

toxin was accessed, the purpose for accessing the toxin, the name of the individual accessing the toxin, the date the toxin was returned back to storage, the name of the individual returning the toxin back to storage, and date of final disposition of the toxin and by whom;

(vi) Records created under § 121.16;

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the toxin, the date of the transfer, the number of vials or quantity of the toxin transferred, the name of the sender, and the name of the recipient; and

(viii) Records created under § 121.19.

\* \* \* \* \*

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a validated viable select agent removal procedure:

(i) A written description of the validated inactivation procedure or validated viable select agent removal procedure used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity's responsible official involving a validated inactivation or validated viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated select agent inactivation or validated viable select agent removal;

(v) The date(s) the validated inactivation or validated viable select agent removal was completed;

(vi) The location where the validated inactivation or validated viable select agent removal was performed; and

(vii) A signed certificate that must:

(A) Include the date(s) the validated inactivation or validated viable select agent removal was completed.

(B) Include the validated inactivation procedure or validated viable select agent removal procedure used.

(C) Include the name of the principal investigator.

(D) Include an attestation statement certifying that the information on the certificate is true, complete, and accurate, and that the validated inactivation or validated viable select agent removal was performed as described in paragraph (a)(8)(i) of this section.

(E) Be signed by the principal investigator or designee within 7 days after completion of the validated

inactivation or validated viable select agent removal. Such designee must be listed on the entity's registration and have the knowledge and expertise to provide scientific and technical direction regarding the validated inactivation procedure or the validated viable select agent removal procedure to which the certificate refers.

(F) Be maintained for as long as the material is in the possession of the registered individual or entity plus an additional 3 years.

(G) A copy of the certificate must accompany all transfers of inactivated or select agent removed material including intra-entity transfers.

\* \* \* \* \*

(d) All records created in accordance with the regulations of this part must be maintained for 3 years unless otherwise stated.

#### § 121.19 [Amended]

■ 36. Amend § 121.19, in paragraphs (a)(1) introductory text and (b)(1) introductory text, by removing the words "telephone, facsimile, or email" and adding the words "eFSAP information system, telephone, or email" in their place.

Done in Washington, DC, this 19th day of January 2024.

Jennifer Moffitt,

*Undersecretary, Marketing and Regulatory Programs, USDA.*

[FR Doc. 2024-01501 Filed 1-26-24; 8:45 am]

BILLING CODE 3410-34-P

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### 23 CFR Part 172

[FHWA Docket No. FHWA-2023-0046]

RIN 2125-AG12

#### Procurement, Management, and Administration of Engineering and Design Related Services

**AGENCY:** Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

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

**SUMMARY:** This proposed rule would update the regulations governing the procurement, management, and administration of engineering and design related services directly related to a highway construction project that is funded through a discretionary grant administered by FHWA. The intent of the proposed rule is to clarify how the regulations apply to recipients other

than State transportation agencies (STA). This proposed rulemaking would also make technical changes and corrections to improve the administration of these regulations.

**DATES:** Comments must be received on or before April 1, 2024. Late comments will be considered to the extent practicable.

**ADDRESSES:** You may submit comments by any of the following methods:

• *Fax:* (202) 493-2251;

• *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590;

• *Hand Delivery:* U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays; or

• *Electronically through the Federal eRulemaking Portal:* [www.regulations.gov](http://www.regulations.gov). Follow the online instructions for submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Mr. John McAvoy, Consultant Services Program Manager, FHWA Office of Preconstruction, Construction, and Pavements, (202) 853-5593, or via email at [john.mcavoy@dot.gov](mailto:john.mcavoy@dot.gov), or Mr. Lev Gabrilovich, Senior Attorney Advisor, FHWA Office of the Chief Counsel, (202) 366-3813, or via email at [lev.gabrilovich@dot.gov](mailto:lev.gabrilovich@dot.gov). Office hours for the FHWA are from 8 a.m. to 4:30 p.m., ET, Monday through Friday, except Federal holidays.

#### SUPPLEMENTARY INFORMATION:

##### Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at [www.regulations.gov](http://www.regulations.gov). The website is available 24 hours each day, 366 days this year. Please follow the instructions. Electronic submission and retrieval help and guidelines are available under the help section of the website.

An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at [www.FederalRegister.gov](http://www.FederalRegister.gov), or the Government Printing Office's website at [www.GovInfo.gov](http://www.GovInfo.gov).

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. In addition to late

comments, FHWA will also continue to file relevant information in the docket as it becomes available after the comment period closing date and interested persons should continue to examine the docket for new material. A final rule may be published at any time after the close of the comment period and after FHWA has had the opportunity to review the comments submitted.

### Background and Legal Authority

Through this NPRM, FHWA proposes to modify existing regulations for the administration of engineering and design related service contracts to clarify how the regulations apply to recipients other than STAs that are awarded FHWA-administered discretionary grants and to make technical amendments to improve the regulations. The FHWA, through the Federal-aid Highway Program (FAHP) and other programs administered under chapter 1 of title 23, United States Code (U.S.C.), provides financial resources and technical assistance to State and local governments and other public authorities for planning, design, constructing, operating, preserving, and improving public roads and other surface transportation infrastructure. The primary authority for the procurement, management, and administration of engineering and design related services funded with a highway construction grant administered under chapter 1 of 23 U.S.C. is codified at 23 U.S.C. 112(b)(2). Generally, each contract for engineering and design related services paid for with Federal funds and leading to a construction project must be awarded in accordance with the qualifications-based selection procedures prescribed in the Brooks Act (40 U.S.C. 1101 *et seq.*) and must accept and apply consultant indirect cost rates established by a cognizant Federal or State agency in accordance with the Federal Acquisition Regulation (FAR) cost principles (48 CFR part 31). The FHWA promulgated 23 CFR part 172 as a means of implementing the Brooks Act. Part 172 defines and illustrates specific responsibilities of an STA and its subrecipients (entities that receive a subaward from their STA).

The Infrastructure Investment and Jobs Act, (Pub. L. 117–58) also known as the “Bipartisan Infrastructure Law,” (BIL) provided \$550 billion over fiscal years 2022 through 2026 in new Federal investment in roads, bridges, mass transit, water infrastructure, resilience improvements, and broadband. The BIL provides approximately \$350 billion for Federal highway programs.

### Statement of the Problem

Most of the funding in the BIL for highway projects is distributed to STAs based on formulas specified in Federal law. However, the BIL also provides funding through a wide range of discretionary grant programs, including the “Rebuilding American Infrastructure with Sustainability and Equity” (RAISE) program, the “Nationally Significant Multimodal Freight and Highway Projects” (INFRA) program, the “National Infrastructure Project Assistance Program” (MEGA), the “Safe Streets and Roads for All” (SS4A) program, and others. Each of these discretionary grant programs has its own eligibility requirements, but for many programs, entities other than STAs are eligible to apply for and receive grant awards. For example, under the RAISE grant program, in addition to STAs, eligible entities include U.S. territories, Metropolitan Planning Organizations (MPO), federally recognized Indian Tribes, local governments, and other public authorities.<sup>1</sup> The SS4A grants are only available to MPOs, political subdivisions of a State, and federally recognized Indian Tribes.<sup>2</sup>

When a recipient other than an STA is awarded a discretionary grant under the programs described above, the award is made through an executed grant agreement with DOT rather than as a subaward from the STA. This non-STA recipient is responsible for compliance with all Federal regulations pertaining to the grant, including those covering the procurement of professional services. In their current form, the regulations at 23 CFR part 172 could be interpreted as applying to all recipients of discretionary grants administered under chapter 1 of 23 U.S.C., not just STAs. Consequently, non-STA recipients would be responsible for compliance with part 172, including the requirement that recipients prepare and maintain written policies and procedures for the procurement, management, and administration of engineering and design related consultant services. However, the requirements of 23 U.S.C. 112(b)(2), and therefore 23 CFR part 172, apply only to the procurement, management, and administration of engineering and design related consultant services for projects “under [the] supervision” of an STA.<sup>3</sup> This includes projects administered by entities other than STAs when these

entities are subrecipients of STAs but not when these entities are recipients of an award directly from DOT, and FHWA did not intend for 23 CFR part 172 to apply beyond the scope of 23 U.S.C. 112(b)(2). Non-STA recipients that receive or are eligible to receive discretionary grant funds directly from FHWA do not necessarily have FHWA-approved written policies and procedures in place for the procurement of professional services that comply with 23 CFR part 172, and creating these policies and procedures from scratch would create an undue burden on non-STA recipients and FHWA. By removing any ambiguity regarding the applicability of 23 CFR part 172, this NPRM proposes to clarify the responsibilities of the non-STA recipients to remain compliant with Federal regulations while reducing unnecessary regulatory burden.

### Section-by-Section Discussion of the Proposals

The FHWA proposes to revise 23 CFR part 172—Administration of Engineering and Design Related Service Contracts as follows:

#### Authority Citation

The FHWA proposes to revise the authority citation for 23 CFR part 172 to remove the reference to 23 U.S.C. 402. Part 172 no longer applies to programs and activities authorized under 23 U.S.C. 402, and the remaining authorities cited provide the necessary authority for 23 CFR part 172; therefore, citation to 23 U.S.C. 402 is unnecessary.

#### Section 172.1—Purpose and Applicability

Section 172.1 would be amended to clarify that the provisions of 23 CFR part 172 apply only to STAs and their subrecipients.

#### Section 172.3—Definitions

In section 172.3, the definitions for the terms “Consultant” and “Subconsultant” would be modified to remove outdated citations to 2 CFR part 200 that formerly contained definitions of “Recipient” and “Subrecipient.” The proposed rule would add definitions for “Recipient” and “Subrecipient” and give those terms the same meaning as they are defined in 2 CFR 200.1. Finally, the definition of “Contracting agencies” would be revised to eliminate reference to “other recipients.”

#### Section 172.5—Program Management and Oversight

Section 172.5 would be amended to remove the references to “recipient” and “other recipient” to clarify that the

<sup>1</sup> 49 U.S.C. 6702(a)(2).

<sup>2</sup> BIL, sec. 24112(a)(2).

<sup>3</sup> 23 U.S.C. 112(a).

regulations apply only to STAs and their subrecipients. Also, a reference to a provision in 2 CFR part 200 would be revised to reflect the current location of that provision in 2 CFR part 200.

*Section 172.7—Procurement Methods and Procedures*

Section 172.7 would be amended to remove the references to “recipient” and “other recipient” to clarify the applicability of the regulations only to STAs and their subrecipients. Also, references to a provision in 2 CFR part 200 would be revised to reflect the current location of that provision in 2 CFR part 200.

*Section 172.9—Procurement Methods and Procedures*

Section 172.9 would be amended to remove a reference to “recipient” to clarify the applicability of the regulations only to STAs and their subrecipients. A reference to a provision in 2 CFR part 200 would be revised to reflect the current location of that provision in 2 CFR part 200. Also, a typographical error in an internal cross-reference in § 172.9(a)(3)(iv)(B)(1) will be corrected. The regulation in this paragraph currently references § 172.5(a)(1)(ii); the corrected reference would read § 172.7(a)(1)(ii).

*Section 172.11—Allowable Costs and Oversight*

Section 172.11 would be amended to remove references to “recipient” and “other recipient,” and where appropriate, substitute “STA” to clarify that the regulations apply only to STAs and their subrecipients.

**Rulemaking Analyses and Notices**

*Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures*

The FHWA has considered the impacts of this rule under Executive Order (E.O.) 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, as amended by E.O. 14094 (“Modernizing Regulatory Review”), and DOT’s regulatory policies and procedures. This proposed rule complies with E.O. 12866 and E.O. 13563 to improve regulation. The Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB) has determined that this rulemaking is not a significant regulatory action under section 3(f) of E.O. 12866. Accordingly, OMB has not reviewed it under that E.O.

It is anticipated that the proposed rule would not be economically significant

for purposes of E.O. 12866. The proposed rule would not have an annual effect on the economy of \$200 million or more. The proposed rule would not adversely affect in a material way the economy, any sector of the economy, productivity, competition, or jobs. In addition, the 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.

*Regulatory Flexibility Act*

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), FHWA has evaluated the effects of this proposed rule on small entities, such as local governments and businesses. Based on the evaluation, FHWA anticipates that this action would not have a significant economic impact on a substantial number of small entities. The proposed rule would clarify the applicability of the requirements for the procurement, management, and administration of engineering and design related services that use FHWA-administered funding and are directly related to a construction project. Specifically, the proposed rule would clarify that the regulations in 23 CFR part 172 do not apply to recipients of FHWA-administered grants that are not STAs. Consequently, the economic impact of this proposed rule on small entities is expected to be minimal. Therefore, FHWA certifies that the proposed action would not have a significant economic impact on a substantial number of small entities.

*Unfunded Mandates Reform Act of 1995*

This proposed rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48). The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires Federal Agencies to prepare a written statement, which includes estimates of anticipated impacts, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$183 million or more in any one year (2 U.S.C. 1532). Further, in compliance with the Unfunded Mandates Reform

Act of 1995, FHWA will evaluate any regulatory action that might be proposed in subsequent stages of the proceeding to assess the effects on State, local, and Tribal governments and the private sector. In addition, 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 FAHP and other FHWA-administered financial assistance impacted by this proposed rule permit this type of flexibility.

*Executive Order 13132 (Federalism Assessment)*

The E.O. 13132 requires Agencies to ensure meaningful and timely input by State and local officials in the development of regulatory policies that may have a substantial, direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The FHWA has analyzed this proposed rule in accordance with the principles and criteria contained in E.O. 13132. The FHWA has determined that this proposed rule would not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this proposed rule would not preempt any State law or State regulation or affect the States’ ability to discharge traditional State governmental functions.

*Paperwork Reduction Act*

Federal Agencies must obtain approval from OMB for each collection of information they conduct, sponsor, or require through regulations. 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, *et seq.*).

*National Environmental Policy Act*

The FHWA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA) and has determined that it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Categorically excluded actions meet the criteria for categorical exclusions under the Council on Environmental Quality regulations and under 23 CFR 771.117(a) and normally do not require any further NEPA approvals by FHWA. This proposed rule

would clarify the applicability of FHWA regulations governing the requirements for the procurement, management, and administration of engineering and design related services that use FHWA-administered grant funding and are directly related to a construction project. The FHWA does not anticipate any adverse environmental impacts from this rule; moreover, no unusual circumstances are present under 23 CFR 771.117(b).

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this proposed action under E.O. 13175, dated November 6, 2000, and believes that this proposed action would not have substantial direct effects on one or more Indian Tribes, would not impose substantial direct compliance costs on Indian Tribal governments, and would not preempt Tribal law. This proposed rule would clarify the applicability of FHWA regulations governing the requirements for the procurement, management, and administration of engineering and design related services that use FHWA-administered grant funding and are directly related to a construction project. As such, this proposed rule would not impose any direct compliance requirements on Indian Tribal governments nor would it have any economic or other impacts on the viability of Indian Tribes. Therefore, a Tribal summary impact statement is not required.

Executive Order 12898 (Environmental Justice)

The E.O. 12898 requires that each Federal Agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. The FHWA has determined that this proposed rule does not raise any environmental justice issues.

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.

Shaile P. Bhatt, Administrator, Federal Highway Administration.

For the reasons stated in the preamble, FHWA proposes to amend title 23, Code of Federal Regulations, part 172, as follows:

PART 172—PROCUREMENT, MANAGEMENT, AND ADMINISTRATION OF ENGINEERING AND DESIGN RELATED SERVICES

1. The authority citation for part 172 is revised to read as follows:

Authority: 23 U.S.C. 106, 112, 114(a), 302, and 315; 40 U.S.C. 1101 et seq.; 48 CFR part 31; 49 CFR 1.48(b); and 2 CFR part 200.

2. Amend § 172.1 by revising the fourth sentence and adding a sentence at the end of the section. The revision and addition read as follows:

§ 172.1 Purpose and applicability.

State transportation agencies (STA) shall ensure that subrecipients comply with the requirements of this part and the Uniform Administrative Requirements, Cost Principles and Audit Requirements For Federal Awards rule. The provisions of this part shall only apply to State transportation agencies and their subrecipients.

3. Amend § 172.3 as follows:

- a. Revise the definitions for Consultant and Contracting agencies;
b. Add a definition in alphabetical order for Recipient;
c. Revise the definition of Subconsultant; and
b. Add a definition in alphabetical order for Subrecipient.

The revisions and additions read as follows:

§ 172.3 Definitions.

Consultant means the individual or firm providing engineering and design related services as a party to a contract with a recipient or subrecipient of Federal assistance.

Contracting agencies means a State transportation agency or a procuring agency of the State acting in conjunction with and at the direction of the State transportation agency and all subrecipients that are responsible for the procurement, management, and administration of engineering and design related services.

Recipient has the same meaning as defined in 2 CFR 200.1.

Subconsultant means the individual or firm contracted by a consultant to provide engineering and design related or other types of services that are part of the services which the consultant is under contract to provide to a recipient or subrecipient (as defined in of Federal assistance).

Subrecipient has the same meaning as defined in 2 CFR 200.1.

4. Amend § 172.5 by revising paragraph (a) introductory text, the third sentence of paragraph (a)(4), paragraph (b)(1) introductory text, the second and third sentences of paragraph (c) introductory text, and paragraph (c)(15) to read as follows:

§ 172.5 Program management and oversight.

(a) STA responsibilities. STAs shall develop and sustain organizational capacity and provide the resources necessary for the procurement, management, and administration of engineering and design related consultant services, reimbursed in whole or in part with FAHP funding, as specified in 23 U.S.C. 302(a). Responsibilities shall include the following:

(4) Nothing in this part shall be taken as relieving the STA of its responsibility under laws and regulations applicable to the FAHP for the work performed under any consultant agreement or contract entered into by a subrecipient.

(1) Adopting written policies and procedures prescribed by the awarding STA for the procurement, management, and administration of engineering and design related consultant services in accordance with applicable Federal and State laws and regulations; or when not prescribed, shall include:

(c) The FHWA shall approve the written policies and procedures, including all revisions to such policies and procedures, of the STA to assess compliance with applicable requirements. The STA shall approve the written policies and procedures, including all revisions to such policies and procedures, of a subrecipient to assess compliance with applicable requirements.

(15) Retaining supporting programmatic and contract records, as

specified in 2 CFR 200.334 and the requirements of this part;

■ 5. Amend § 172.7 by revising paragraph (a)(1)(iv)(F), the first sentence of paragraph (a)(1)(v)(E), paragraph (b)(1)(i), and the first sentence of paragraph (b)(5)(i) to read as follows:

§ 172.7 Procurement methods and procedures.

- (a) \* \* \*
(1) \* \* \*
(iv) \* \* \*

(F) The contracting agency shall retain supporting documentation of the solicitation, proposal, evaluation, and selection of the consultant in accordance with this section and the provisions of 2 CFR 200.334.

- (v) \* \* \*

(E) The contracting agency shall retain documentation of negotiation activities and resources used in the analysis of costs to establish elements of the contract in accordance with the provisions of 2 CFR 200.334.

\* \* \* \* \*

- (b) \* \* \*
(1) \* \* \*

(i) STAs and their subrecipients shall comply with procurement requirements established in State and local laws, regulations, policies, and procedures that are not addressed by or are not in conflict with applicable Federal laws and regulations, as specified in 2 CFR part 1201.

\* \* \* \* \*

- (5) \* \* \*

(i) When FAHP funds participate in a consultant services contract, the contracting agency shall receive approval from FHWA, or the STA, as appropriate, before utilizing a consultant to act in a management support role for the contracting agency; unless an alternate approval procedure has been approved.

\* \* \* \* \*

■ 6. Amend § 172.9 by revising paragraph (a)(3)(iv)(B)(1), paragraph (c)(1)(iv), and paragraph (d)(1)(vii) to read as follows:

§ 172.9 Contracts and administration.

- (a) \* \* \*
(3) \* \* \*
(iv) \* \* \*
(B) \* \* \*

(1) Through an additional qualifications-based selection procedure, which may include, but does not require, a formal RFP in accordance with § 172.7(a)(1)(ii); or

\* \* \* \* \*

- (c) \* \* \*
(1) \* \* \*

(iv) Access by the STA, subrecipient, FHWA, the U.S. Department of Transportation's Inspector General, the Comptroller General of the United States, or any of their duly authorized representatives to any books, documents, papers, and records of the consultant which are directly pertinent to that specific contract for the purpose of making audit, examination, excerpts, and transcriptions;

\* \* \* \* \*

- (d) \* \* \*
(1) \* \* \*

(vii) Documenting contract monitoring activities and maintaining supporting contract records, as specified in 2 CFR 200.334.

\* \* \* \* \*

■ 7. Amend § 172.11 by revising paragraph (b)(1)(iii) introductory text, the second and third sentences of paragraph (c)(2) introductory text, the second sentence of paragraph (c)(3)(i), and the second and third sentences of paragraph (d) to read as follows:

§ 172.11 Allowable costs and oversight.

\* \* \* \* \*

- (b) \* \* \*
(1) \* \* \*

(iii) When the indirect cost rate has not been established by a cognizant agency in accordance with paragraph (b)(1)(ii) of this section, the STA shall perform an evaluation of a consultant's or subconsultant's indirect cost rate prior to acceptance and application of the rate to contracts administered by the STA or its subrecipients. The evaluation performed by STAs to establish or accept an indirect cost rate shall provide assurance of compliance with the Federal cost principles and may consist of one or more of the following:

\* \* \* \* \*

- (c) \* \* \*
(2) \* \* \*

An STA may employ a risk-based oversight process to provide reasonable assurance of consultant compliance with Federal cost principles on FAHP funded contracts administered by the STA or its subrecipients. If employed, this risk-based oversight process shall be incorporated into STA written policies and procedures, as specified in § 172.5(c).

\* \* \* \* \*

- (3) \* \* \*
(i) \* \* \*

The certification requirement shall apply to all indirect cost rate proposals submitted by consultants and subconsultants for acceptance by an STA.

\* \* \* \* \*

- (d) \* \* \*

FHWA, STAs, and subrecipients of FAHP funds may share audit information in complying with the

STA's or subrecipient's acceptance of a consultant's indirect cost rates pursuant to 23 U.S.C. 112 and this part provided that the consultant is given notice of each use and transfer. Audit information shall not be provided to other consultants or any other government agency not sharing the cost data, or to any firm or government agency for purposes other than complying with the STA's or subrecipient's acceptance of a consultant's indirect cost rates pursuant to 23 U.S.C. 112 and this part without the written permission of the affected consultants.

[FR Doc. 2024-01705 Filed 1-29-24; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC-2020-0024]

42 CFR Part 73

RIN 0920-AA71

Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: In accordance with the Public Health Service Act, the Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) reviewed the HHS list of select agents and toxins with the potential to pose a severe threat to public health and safety. HHS/CDC proposes to amend the list by removing three biological agents, raising one toxin's exclusion amounts, renaming a virus, designating a current agent as a Tier 1 agent, and removing the designation of Tier 1 status from one agent. HHS/CDC also proposes to clarify language and add requirements as discussed below.

DATES: Submit written or electronic comments by April 1, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0024 or Regulation Identifier Number (RIN) 0920-AA71, by any of the following methods:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments.
Mail: Division of Regulatory Science and Compliance, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21-4,