAFETEA-LU (Pub. L. 109-59; August 10, 2005, 119 Stat. 1144) revises the definition of a design-build "qualified project" (23 U.S.C. 112(b)(3)). This change removes a previous monetary threshold for design-build projects, thus eliminating the requirement to approve Federal-aid design-build projects exceeding certain dollar thresholds under Special Experimental Project No. 14 (SEP-14).¹ When appropriate, the FHWA will continue to make SEP-14 available for

projects that do not conform to the requirements of 23 CFR part 636.

Section 1503 also requires the Secretary of Transportation to make certain changes to the design-build regulations at 23 CFR part 636. Generally, section 1503 requires the Secretary to amend the design-build rule to permit a State transportation department to release requests for proposals and award design-build contracts prior to the completion of the NEPA process, but preclude a contractor from proceeding with final design or construction before NEPA is complete.

Notice of Proposed Rulemaking (NPRM)

The FHWA published a NPRM on May 25, 2006, (71 FR 30100) proposing certain changes to comply with section 1503 of SAFETEA-LU. All comments received in response to the NPRM have been considered in drafting this final rule. We received 36 comments. The commenters include: one private individual, one Federal agency, the Governor of the State of Indiana, 18 State departments of transportation (State DOTs), 3 local public agencies, 8 industry organizations, and 4 firms that provide engineering and construction services. We classified the American Association of State Highway and Transportation Officials (AASHTO) as a State DOT, because it represents State DOT interests. It is noted that the State DOTs of Idaho, Montana, North Dakota, and South Dakota submitted a combined comment. It is also noted that these State DOTs, as well as the Wyoming Department of Transportation, simply commented that they support the comments submitted by AASHTO. Additionally, an organization known as the E-470 Public Highway Authority simply commented that it supports the comments submitted by the Texas Department of Transportation (TxDOT). Lastly, the FHWA notes that the Southern California Association of Governments (SCAG) submitted its comments on the design-build NPRM to the docket for the FHWA's planning NPRM (Docket No. FHWA-2005-22986). The FHWA considered SCAG's comments along with all other comments submitted to the rulemaking docket for the design-build NPRM in developing this final rule.

General

The following discussion summarizes the major comments submitted to the docket by the commenters on the NPRM, notes where and why changes have been made to the rule, and, where relevant, states why particular recommendations or suggestions have

¹ Information concerning Special Experimental Project No. 14 (SEP-14), "Innovative Contracting Practices," is available on FHWA's home page: <http://www.fhwa.dot.gov>. Additional information may be obtained from the FHWA Division Administrator in each State.

not been incorporated into the final rule.

Analysis of NPRM Comments and FHWA Response by Section

Section 630.106 Authorization to proceed

The Virginia Department of Transportation (VDOT), Utah Department of Transportation (UDOT), TxDOT, Associated General Contractors (AGC) of America, Design-Build Institute of America (DBIA), and Bechtel Infrastructure Corporation (Bechtel) each commented on the changes proposed for this section. Bechtel commented that the project agreement for a design-build project should be executed prior to the completion of the NEPA process. The FHWA disagrees with this comment to the extent that Bechtel is requesting that the project agreement cover final design and physical construction. The execution of the project agreement for a project constitutes an obligation of Federal funds to the project, and the FHWA is precluded under 40 CFR 1508.18 and 23 CFR 771.109 and 771.113 from funding final design or physical construction. However, the FHWA agrees that project agreements may be executed for preliminary engineering, preliminary design, and other preconstruction activities for design-build projects. Accordingly, we have amended the final regulatory text in section 630.106(a)(3) to clarify that only project agreements for final design and physical construction must wait until the conclusion of the NEPA process.

AGC of America commented that there is no definition of preliminary engineering, while preliminary design is defined in section 636.103. Preliminary design is defined because the amendments to 23 U.S.C. 112(b)(3) in section 1503 of SAFETEA-LU make a distinction between preliminary design and final design. Under these amendments, a design-builder may proceed to conduct preliminary design, but not final design. There is nothing in the SAFETEA-LU amendments to preclude preliminary engineering, which generally consists of those activities necessary for the analysis of a project or project alternatives, including environmental impacts, as necessary to complete the NEPA process. As such, preliminary engineering may continue to be authorized prior to the completion of the NEPA process as it has been prior to the SAFETEA-LU amendments. Thus, the FHWA does not believe that a separate definition of preliminary engineering is necessary.

TxDOT, UDOT, and DBIA were each concerned that the language would preclude authorization for activities which may be carried out prior to the completion of the NEPA process other than preliminary engineering. Similarly, VDOT commented that the proposed regulatory change would preclude authorization for preconstruction activities that may not necessarily be preliminary engineering. The FHWA agrees with these comments and has amended the final regulation to include the term "preliminary design" as defined in section 636.103. It is not FHWA's intent to preclude Federal participation in preliminary engineering or other activities that can be carried out consistent with NEPA.

Section 635.112 Advertising for bids and proposals

Bechtel and the National Council for Public Private Partnerships (NCPPT) both commented on the proposed changes to this section. In general, both suggested that the FHWA should extend the FHWA's concurrence to the selection of the proposer and execute a project agreement. The FHWA disagrees with these comments. First, the FHWA cannot commit funds to a project before the NEPA process is complete. The execution of a project agreement for a design-build project would result in the obligation of Federal funds for the construction of the project prior to the completion of the NEPA process. Second, section 1503 of SAFETEA-LU amended 23 U.S.C. 112(b)(3) to expressly require the Secretary's concurrence prior to issuing a request for proposals (RFP), awarding a design-build contract, and issuing notices to proceed with preliminary design. Bechtel and NCPPT's comments would result in the Secretary only concurring in the RFP.

Section 635.309 Authorization

The FHWA is making a technical, conforming amendment to the regulation at section 635.309(p)(1). Specifically, the FHWA is deleting the parenthetical providing that the States' authority to advertise or release a request for proposals document may not be granted until the NEPA review process has been concluded. In place of the parenthetical, the FHWA has inserted the words "for final design and physical construction." This amendment is necessary to ensure that there is no confusion in the regulations concerning whether a request for proposals document may be released, or a design-build contract may be awarded, in accordance with 23 U.S.C. 112(b)(3)(D). However, this section

would continue to preclude project authorization for final design and physical construction of a design-build project until after the NEPA review process is complete.

The substance of this amendment, which is to allow the release of a request for proposals document prior to the completion of the NEPA process, was addressed in the NPRM. Specifically, the proposed changes to sections 635.112 and 636.109 both expressly dealt with the advertising and release of a request for proposals document for a design-build project prior to the conclusion of the NEPA process. Additionally, the decision to prohibit project authorization for the final design and physical construction of a design-build project were proposed in sections 630.106 and 636.109 of the NPRM.

Section 635.413 Guaranty and warranty clauses

Bechtel and NCPPT commented on the proposed amendments to this section. In general, Bechtel and NCPPT commented that this section should be revised to allow for additional warranties beyond the normal construction/contractor warranties of 1–2 years. The FHWA disagrees with these comments. The FHWA's funding authority is generally limited to participation in construction and preventive maintenance. The FHWA will authorize the use of Federal funding to procure a warranty, if the warranty is for a construction or preventative maintenance project. The proposed regulatory language does not preclude the contracting agency from procuring warranties for projects other than construction and preventative maintenance with its own funds.

Section 636.103 What are the definitions of terms used in this part?

We received several comments on the proposed definitions under this section in the NPRM. These comments are discussed under each respective definition below.

"Developer"

VDOT, UDOT, TxDOT, AASHTO, and DBIA each commented on the proposed definition of "developer." These comments generally stated that the distinction between developer and design-builder is unclear and that the definition duplicates the language in the proposed definition of public-private agreement. The FHWA agrees with these comments and has decided to strike the definition of developer from the final rule. Since the FHWA has struck the changes to 636.119, as discussed below,

the term developer no longer has any significance to the regulations.

“Final Design”

TxDOT, UDOT, Maryland State Highway Administration (MdSHA), Pennsylvania Department of Transportation (PennDOT), Missouri Department of Transportation (MoDOT), New Jersey Department of Transportation (NJDOT), Louisiana Department of Transportation and Development (LDOTD), Indiana Governor Mitch Daniels, AASHTO, AGC of America, DBIA, Jacobs Civil, Inc. (JCI), and the Nossaman, Guthner, Knox, and Elliott LLP law firm/The Ferguson Group LLC (Nossaman) each commented on this proposed definition. In general, the comments stated that the definition is too restrictive and that the definition should be limited to work directly associated with the preparation of final construction plans and detailed technical specifications. The comments arguing that the definition is too restrictive are based on the comments to the proposed definition of preliminary design, which are discussed below. As explained below, the proposed definition of preliminary design has been broadened in the final rule. Thus, the language in the definition of final design stating that final design includes any design activities following preliminary design has been retained and the language concerning any design activities not necessary to complete the NEPA process has been stricken. Moreover, since a number of commenters stated that final design includes work directly related to the preparation of final construction plans and detailed specifications, these activities have been expressly included in the definition of final design.

“Preliminary Design”

All of the commenters substantially commented on the proposed definition of “preliminary design.” Specifically, LDOTD, Georgia Department of Transportation (GDOT), Indiana Governor Mitch Daniels, NJDOT, MoDOT, PennDOT, Knik Arm Bridge and Toll Authority (KABATA), California Department of Transportation (Caltrans), VDOT, Ohio Department of Transportation (OhDOT), Oregon Department of Transportation (OrDOT), UDOT, Minnesota Department of Transportation (Mn/DOT), Florida Department of Transportation (FDOT), MdSHA, TxDOT, AASHTO, AGC of America, American Council of Engineering Companies (ACEC), NCPPP, Nossaman, Bechtel, Washington Group International (WGI), JCI, Michael T. McGuire, Professional Engineers in

California Government, and SCAG all commented on this proposed definition.

Michael T. McGuire commented that allowing a design-builder to proceed with preliminary design prior to NEPA is a conflict of interest. The FHWA disagrees with this comment. So long as the design-builder does not prepare the NEPA documents, the conflict of interest provision in the Council on Environmental Quality (CEQ) regulation, 40 CFR 1506.5(c), is met.

The Professional Engineers in California Government commented that they agreed with the proposed definition of “preliminary design.” All other commenters felt that the proposed definition is too narrow. In general, these commenters were concerned that the definition would exclude activities needed to comply with other environmental laws and omit activities that have been traditionally considered preliminary engineering, that do not materially affect the consideration of alternatives in the NEPA analysis, and that work to advance the design of the preferred alternative as permitted in 23 U.S.C. 139(f)(4)(D), which was added by section 6002 of SAFETEA-LU. Several commenters also listed specific activities that have traditionally been allowed to proceed during the NEPA review process. After considering these comments, the FHWA agrees that the proposed definition is too narrow. It is not the FHWA’s intent to preclude the States from conducting preliminary engineering and other pre-decisional project-related activities consistent with NEPA when a request for proposals is issued or design-build contract is awarded, prior to the completion of the NEPA process. Accordingly, the FHWA has revised the definition of preliminary design to mean activities undertaken to define the general project location and design concepts. The FHWA has also specified some general activities that may be conducted as preliminary design that typically do not compromise the objectivity of the NEPA process. These activities were specifically identified by VDOT, OhDOT, MdSHA, TxDOT, UDOT, AASHTO, DBIA, and Nossaman. The activities specified in this definition are not intended to be an exhaustive list of activities that may be considered preliminary design. However, any activity, regardless of its inclusion in the definition of preliminary design, must not materially affect the object consideration of alternatives in the NEPA review process.

“Public-Private Agreement”

UDOT, TxDOT, AASHTO, and DBIA each submitted comments on the

proposed definition of “public-private agreement.” In general, these comments stated that the definition is overly broad and makes the distinction between design-build contracts and public-private agreements unclear. The FHWA agrees with these comments and has adopted a modified version of the language suggested by UDOT, TxDOT, and DBIA to the definition of public-private agreement in the final rule.

“Qualified Project”

The AGC of Texas, NJDOT, and GDOT each commented on the proposed definition of “qualified project.” GDOT commented that it agrees with the definition. NJDOT asked whether FHWA approval is needed to award any design-build contract, even if it has limited scope and low total project cost. Pursuant to 23 CFR 636.109(c), FHWA approval is needed before awarding any design-build contract funded under title 23, United States Code. AGC of Texas commented that the regulation should retain the \$50 million general project and \$5 million Intelligent Transportation System (ITS) project thresholds in the final rule. Since Congress specifically amended 23 U.S.C. 112(b)(3)(C) in section 1503 of SAFETEA-LU to abolish these monetary thresholds, the FHWA does not believe that retaining them in the final rule is appropriate.

Section 636.106 Is the FHWA’s Special Experimental Project No. 14—“Innovative Contracting” (SEP-14) approval necessary for a design-build project?

MoDOT, PennDOT, and Mn/DOT each commented on the changes proposed for this section. MoDOT pointed out that the preamble to the NPRM mentioned a monetary threshold while the proposed regulation did not. To clarify this apparent inconsistency, the proposed regulation was intended to abolish the monetary threshold for SEP-14 approval. Since Congress amended 23 U.S.C.112 to eliminate the design-build contracting monetary thresholds, SEP-14 approval is no longer needed for design-build projects below a certain monetary threshold. After considering this comment, the FHWA has decided that it is not necessary to expressly include SEP-14 as part of the final regulations, since it appears that SEP-14 is no longer needed. However, SEP-14 will continue to be available on a case-by-case basis as new innovative approaches to delivering design-build projects are proposed.

PennDOT requested clarification that the reporting requirements are no longer necessary. To answer this question,

there are no reporting requirements contained in this final rule. Mn/DOT asked whether this rule replaces the SEP-15 program. The answer to the question is "no." SEP-15 continues to be available on a case-by-case basis consistent with the parameters of the program. (For more information, see 69 FR 59983, October 6, 2004.)

Section 636.107 May contracting agencies use geographic preference in Federal-aid design-build or public-private partnership projects?

TxDOT, UDOT, MoDOT, DBIA, and AGC of America each commented on the proposed changes to this section. AGC of America supports the prohibition on geographic preferences. MoDOT suggested deleting the parenthetical contained in the proposed language in order to avoid future misinterpretation that would exclude non-geographic based incentives. This section only applies to geographic preferences and the parenthetical is merely intended to clarify that all means of such preferences are prohibited. Thus, the FHWA has retained the parenthetical in the final language.

TxDOT, UDOT, and DBIA suggested eliminating the word "prohibit" and making other minor revisions because they felt that this language implies that the contract documents must affirmatively address these issues. The FHWA agrees with these comments and has revised the final rule to incorporate the suggested language.

Section 636.109 How does the NEPA process relate to the design-build procurement process?

There were several comments on the changes to this proposed section in the NPRM. These comments are discussed under each respective subsection below.

Section 636.109(a)

PennDOT, UDOT, TxDOT, DBIA, and WGI each commented on the proposed changes to section 636.109(a). WGI commented that it supports these changes. PennDOT commented that it needs clarification that the FHWA will grant concurrence to proceed with the activities outlined in section 636.109(a), so long as the conditions outlined in the proposed rule are met. The FHWA assumes that PennDOT's comments are based on the preamble to the NPRM, where the FHWA stated that contracting agencies need FHWA concurrence prior to proceeding with any of the activities specified in the proposed subsection. To clarify this issue, a contracting agency does not need FHWA concurrence to issue a request for qualifications at any point in the process. However, FHWA

concurrence for the other activities specified in this subsection is required. FHWA intends to concur with the activities outlined in section 636.109(a), (such as issuing an RFP, awarding a contract, proceeding with preliminary design, etc.), provided all applicable Federal requirements are met.

UDOT, TxDOT, and DBIA stated that some minor changes are needed in order to clarify the intent in the first paragraph under section 636.109 as well as section 636.109(a)(1). The FHWA agrees to add the language suggested by UDOT, TxDOT, and DBIA in section 636.109(a)(1) concerning the protection of contracting agencies in the first paragraph of section 636.109, but does not agree to strike the language concerning the protection of design-build proposers in the first paragraph. The FHWA believes that this section protects the interests of both contracting agencies and design-build proposers. Additionally, UDOT, TxDOT, and DBIA requested that language be added to clarify that a design-builder can proceed with final design and construction for projects that have already obtained final NEPA approval. An example to amplify these comments would be a project that is being conducted under a tiered NEPA analysis. At any given point, tier 2 NEPA approvals could be given at different times for any portions with independent utility and logical termini within the tier 1 NEPA document. The FHWA agrees with these comments and has added a new paragraph (6) to section 636.109(a) to clarify this issue.

Section 636.109(b)

MdSHA, FDOT, Mn/DOT, UDOT, VDOT, TxDOT, Caltrans, MoDOT, Indiana Governor Mitch Daniels, AASHTO, DBIA, ACEC, NCPPP, Bechtel, Wilbur Smith Associates, Nossaman, and the Environmental Protection Agency (EPA) each commented on proposed 636.109(b). First, UDOT, TxDOT, and DBIA commented that the language should be clarified to ensure that a design-builder can proceed with final design and construction on projects that have already obtained NEPA approval. The FHWA agrees that a design-builder should be allowed to proceed with such work on projects for which NEPA approval has been obtained and intends that design-builders be allowed to do so under these regulations. However, the FHWA does not believe that additional language is needed to clarify this intent.

Second, MdSHA, FDOT, Mn/DOT, UDOT, Indiana Governor Mitch Daniels, AASHTO, ACEC, NCPPP, and Nossaman each commented that the contracting agencies and design-

builders should be allowed to proceed with final design activities at risk. In general, States can proceed with final design activities under the design-bid-build method of contracting so long as those activities include no Federal funding and the State understands that its preferred alternative could ultimately be rejected by the FHWA. *See, e.g., Burkholder v. Wykle*, 268 F. Supp. 2d 835 (N.D. Ohio 2002). However, the amendment to 23 U.S.C. 112(b)(3)(D)(iii) in section 1503 of SAFETEA-LU expressly requires the design-build regulations to "preclude the design-build contractor from proceeding with final design or construction of any permanent improvement prior to the completion of the process of such section 102." In other words, Congress has directed that the regulations must preclude the design-build contractor from proceeding with either final design or construction. Therefore, the FHWA is unable to permit the design-builder to proceed with final design, regardless of whether these activities are funded by the FHWA, the State, or the contractor itself.

Third, FDOT, UDOT, TxDOT, VDOT, Caltrans, Indiana Governor Mitch Daniels, AASHTO, DBIA, and ACEC each commented on whether the design-builder is precluded from preparing the NEPA decision document or any NEPA document. In general, these comments pointed out an inconsistency between the preamble to the NPRM, which refers to NEPA documents, and the proposed regulatory text in sections 636.109(b)(4) and (5), which uses the term "NEPA decision document." To clarify this issue, the FHWA intends for the regulations to preclude a design-builder from preparing not only the NEPA decision documents (*i.e.* Categorical Exclusion (CE), Finding of No Significant Impact (FONSI), and Record of Decision (ROD)), but also the NEPA analysis documents (*i.e.* Environmental Assessment (EA) and Environmental Impact Statement (EIS)). The CEQ conflict of interest regulation at 40 CFR 1506.5(c) expressly prohibits a contractor, who has an interest in the outcome of the NEPA process, from preparing an EIS. Additionally, this regulation has also been applied to EAs. *See, e.g., Burkholder v. Peters*, 58 Fed. Appx. 94 (6th Cir. 2003). Thus, the final regulations at section 636.109(b)(6) and (7) have been amended to clarify that the design-builder is precluded from preparing all NEPA documents, rather than just the NEPA decision documents. However, while the design-builder cannot prepare the NEPA documents, the FHWA notes that there is nothing in

the final regulations that would prohibit a design-builder from financing the preparation of the NEPA documents, so long as the criteria in section 636.109(b)(7) are met.

Fourth, UDOT, TxDOT, and DBIA suggested some minor clarifications to proposed section 636.109(b)(6) to ensure that the States can consider any work provided by the design-builder in the NEPA analysis. The FHWA agrees with these comments and has revised section 636.109(b)(8) to incorporate UDOT, TxDOT, and DBIA's suggested language.

Fifth, Wilbur Smith Associates commented that barring consultants who are participating in the preparation of the NEPA documents from joining a design-build team will result in less economical projects. Although the FHWA appreciates eliminating unnecessary costs, FHWA notes that the CEQ regulations at 40 CFR 1506.5(c) prohibit such consultants from having a financial or other interest in the outcome of the project to avoid either the reality or the appearance of a conflict, thereby maintaining the credibility of the environmental review process. Sixth, the EPA had several general comments on section 636.109(b). The EPA states that it is supportive of the provisions in the proposed rule intended to ensure an adequate review process and supports the prohibition on the design-builder from having any decisionmaking responsibility on the NEPA process. The EPA further commented that avoiding conflicts of interest and premature commitments to a particular alternative are difficult to ensure in practice. As such, the EPA suggested that the FHWA provide examples of appropriate contract provisions that would ensure that the merits of all alternatives are evaluated. An example of one such provision would be one precluding the commitment of significant financial resources to any particular alternative. Another example would be a provision that clearly allows the State to decide not to move forward with the project in the event the no-build alternative is selected, while allowing the design-build contractor to receive a reasonable reimbursement of certain costs the contractor may have incurred in advancing the project. The FHWA is committed to work with the States to develop any such provisions to also ensure the integrity of the NEPA process is maintained.

The EPA also expressed a concern about using financial incentives linked to milestones that could result in contractor reluctance to revise the NEPA analysis when appropriate. While the FHWA is not aware of any specific

problems in this area, the FHWA shares the EPA's concern and will discourage the use of any timeline-based incentives that may have an undue influence on the NEPA process. Additionally, the EPA commented on how appropriate oversight will be maintained under the surface transportation project delivery pilot program at 23 U.S.C. 327. Since this pilot program is limited only to the States' assumption of the Secretary's environmental responsibilities, the FHWA will retain full oversight over the contracting process. Moreover, the pilot program requires a memorandum of understanding to be executed between the State and the FHWA whenever a State assumes any of the Secretary's responsibilities under the pilot program. Appropriate oversight provisions will be specified in these MOUs.

Lastly, the FHWA is adding two new provisions at sections 636.109(b)(1) and (2). Section 636.109(b)(1) is intended to clarify that the design-builder may proceed with preliminary design under a design-build contract. Section 636.109(b)(2) is intended to clarify that the States may permit any design and engineering activities to be undertaken for the purposes of defining the project alternatives and completing the NEPA alternatives analysis and review process; complying with other related environmental laws and regulations; supporting agency coordination, public involvement, permit applications, or development of mitigation plans; or developing the design of the preferred alternative to a higher level of detail when the lead agencies agree that it is warranted in accordance with 23 U.S.C. 139(f)(4)(D). As previously discussed, several comments on the proposed definition of preliminary design expressed the concern that the States would not be able to conduct activities needed to comply with other related environmental laws or advance the design of the preferred alternative as permitted in 23 U.S.C. 139(f)(4)(D). The addition of section 636.109(b)(2) clarifies that the States may conduct these types of activities.

Section 636.109(c) and (d)

UDOT, TxDOT, MdSHA, DBIA, Association of Engineering Employees of Oregon, and Profession Engineers in California Government each commented on the proposed changes in section 636.109(c) and (d). The Association of Engineering Employees of Oregon and Professional Engineers in California Government commented that section 636.109(c) does not go far enough in protecting the integrity of the NEPA process. Section 636.109(c) would require certain FHWA approvals during

the project development process and would clarify that any such approval is not a commitment of Federal funds. The FHWA believes that not committing any Federal funds until after the NEPA process is complete, in conjunction with the various FHWA approvals during the project development process as well as the requirements in section 636.109(b), adequately protect the integrity of the NEPA process.

UDOT, TxDOT, MdSHA, and DBIA questioned why the FHWA is requiring concurrence in the issuance of a notice to proceed with preliminary design. Section 1503 of SAFETEA-LU amended 23 U.S.C. 112(b)(3)(D)(ii) to require the States to receive concurrence from the Secretary prior to carrying-out any activity specified in 23 U.S.C. (b)(3)(D)(i), which includes the issuance of notices to proceed with preliminary design work. Thus, the States must receive FHWA concurrence prior to issuing a notice to proceed with preliminary design work.

Section 636.116 What organizational conflict of interest requirements apply to design-build projects?

TxDOT, UDOT, VDOT, PennDOT, DBIA, ACEC each commented on the proposed changes to section 636.116. ACEC supports the proposed changes to section 636.116, because it believes that firms have been unfairly eliminated from competing for design-build contracts merely by virtue of providing some technical work on a NEPA document. ACEC further suggests that the language be revised to preclude the States from disallowing such firms to compete for design-build contracts. In contrast to ACEC's comments, PennDOT commented that it is concerned about the conflict of interest that may arise if the State subsequently needs the firm to provide additional input or work on the NEPA analysis for the project. The FHWA agrees with both ACEC and PennDOT. The FHWA has accommodated ACEC's concern in the final rule by giving the States the flexibility to allow such firms to compete for design-build contracts. The FHWA has also accommodated PennDOT's concern by making the changes discretionary on the part of the States rather than mandatory as requested by ACEC.

VDOT, TxDOT, UDOT, and DBIA all supported the proposed changes to section 636.116. However, TxDOT, UDOT, and DBIA further commented that the contracting agency should have the flexibility to release a subconsultant to the consultant responsible for preparing the NEPA documents from further NEPA responsibilities and allow

such firm to compete for a design-build contract. The FHWA supports giving the States this flexibility and has added a new subsection (d) to section 636.116 in the final rule.

Section 636.119 How does this Part apply to public-private agreements?

TxDOT, FDOT, UDOT, MdSHA, Indiana Governor Mitch Daniels, AGC of America, NCPPP, WGI, and Bechtel each commented on this proposed section. WGI commented that it supports making public-private agreement procurements subject to State law. SCAG, Bechtel, and NCPPP were concerned that the numerous approvals required under this proposed section would add time and cost to the project delivery process. AGC of America commented that it supports the oversight provisions in the proposed section. TxDOT, UDOT, Indiana Governor Mitch Daniels, and SCAG commented that it is inappropriate for the FHWA to assert approval rights over State procedures. TxDOT, UDOT, and MdSHA commented that it is unnecessary for the FHWA to concur in requests for qualifications. TxDOT and UDOT further commented that some provisions of this proposed section were unclear, and FDOT commented that public-private agreement requirements should be an entirely separate part in the Code of Federal Regulations.

After considering these comments, the FHWA agrees that some further revisions may be necessary and that it is more appropriate for these requirements to be contained in a separate part in the Code of Federal Regulations. Accordingly, the FHWA has struck the proposed changes to section 636.119 and will consider whether a future rulemaking for these requirements is necessary. Minor revisions have been made to section 636.119(b) to define the FHWA's requirements for preserving Federal-aid eligibility in any procurement actions under a public-private partnership.

Section 636.302 Are there any limitations on the selection and use of proposal evaluation factors?

TxDOT, UDOT, PennDOT, DBIA, Professional Engineers in California Government, and Association of Engineering Employees of Oregon each commented on the proposed changes to section 636.302. Professional Engineers in California Government and Association of Engineering Employees of Oregon commented that the price evaluation requirements should continue. The FHWA shares the concern about eliminating the price evaluation requirement. After considering these

comments and taking a closer look at the proposed regulation, the FHWA has decided to add a new subparagraph to section 636.302(a)(1)(ii) to require that price be considered to the extent that the contract requires payment from the contracting agency utilizing Federal-aid highway funds to the design-builder for any services to be provided prior to final design or construction. The FHWA is adding this requirement, because the FHWA believes that the consideration of price will ensure that a project does not incur unreasonable costs. This provision will ensure that, to the extent the State must make any payments to the design-builder, the price to be paid for these services is one of the factors that States must consider.

The FHWA has also added language to section 636.302(a)(1)(iv) to clarify that the price reasonableness requirement only applies to the extent that the contracting agency wishes to use Federal funds for final design or construction. These provisions also respond to the comments made by TxDOT, UDOT, and DBIA who were concerned that some public-private agreements may not require any payment to be made to the design-builder. However, whenever a contract is awarded prior to the completion of the NEPA process, it is impossible to consider the price of the total contract because an alternative has not yet been selected and final design has not yet been completed. Thus, a contracting agency will be able to consider price only to a certain extent.

PennDOT commented that the proposed procedures in section 636.302(a)(1) would be very complex and hard to implement. Since the statute now permits States to award contracts prior to the conclusion of the NEPA process, which will require the costs for final design and construction to be negotiated later, the States and FHWA must find a way to control the costs under the contract and ensure that the public gets a fair price for these services. Thus, the State will need to develop methodologies through which the State can determine whether the final fixed price for the project is reasonable. An open-book negotiation method through which both the contractor and the State share supporting data on the prices of the items being negotiated can be an effective way to make this determination. While the FHWA recognizes the difficulties in ensuring that the public gets the best price whenever a design-build contract is awarded prior to the conclusion of the NEPA process, we believe that a price reasonableness standard for these costs

will be the most effective approach. The FHWA will provide appropriate guidance and support to the States in implementing this standard.

Finally, TxDOT, UDOT, and DBIA each commented that the FHWA should not concur in the States' price reasonableness determination, but rather only the methodologies the States use to make that determination. The FHWA disagrees with this comment. The FHWA is the steward of all Federal funds that are used in highway projects. Since total contract price cannot be considered during the competition to award a contract prior to the conclusion of the NEPA process, the FHWA must have some mechanism to ensure that price for the project for which Federal funds proposed to be used is reasonable.

Rulemaking Analyses and Notices

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

The FHWA has determined that this rule is a significant regulatory action within the meaning of Executive Order 12866, and within the meaning of the U.S. Department of Transportation's regulatory policies and procedures. The Office of Management and Budget (OMB) has reviewed this document under E.O. 12866. This rule is significant, because of the substantial State, environmental, and industry interest in the design-build contracting technique.

The economic impact of this rulemaking will be minimal and it will not adversely affect, in a material way, any sector of the economy. This rulemaking merely revises the FHWA's policies concerning the design-build contracting technique. The final rule will not affect the total Federal funding available to the State DOTs under the Federal-aid highway program. Therefore, an increased use of design-build delivery method will not yield significant economic impacts to the Federal-aid highway program. Additionally, this rule will not interfere with any action taken or planned by another agency and will not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. Consequently, a full regulatory evaluation is not required.

The FHWA does not have sufficient data to quantify the economic impacts of this rule. However, the FHWA believes that increased use of the design-build contracting method may result in certain efficiencies in the cost and time it normally takes to deliver a transportation project. We also believe that States will not use the design-build

contracting technique if using such a technique will increase the cost of a project.

The design-build contracting technique is important to increasing the involvement of the private sector in the delivery of transportation projects. Insofar as this rule will increase the uses of the design-build contracting technique, it may result in increased private sector financial investment in transportation. The FHWA did not receive any comments on the economic impacts analysis in the NPRM.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), we have evaluated the effects of this action on small entities and have determined that the action will not have a significant economic impact on a substantial number of small entities. The rule addresses the obligation of Federal funds to States for Federal-aid highway projects. As such, it affects only States and States are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, the Regulatory Flexibility Act does not apply, and the FHWA certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48, March 22, 1995), because it will not result in the expenditure by State, local, tribal governments, or by the private sector, of \$128.1 million or more in any 1 year (2 U.S.C. 1532 *et seq.*). This rule merely updates the design-build regulation to reflect the changes made by SAFETEA–LU. The design-build regulation allows, but does not require, States to use the design-build technique for the delivery of Federal-aid projects. States use the design-build contracting technique because, in some instances, it may reduce the time and cost of delivering a project.

Further, the definition of “Federal Mandate” in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism)

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 dated August 4, 1999, and the FHWA has determined that this rule will not have a substantial direct effect or sufficient federalism implications on the States. The FHWA has also determined that this final rule will not preempt any State law or regulation or affect the States’ ability to discharge traditional State governmental functions.

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. The FHWA did not receive any comments on the intergovernmental review analysis.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), the FHWA must obtain approval from the OMB for each collection of information we conduct, sponsor, or require through regulations. The FHWA has determined that this rule does not contain a collection of information requirement for purposes of the PRA.

National Environmental Policy Act

The FHWA has analyzed this rule for the purpose of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), and has determined that this rule will not have any effect on the quality of the environment. The promulgation of regulations has been identified as a categorical exclusion under 23 CFR 771.117(c)(20). However, Federal-aid highway projects on which design-build is used, must still comply with the National Environmental Policy Act of 1969, as amended.

Executive Order 12630 (Taking of Private Property)

The FHWA has analyzed this rule under Executive Order 12630, Governmental Actions and Interface with Constitutionally Protected Property Rights. This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 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 rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. The FHWA certifies that this rule will not cause an environmental risk to health or safety that might disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this rule under Executive Order 13175, dated November 6, 2000, and believes that the rule will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; and will not preempt tribal laws. The rule addresses obligations of Federal funds to States for Federal-aid highway projects and will not impose any direct compliance requirements on Indian tribal governments. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

The FHWA has analyzed this action under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use dated May 18, 2001. We have determined that it is not a significant energy action under that order, because, although it is a significant regulatory action under Executive Order 12866, it will not have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

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

23 CFR Part 630

Bonds, Government contracts, Grant programs—transportation, Highways and roads, Reporting and recordkeeping requirements.

23 CFR Part 635

Construction and maintenance, Grant programs—transportation, Highways and roads, Reporting and recordkeeping requirements.

23 CFR Part 636

Design-build, Grant programs—transportation, Highways and roads.

Issued on: August 7, 2007.

J. Richard Capka,

FHWA Administrator.

In consideration of the foregoing, the FHWA amends parts 630, 635, and 636 of title 23, Code of Federal Regulations, as follows:

PART 630—PRECONSTRUCTION PROCEDURES

1. Revise the authority citation for part 630 to read as follows:

Authority: Sec. 1503 of Pub. L. 109–59, 119 Stat.1144; 23 U.S.C. 106, 109, 112, 115, 315, 320, and 402(a); 23 CFR 1.32 and 49 CFR 1.48(b).

2. Amend § 630.106 by revising the section heading and adding paragraph (a)(7) to read as follows:

§ 630.106 Authorization to proceed.

(a) (7) For design-build projects, the execution or modification of the project agreement for final design and physical construction, and authorization to proceed, shall not occur until after the completion of the NEPA process. However, preliminary design (as defined in 23 CFR 636.103) and preliminary engineering may be authorized in accordance with this section.

PART 635—CONSTRUCTION AND MAINTENANCE

3. Revise the authority citation for part 635 to read as follows:

Authority: Sec. 1503 of Pub. L. 109–59, 119 Stat.1144; 23 U.S.C. 101 (note), 109, 112, 113, 114, 116, 119, 128, and 315; 31 U.S.C. 6505; 42 U.S.C. 3334, 4601 et seq.; Sec. 1041 (a), Pub. L. 102–240, 105 Stat. 1914; 23 CFR 1.32; 49 CFR 1.48(b).

4. Amend § 635.112 by revising paragraph (i)(1); by redesignating paragraphs (i)(2) and (i)(3) as (i)(3) and (i)(4), respectively; and by adding a new paragraph (i)(2) to read as follows:

§ 635.112 Advertising for bids and proposals.

(i) (1) When a Request for Proposals document is issued after the NEPA process is complete, the FHWA Division Administrator’s approval of the Request for Proposals document will constitute the FHWA’s project authorization and the FHWA’s approval of the STD’s request to release the document. This approval will carry the same significance as plan, specification and estimate approval on a design-bid-build Federal-aid project.

(2) Where a Request for Proposals document is issued prior to the completion of the NEPA process, the FHWA’s approval of the document will only constitute the FHWA’s approval of the STD’s request to release the document.

5. Revise § 635.309(p)(1) introductory text to read as follows:

§ 635.309 Authorization.

(p) (1) The FHWA’s project authorization for final design and physical construction will not be issued until the following conditions have been met:

6. Revise § 635.413(e)(1)(i) to read as follows:

§ 635.413 Guaranty and warranty clauses.

(e) (1) The term of the warranty is short (generally one to two years); however, projects developed under a public-private agreement may include warranties that are appropriate for the term of the contract or agreement.

7. Revise the authority citation for part 636 to read as follows:

Authority: Sec. 1503 of Pub. L. 109–59, 119 Stat. 1144; Sec. 1307 of Pub. L. 105–178, 112 Stat. 107; 23 U.S.C. 101, 109, 112, 113, 114, 115, 119, 128, and 315; 49 CFR 1.48(b).

8. Amend § 636.103 by adding in alphabetical order the definitions of “final design,” “preliminary design,” “price reasonableness,” and “public-private agreement,” and by revising the definition of a “qualified project” as follows:

PART 636—DESIGN-BUILD CONTRACTING

9. Remove and reserve § 636.106.

10. Revise § 636.107 to read as follows:

Subpart A—General

Final design means any design activities following preliminary design and expressly includes the preparation of final construction plans and detailed specifications for the performance of construction work.

§ 636.103 What are the definitions of terms used in this Part?

Preliminary design defines the general project location and design concepts. It includes, but is not limited to, preliminary engineering and other activities and analyses, such as environmental assessments, topographic surveys, metes and bounds surveys, geotechnical investigations, hydrologic analysis, hydraulic analysis, utility engineering, traffic studies, financial plans, revenue estimates, hazardous materials assessments, general estimates of the types and quantities of materials, and other work needed to establish parameters for the final design. Prior to completion of the NEPA review process, any such preliminary engineering and other activities and analyses must not materially affect the objective consideration of alternatives in the NEPA review process.

Price reasonableness means the determination that the price of the work for any project or series of projects is not excessive and is a fair and reasonable price for the services to be performed.

Public-private agreement means an agreement between a public agency and a private party involving design and construction of transportation improvements by the private party to be paid for in whole or in part by Federal-aid highway funds. The agreement may also provide for project financing, at-risk equity investment, operations, or maintenance of the project.

Qualified project means any design-build project (including intermodal projects) funded under Title 23, United States Code, which meets the requirements of this Part and for which the contracting agency deems to be appropriate on the basis of project delivery time, cost, construction schedule, or quality.

§ 636.106 [Removed]

9. Remove and reserve § 636.106.

10. Revise § 636.107 to read as follows:

§ 636.107 May contracting agencies use geographic preference in Federal-aid design-build or public-private partnership projects?

No. Contracting agencies must not use geographic preferences (including contractual provisions, preferences or incentives for hiring, contracting, proposing, or bidding) on Federal-aid highway projects, even though the contracting agency may be subject to statutorily or administratively imposed in-State or local geographical preferences in the evaluation and award of such projects.

§ 636.108 [Removed]

- 11. Remove and reserve § 636.108.
- 12. Revise § 636.109 to read as follows:

§ 636.109 How does the NEPA process relate to the design-build procurement process?

The purpose of this section is to ensure that there is an objective NEPA process, that public officials and citizens have the necessary environmental impact information for federally funded actions before actions are taken, and that design-build proposers do not assume an unnecessary amount of risk in the event the NEPA process results in a significant change in the proposal, and that the amount payable by the contracting agency to the design-builder does not include significant contingency as the result of risk placed on the design-builder associated with significant changes in the project definition arising out of the NEPA process. Therefore, with respect to the design-build procurement process:

- (a) The contracting agency may:
 - (1) Issue an RFQ prior to the conclusion of the NEPA process as long as the RFQ informs proposers of the general status of NEPA review;
 - (2) Issue an RFP after the conclusion of the NEPA process;
 - (3) Issue an RFP prior to the conclusion of the NEPA process as long as the RFP informs proposers of the general status of the NEPA process and that no commitment will be made as to any alternative under evaluation in the NEPA process, including the no-build alternative;
 - (4) Proceed with the award of a design-build contract prior to the conclusion of the NEPA process;
 - (5) Issue notice to proceed with preliminary design pursuant to a design-build contract that has been awarded prior to the completion of the NEPA process; and
 - (6) Allow a design-builder to proceed with final design and construction for

any projects, or portions thereof, for which the NEPA process has been completed.

(b) If the contracting agency proceeds to award a design-build contract prior to the conclusion of the NEPA process, then:

- (1) The contracting agency may permit the design-builder to proceed with preliminary design;
 - (2) The contracting agency may permit any design and engineering activities to be undertaken for the purposes of defining the project alternatives and completing the NEPA alternatives analysis and review process; complying with other related environmental laws and regulations; supporting agency coordination, public involvement, permit applications, or development of mitigation plans; or developing the design of the preferred alternative to a higher level of detail when the lead agencies agree that it is warranted in accordance with 23 U.S.C. 139(f)(4)(D);
 - (3) The design-build contract must include appropriate provisions preventing the design-builder from proceeding with final design activities and physical construction prior to the completion of the NEPA process (contract hold points or another method of issuing multi-step approvals must be used);
 - (4) The design-build contract must include appropriate provisions ensuring that no commitments are made to any alternative being evaluated in the NEPA process and that the comparative merits of all alternatives presented in the NEPA document, including the no-build alternative, will be evaluated and fairly considered;
 - (5) The design-build contract must include appropriate provisions ensuring that all environmental and mitigation measures identified in the NEPA document will be implemented;
 - (6) The design-builder must not prepare the NEPA document or have any decisionmaking responsibility with respect to the NEPA process;
 - (7) Any consultants who prepare the NEPA document must be selected by and subject to the exclusive direction and control of the contracting agency;
 - (8) The design-builder may be requested to provide information about the project and possible mitigation actions, and its work product may be considered in the NEPA analysis and included in the record; and
 - (9) The design-build contract must include termination provisions in the event that the no-build alternative is selected.
- (c) The contracting agency must receive prior FHWA concurrence before

issuing the RFP, awarding a design-build contract and proceeding with preliminary design work under the design-build contract. Should the contracting agency proceed with any of the activities specified in this section before the completion of the NEPA process (with the exception of preliminary design, as provided in paragraph (d) of this section), the FHWA's concurrence merely constitutes the FHWA approval that any such activities complies with Federal requirements and does not constitute project authorization or obligate Federal funds.

(d) The FHWA's authorization and obligation of preliminary engineering and other preconstruction funds prior to the completion of the NEPA process is limited to preliminary design and such additional activities as may be necessary to complete the NEPA process. After the completion of the NEPA process, the FHWA may issue an authorization to proceed with final design and construction and obligate Federal funds for such purposes.

- 13. Amend § 636.116 by adding paragraphs (c) and (d) to read as follows:

§ 636.116 What organizational conflict of interest requirements apply to design-build projects?

* * * * *

(c) If the NEPA process has been completed prior to issuing the RFP, the contracting agency may allow a consultant or subconsultant who prepared the NEPA document to submit a proposal in response to the RFP.

(d) If the NEPA process has not been completed prior to issuing the RFP, the contracting agency may allow a subconsultant to the preparer of the NEPA document to participate as an offeror or join a team submitting a proposal in response to the RFP only if the contracting agency releases such subconsultant from further responsibilities with respect to the preparation of the NEPA document.

- 14. Revise § 636.119(b)(1) and (2) to read as follows:

§ 636.119 How does this part apply to a project developed under a public-private partnership?

* * * * *

(b) * * *
 (1) If the public-private agreement establishes price, then all subsequent contracts executed by the developer are considered to be subcontracts and are not subject to Federal-aid procurement requirements.

(2) If the public-private agreement does not establish price, the developer is considered to be an agent of the

owner, and the developer must follow the appropriate Federal-aid procurement requirements (23 CFR part 172 for engineering service contracts, 23 CFR part 635 for construction contracts and the requirements of this part for design-build contracts) for all prime contracts (not subcontracts).

* * * * *

■ 15. Revise § 636.302(a)(1) to read as follows:

§ 636.302 Are there any limitations on the selection and use of proposal evaluation factors?

(a) * * *

(1) You must evaluate price in every source selection where construction is a significant component of the scope of work. However, where the contracting agency elects to release the final RFP and award the design-build contract before the conclusion of the NEPA process (see § 636.109), then the following requirements apply:

(i) It is not necessary to evaluate the total contract price;

(ii) Price must be considered to the extent the contract requires the contracting agency to make any payments to the design-builder for any work performed prior to the completion of the NEPA process and the contracting agency wishes to use Federal-aid highway funds for those activities;

(iii) The evaluation of proposals and award of the contract may be based on qualitative considerations;

(iv) If the contracting agency wishes to use Federal-aid highway funds for final design and construction, the subsequent approval of final design and construction activities will be contingent upon a finding of price reasonableness by the contracting agency;

(v) The determination of price reasonableness for any design-build project funded with Federal-aid highway funds shall be based on at least one of the following methods:

(A) Compliance with the applicable procurement requirements for part 172, 635, or 636, where the contractor providing the final design or construction services, or both, is a person or entity other than the design-builder;

(B) A negotiated price determined on an open-book basis by both the design-builder and contracting agency; or

(C) An independent estimate by the contracting agency based on the price of similar work;

(vi) The contracting agency's finding of price reasonableness is subject to FHWA concurrence.

* * * * *

[FR Doc. 07-3959 Filed 8-9-07; 3:55 pm]

BILLING CODE 4910-22-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9354]

RIN 1545-BB86

Expenses for Household and Dependent Care Services Necessary for Gainful Employment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations regarding the credit for expenses for household and dependent care services necessary for gainful employment. The regulations reflect statutory amendments under the Deficit Reduction Act of 1984, the Tax Reform Act of 1986, the Omnibus Budget Reconciliation Act of 1987, the Family Support Act of 1988, the Small Business Job Protection Act of 1996, the Economic Growth and Tax Relief Reconciliation Act of 2001, the Job Creation and Worker Assistance Act of 2002, the Working Families Tax Relief Act of 2004, and the Gulf Opportunity Zone Act of 2005. The regulations affect taxpayers who claim the credit for expenses for household and dependent care services, and dependent care providers.

DATES: *Effective Date:* These regulations are effective August 14, 2007.

Applicability Date: For date of applicability, see § 1.21-1(l).

FOR FURTHER INFORMATION CONTACT: Amy Pfalzgraf, (202) 622-4960 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains final amendments to the Income Tax Regulations, 26 CFR part 1, relating to the credit for expenses for household and dependent care services necessary for gainful employment (the credit) under section 21 of the Internal Revenue Code (Code).

On May 24, 2006, a notice of proposed rulemaking (REG-139059-02) regarding the credit was published in the **Federal Register** (71 FR 29847).

Written and electronic comments responding to the notice of proposed rulemaking were received. No public hearing was requested or held. After consideration of all the comments, the proposed regulations are adopted as amended by this Treasury decision. The comments and revisions are discussed in the preamble.

Explanation of Provisions and Summary of Comments

1. Time of Payment and Performance of Services

Section 21(b)(2) provides, in part, that employment-related expenses are amounts paid to enable a taxpayer to be gainfully employed for a period for which there are one or more qualifying individuals with respect to a taxpayer. The proposed regulations provide that a taxpayer may take expenses into account under section 21 only in the later of the taxable year the services are performed or the taxable year the expenses are paid. The proposed regulations also provide that the status of an individual as a qualifying individual is determined on a daily basis, that a taxpayer may take into account only expenses that qualify before a disqualifying event, such as a child turning 13, and that the requirements of section 21 and the regulations are applied at the time the services are performed, regardless of when the expenses are paid.

A verbal comment inquired whether, to be creditable, expenses must be paid and services must be performed before a disqualifying event.

The determination of whether expenses qualify as employment-related expenses, including whether an individual is a qualifying individual, can be made only at the time services are performed. Only expenses for the care of a qualifying individual that are for the purpose of enabling the taxpayer to be gainfully employed qualify for the credit. Therefore, services must be performed prior to a disqualifying event and at a time when the purpose is to enable the taxpayer to be gainfully employed. For purposes of determining whether expenses are employment-related expenses, the time of payment is irrelevant, although payment must be made before the credit is claimed. The final regulations provide examples to illustrate these rules.

2. Care of Qualifying Individual and Household Services

Under section 21(b)(2)(A), expenses are employment-related only if the expenses are primarily for household services or for the care of a qualifying