following performance characteristics must be demonstrated:

(i) Ability of the device to detect diurnal changes.

(ii) Tolerability of the system at the corneoscleral interface in the intended use population.

(2) Nonclinical testing must validate measurements in an appropriate nonclinical testing model to ensure ability to detect changes in intraocular pressure.

(3) Patient-contacting components must be demonstrated to be biocompatible.

(4) Any component that is intended to contact the eye must be demonstrated to be sterile throughout its intended shelf life.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Performance testing must demonstrate the electromagnetic compatibility and electromagnetic interference of the device.

(7) Performance testing must demonstrate electrical safety of the device.

(8) Labeling must include the following:

(i) Warning against activities and environments that may put the user at greater risk.

(ii) Specific instructions for the safe use of the device, which includes:

(A) Description of all device components and instructions for assembling the device;

(B) Explanations of all available programs and instructions for their use;

(C) Instructions and explanation of all user-interface components;

(D) Instructions on all safety features of the device; and

(E) Instructions for properly maintaining the device.

(iii) A summary of nonclinical testing information to describe EMC safety considerations.

(iv) A summary of safety information obtained from clinical testing.

(v) Patient labeling to convey information regarding appropriate use of device.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12683 Filed 5–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 771

Federal Transit Administration

49 CFR Part 622

[Docket No. FHWA–2016–0008]

RIN 2125–AF69; 2132–AB29

Categorical Exclusions

AGENCY: Federal Highway Administration (FHWA), Federal Transit Administration (FTA), DOT.

ACTION: Final rule.

SUMMARY: This final rule amends FHWA and FTA categorical exclusions (CE) for projects receiving limited Federal assistance to reflect a requirement in the Fixing America's Surface Transportation (FAST) Act to index for inflation the monetary thresholds for these CEs. This final rule also implements a provision in the FAST Act that directs FHWA to amend its rules on programmatic agreements for CEs. The amendments contained in this rule reflect statutory language in the FAST Act.

DATES: Effective on June 30, 2016.

FOR FURTHER INFORMATION CONTACT: For the Federal Highway Administration: Owen Lindauer, Ph.D., Office of Project Delivery and Environmental Review, HEPE, (202) 366–2655, *Owen.Lindauer@dot.gov,* or Jennifer Mayo, Office of the Chief Counsel, (202) 366–1523, *Jennifer.Mayo@dot.gov.* For FTA: Megan Blum, Office of Planning and Environment, (202) 366–0463, *Megan.Blum@dot.gov,* or Nancy-Ellen Zusman, Office of Chief Counsel, (312) 353–2577, *NancyEllen.Zusman@dot.gov.* The FHWA and FTA are both located at 1200 New Jersey Ave. SE., Washington, DC 20590–0001. Office hours are from 8:00 a.m. to 4:30 p.m. E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

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Background

On December 4, 2015, President Obama signed into law the FAST Act, Public Law 114–94, 129 Stat. 1312, which contains new requirements that FHWA and FTA (hereafter referred to as ''the Agencies'') must meet in complying with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*). Section 1314(a) of the FAST Act amends section 1317 of the Moving Ahead for Progress in the 21st Century Act (MAP–21), Public Law 112–141, 126 Stat. 405, by inserting ''(as adjusted annually by the Secretary to reflect any increases in the Consumer Price Index prepared by the Department of Labor)'' after ''$5,000,000'' in paragraph (1)(A) and after ''$30,000,000'' in paragraph (1)(B) of the CE for projects receiving limited Federal financial assistance. The Agencies relied on the authority in MAP–21, section 1317 to establish limited Federal financial assistance CEs for FHWA at 23 CFR 771.117(c)(23) and for FTA at 23 CFR 771.118(c)(13). Those CEs were published in a final rule in the **Federal Register** on January 13, 2014 (79 FR 2107). With this final rule, the Agencies are amending the limited Federal financial assistance CEs to incorporate the adjustment for inflation requirement created by the FAST Act.

The Agencies included a reference to their respective Web sites (*www.fhwa.dot.gov* and *www.fta.dot.gov*) in the CE language in order to provide a source for locating the consumer price index (CPI), as adjusted annually. Per the FAST Act, section 1314(b), the first adjustment made pursuant to section 1314(a) must reflect the increase in the CPI since July 1, 2012. The Agencies divided the November 2015 CPI figure (237.336)—the latest data from the Department of Labor—by the July 2012 CPI figure (229.104), and multiplied the product (1.0359) by $5,000,000. The resulting value is $5,179,656.40, which is the $5 million limit found in sections 771.117(c)(23)(i) and 771.118(c)(13)(i) after adjusting for inflation, and should be considered when applying the limited Federal financial assistance CE to projects during the 2016 calendar year. Similarly, to determine the inflation figure for subparagraph (ii) under sections 771.117(c)(23) and 771.118(c)(13), the Agencies multiplied 1.0359 by $30,000,000 with the following result: $31,077,938.44. These figures ($5,179,656.40 and $31,077,938.44) are posted on the Agencies' Web sites and will be updated annually in January of subsequent years. Posting these figures also complies with

section 1314(b)(1) which requires providing the first adjustment ''not later than 60 days after the date of enactment of [the FAST] Act.''

Section 1315(b) requires FHWA to revise its CE regulation on programmatic agreements. Specifically, FHWA must revise 23 CFR 771.117(g) to allow a State Department of Transportation (State DOT) to make a CE determination on behalf of FHWA. The revision must clarify that the authority under such agreements may include the responsibility to make CE determinations for actions described in 23 CFR 771.117(c)–(d) that meet the criteria for a CE under 40 CFR 1508.4 (the President's Council on Environmental Quality's Regulations for Implementing the Procedural Provisions of NEPA) and are identified in the programmatic agreement.

This rulemaking adopts the language used in FAST Act section 1315(b) with two minor changes to retain the style used throughout the regulation: FHWA uses the abbreviation ''CE'' instead of ''categorical exclusion'' and ''40 CFR 1508.4'' instead of the statutory language of ''section 1508.4 of title 40, Code of Federal Regulations.'' The rule set forth below incorporates the new phrase ''and that meet the criteria for a CE under 40 CFR 1508.4, and are identified in the programmatic agreement'' into the otherwise existing regulatory language in 23 CFR 771.117(g). The FHWA reprints below the paragraph 771.117(g) to show how the statutory language is incorporated into the paragraph as a whole.

The Agencies have determined that a final rule is appropriate in this instance because the language in the FAST Act is clear and does not require interpretive text. Therefore the amendments to 23 CFR 771.117(c)(23), 23 CFR 771.118(c)(13), and 23 CFR 771.117(g) follow the statutory language without substantive modification.

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment procedure if it finds, for good cause, that it would be impracticable, unnecessary, or contrary to the public interest. The Agencies find good cause as notice and comment for this rule would be unnecessary due to the nature of the revisions (*i.e.,* the rule simply incorporates the statutory language found in sections 1315(b) and 1314 of FAST without interpretation). The statutory language does not require regulatory interpretation to carry out its intent. The regulatory amendments in this final rule incorporate the statutory language, and comments cannot alter the regulation given the explicit mandate. Accordingly, the Agencies find good cause under 5 U.S.C. 553(b)(3)(B) to waive notice and opportunity for comment.

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 Agencies have determined this action is not 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. Since this rulemaking implements a congressional mandate to allow States to make a CE determination on behalf of FHWA in specific instances and to adjust existing monetary-based CEs for inflation, the Agencies anticipate that the economic impact of this rulemaking would be minimal. This final rule will not adversely affect, in a material way, any sector of the economy. Additionally, this action complies with the principles of Executive Order 13563. In addition, these changes will 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. Consequently, a full regulatory evaluation is not required.

Regulatory Flexibility Act

Since the Agencies find good cause under 5 U.S.C. 553(b)(3)(B) to waive notice and opportunity for comment for this rule, the provisions of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612) do not apply. However, the Agencies evaluated the effects of this action on small entities and determined the action would not have a significant economic impact on a substantial number of small entities. This final rule will not make any substantive changes to the Agencies' regulations or in the way that the Agencies' regulations affect small entities; it merely incorporates statutory text. For this reason, the Agencies certify that this action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This final rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48, March 22, 1995) as it will not result in the expenditure by State, local, tribal governments, in the aggregate, or by the private sector, of $155 million or more in any one year (2 U.S.C. 1532).

Executive Order 13132 (Federalism Assessment)

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

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. The Agencies analyzed this final rule under the PRA and determined this rule does not contain collection of information requirements for the purposes of the PRA.

National Environmental Policy Act

Agencies are required to adopt implementing procedures for NEPA that establish specific criteria for, and identification of, three classes of actions: Those that normally require preparation of an Environmental Impact Statement; those that normally require preparation of an Environmental Assessment; and those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). The CEQ regulations do not direct agencies to prepare a NEPA analysis or document before establishing Agency procedures (such as this regulation) that supplement the CEQ regulations for implementing NEPA. The changes

proposed in this rule are part of those agency procedures, and therefore establishing the proposed changes does not require preparation of a NEPA analysis or document. Agency NEPA procedures are generally procedural guidance to assist agencies in the fulfillment of agency responsibilities under NEPA, but are not the agency's final determination of what level of NEPA analysis is required for a particular proposed action. The requirements for establishing agency NEPA procedures are set forth at 40 CFR 1505.1 and 1507.3.

Executive Order 12898 (Environmental Justice)

Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, and DOT Order 5610.2(a), 77 FR 27534 (May 10, 2012) (available online at *www.fhwa.dot.gov/environment/environmental_justice/ej_at_dot/order_56102a/index.cfm*), require DOT agencies to achieve environmental justice (EJ) as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects, of their programs, policies, and activities on minority populations and low-income populations in the United States. The DOT Order requires DOT agencies to address compliance with the Executive Order and the DOT Order in all rulemaking activities. In addition, the Agencies have issued additional documents relating to administration of the Executive Order and the DOT Order. On June 14, 2012, FHWA issued an update to its EJ order, FHWA Order 6640.23A, FHWA Actions to Address Environmental Justice in Minority Populations and Low Income Populations (available online at *www.fhwa.dot.gov/legsregs/directives/orders/664023a.cfm*). The FTA also issued an update to its EJ policy, FTA Policy Guidance for Federal Transit Recipients, 77 FR 42077 (July 17, 2012) (available online at *http://www.fta.dot.gov/legislation_law/12349_14740.html*).

The Agencies have evaluated this final rule under the Executive Order, the DOT Order, the FHWA Order, and FTA Policy Guidance. They determined that the amendment would not cause disproportionately high and adverse human health and environmental effects on minority or low income populations.

At the time the Agencies apply the NEPA implementing procedures in 23 CFR part 771, they would have an independent obligation to conduct an evaluation of the proposed action under the applicable EJ orders and guidance to determine whether the proposed action has the potential for EJ effects. The rule would not affect the scope or outcome of that EJ evaluation. In any instance where there are potential EJ effects resulting from a proposed Agency action covered under any of the NEPA classes of action in 23 CFR part 771, public outreach under the applicable EJ orders and guidance would provide affected populations with the opportunity to raise any concerns about those potential EJ effects. *See* DOT Order 5610.2(a), FHWA Order 6640.23A, and FTA Policy Guidance for Transit Recipients (available at links above). Indeed, outreach to ensure the effective involvement of minority and low income populations where there is potential for EJ effects is a core aspect of the EJ orders and guidance. For these reasons, the Agencies have determined that no further EJ analysis is needed and no mitigation is required in connection with the proposed revisions to the Agencies' NEPA regulations (23 CFR parts 771).

Executive Order 12630 (Taking of Private Property)

The Agencies have analyzed this final rule under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. The Agencies found this final 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)

The Agencies analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. The Agencies certify that this action would not cause an environmental risk to health or safety that might disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

The Agencies have analyzed this action under Executive Order 13175, dated November 6, 2000, and determined the action 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. This final rule addresses obligations of Federal funds to States for Federal-aid highway projects and Federal funds to transit agencies for Federal public transportation 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 Agencies have analyzed this action under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agencies determined this rule is not a significant energy action under that order since it is not a significant regulatory action under Executive Order 12866 and is not likely to 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 771

Categorical exclusions, Environmental review process, Environmental protection, Grant programs—transportation, Highways and roads, Programmatic approaches, Reporting and recordkeeping requirements.

49 CFR Part 622

Categorical exclusions, Environmental review process, Environmental protection, Grant programs—transportation, Public transportation, Transit.

Issued on: May 20, 2016.

Gregory G. Nadeau,

Federal Highway Administrator.

Carolyn Flowers,

Acting Administrator, Federal Transit Administration.

In consideration of the foregoing, the Agencies amend title 23, Code of

Federal Regulations part 771, and title 49, Code of Federal Regulations part 662, as follows:

TITLE 23—Highways

PART 771—ENVIRONMENTAL IMPACT AND RELATED PROCEDURES

■ 1. Revise the authority citation for part 771 to read as follows:

Authority: 42 U.S.C. 4321 *et seq.;* 23 U.S.C. 106, 109, 128, 138, 139, 315, 325, 326, and 327; 49 U.S.C. 303; 40 CFR parts 1500–1508; 49 CFR 1.81, 1.85, and 1.91; Pub. L. 109–59, 119 Stat. 1144, Sections 6002 and 6010; Pub. L. 112–141, 126 Stat. 405, Sections 1315, 1316, 1317, 1318, and 1319; Pub. L. 114–94, 129 Stat. 1312, Sections 1314 and 1315.

■ 2. Revise § 771.117(c)(23) and (g) introductory text to read as follows:

§ 771.117 FHWA categorical exclusions.

* * * * *

(c) * * *

(23) Federally-funded projects:

(i) That receive less than $5,000,000 (as adjusted annually by the Secretary to reflect any increases in the Consumer Price Index prepared by the Department of Labor, see *www.fhwa.dot.gov* or *www.fta.dot.gov*) of Federal funds; or

(ii) With a total estimated cost of not more than $30,000,000 (as adjusted annually by the Secretary to reflect any increases in the Consumer Price Index prepared by the Department of Labor, see *www.fhwa.dot.gov* or *www.fta.dot.gov*) and Federal funds comprising less than 15 percent of the total estimated project cost.

* * * * *

(g) FHWA may enter into programmatic agreements with a State to allow a State DOT to make a NEPA CE certification or determination and approval on FHWA's behalf, for CEs specifically listed in paragraphs (c) and (d) of this section and that meet the criteria for a CE under 40 CFR 1508.4, and are identified in the programmatic agreement. Such agreements must be subject to the following conditions:

* * * * *

■ 3. Revise § 771.118(c)(13) to read as follows:

§ 771.118 FTA categorical exclusions.

* * * * *

(c) * * *

(13) Federally-funded projects:

(i) That receive less than $5,000,000 (as adjusted annually by the Secretary to reflect any increases in the Consumer Price Index prepared by the Department of Labor, see *www.fhwa.dot.gov* or *www.fta.dot.gov*) of Federal funds; or

(ii) With a total estimated cost of not more than $30,000,000 (as adjusted annually by the Secretary to reflect any increases in the Consumer Price Index prepared by the Department of Labor, see *www.fhwa.dot.gov* or *www.fta.dot.gov*) and Federal funds comprising less than 15 percent of the total estimated project cost.

* * * * *

TITLE 49—Transportation

PART 622—ENVIRONMENTAL IMPACT AND RELATED PROCEDURES

■ 4. Revise the authority citation for part 622 to read as follows:

Authority: 42 U.S.C. 4321 *et seq.;* 49 U.S.C. 303 and 5323(q); 23 U.S.C. 139 and 326; Pub. L. 109–59, 119 Stat. 1144, Sections 6002 and 6010; 40 CFR parts 1500–1508; 49 CFR 1.81; Pub. L. 112–141, 126 Stat. 405, Sections 1315, 1316, 1317, 1318, and 1319; and Pub. L. 114–94, 129 Stat. 1312, Section 1314.

[FR Doc. 2016–12577 Filed 5–27–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

30 CFR Part 556

[Docket ID: BOEM–2016–0031]

RIN 1010–AD06

Leasing of Sulfur or Oil and Gas in the Outer Continental Shelf; Correction MMAA104000

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Final rule; correction.

SUMMARY: On March 30, 2016, the Bureau of Ocean Energy Management (BOEM) published in the **Federal Register** a final rule that updates and streamlines the Outer Continental Shelf (OCS) oil and gas and sulfur leasing regulations, which will become effective on May 31, 2016 (81 FR 18111) (''Leasing Rule''). One of the regulations contained in the final rule was incorrectly stated. This document corrects that error

DATES: This correction is effective on May 31, 2016.

FOR FURTHER INFORMATION CONTACT: Robert Sebastian, Office of Policy, Regulation and Analysis at (504) 736–2761 or email at *robert.sebastian@boem.gov*.

SUPPLEMENTARY INFORMATION:

Need for Correction

BOEM has the authority, under certain conditions, to disqualify a party from acquiring a lease or an interest in a lease on the Outer Continental Shelf (OCS). The title, as well as the verbiage, of § 556.403 in the final Leasing Rule, states that BOEM may disqualify entities from ''holding,'' a lease or lease interest on the OCS. This could be interpreted to imply that BOEM would not allow a disqualified party to retain a pre-existing OCS lease interest. That interpretation is incorrect. Disqualified entities may not acquire new leases or lease interests, but they may continue to hold existing leases or lease interests. BOEM is correcting the wording of § 556.403 to avoid the implication that the use of the word ''hold'' might authorize BOEM, under the conditions stated in § 556.403, to require forfeiture of leases already acquired. The final rule was issued under Docket ID: MMS–2007–OMM–0069, which has expired and is no longer accessible. Therefore, BOEM is utilizing a new Docket ID for this correction (BOEM–2016–0031).

Procedural Requirements

Section V, Legal and Regulatory Analyses, of the final rule issued on March 30, 2016 (81 FR 18145), summarizes BOEM's analyses of that rule pursuant to applicable statutes and executive orders. This amendment does not change the conclusions described in that section because the amendment conforms the regulatory text to BOEM's intent in the final rule, as then analyzed. Therefore, no additional analysis is necessary.

The Administrative Procedure Act, 5 U.S.C. 553(b), provides that, when an agency for good cause finds that ''notice and public procedure . . . are impracticable, unnecessary, or contrary to the public interest,'' the agency may issue a rule without providing notice and an opportunity for prior public comment. To the extent this rule has substantive effects, it is to relieve regulated parties from sanctions. It does not require any party to change its conduct, and it does not change the rights of any party affected by the final rule. Therefore, BOEM believes that the public would not be interested in commenting on this correction, and thus notice and comment are unnecessary. Moreover, if BOEM were to first publish a proposed rule, allow the public sufficient time to submit comments, analyze the comments, and then publish a final rule, it would not be possible to correct this error and make it effective on the same day as the earlier final rule, May 31, 2016. Accordingly, notice and comment is impracticable. For these reasons, BOEM finds that soliciting public comment is unnecessary and impracticable and that there is good