

(ix) A limitation statement that detection of a genomic drug resistance mutation may not correlate with phenotypic gene expression.

(x) A limitation statement that the test does not detect all genetic mutations associated with antiviral drugs.

(xi) A limitation statement listing the HIV types for which the test is not intended, if any.

(3) Device verification and validation must include:

(i) Design of primer sequences and rationale for sequence selection.

(ii) Computational path from collected raw data to reported result.

(iii) Detailed documentation of analytical studies including, but not limited to, characterization of the cutoff, analytical sensitivity, inclusivity, reproducibility, interference, cross reactivity, instrument and method carryover/cross contamination, sample stability, and handling for all genomic mutations claimed in the intended use.

(iv) Precision studies that include all genomic mutations claimed in the intended use.

(v) Detailed documentation of a multisite clinical study evaluating the sensitivity and specificity of the device. Clinical study subjects must represent the intended use population and device results for all targets claimed in the intended use must be compared to Sanger sequencing or other methods found acceptable by FDA. Drug resistance-associated mutations at or above the 20 percent frequency level must detect the mutations in greater than 90 percent of at least 10 replicates, for each of drug class evaluated.

(vi) Documentation that variant calling is performed at a level of coverage that supports positive detection of all genomic mutations claimed in the intended use.

(vii) Detailed documentation of limit of detection (LoD) studies in which device performance is evaluated by testing a minimum of 100 HIV-positive clinical samples including samples with analyte concentrations near the clinical decision points and near the LoD.

(A) The LoD for the device must be determined using a minimum of 10 HIV-1 group M genotypes if applicable. A detection rate at $1 \times$ LoD greater than or equal to 95 percent must be demonstrated for mutations with a frequency greater than 20 percent.

(B) The LoD of genetic mutations at frequency levels less than 20 percent must be established.

(viii) A predefined HIV genotyping bioinformatics analysis pipeline (BAP). The BAP must adequately describe the bioinformatic analysis of the sequencing data, including but not limited to read

alignment, variant calling, assembly, genotyping, quality control, and final result reporting.

(ix) A clear description of the selection and use of the standardized database that is used for sequence comparison and results derivation.

(4) Premarket notification submissions must include the information in paragraphs (b)(3)(i) through (ix) of this section.

Dated: January 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-01725 Filed 2-6-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

30 CFR Parts 550 and 553

[Docket ID: BOEM-2019-0079]

RIN 1010-AE05

2020 Civil Penalties Inflation Adjustments for Oil, Gas, and Sulfur Operations in the Outer Continental Shelf

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Final rule.

SUMMARY: This final rule implements the 2020 inflation adjustments to the maximum daily civil monetary penalties contained in the Bureau of Ocean Energy Management (BOEM) regulations for violations of the Outer Continental Shelf Lands Act (OCSLA) and the Oil Pollution Act of 1990 (OPA), pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (FCPIA Improvements Act) and relevant Office of Management and Budget (OMB) guidance. The 2020 adjustment multiplier of 1.01764 accounts for one year of inflation from October 2018 through October 2019.

DATES: This rule is effective on February 7, 2020.

FOR FURTHER INFORMATION CONTACT: Deanna Meyer-Pietruszka, Chief, Office of Policy, Regulation, and Analysis, Bureau of Ocean Energy Management, at (202) 208-6352 or by email at deanna.meyer-pietruszka@boem.gov.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

II. Background

III. Calculation of 2020 Adjustments

IV. Procedural Requirements

A. Statutes

1. National Environmental Policy Act

2. Regulatory Flexibility Act

3. Paperwork Reduction Act

4. Unfunded Mandates Reform Act

5. Small Business Regulatory Enforcement Fairness Act

6. Congressional Review Act

B. Executive Orders (E.O.)

1. Governmental Actions and Interference With Constitutionally Protected Property Rights (E.O. 12630)

2. Regulatory Planning and Review (E.O. 12866); Improving Regulation and Regulatory Review (E.O. 13563); and Reducing Regulation and Controlling Regulatory Costs (E.O. 13771)

3. Civil Justice Reform (E.O. 12988)

4. Federalism (E.O. 13132)

5. Consultation and Coordination With Indian Tribal Governments (E.O. 13175)

6. Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)

I. Legal Authority

OCSLA authorizes the Secretary of the Interior to impose a daily civil monetary penalty for a violation of OCSLA or its regulations, leases, permits, or orders and directs the Secretary to adjust the maximum penalty at least every three years to reflect any inflation increase in the Consumer Price Index. 43 U.S.C. 1350(b)(1). Similarly, OPA authorizes civil monetary penalties for failure to comply with OPA's financial responsibility provisions or its implementing regulations. 33 U.S.C. 2716a(a). OPA does not include a maximum daily civil penalty inflation adjustment provision. Id.

The FCPIA Improvements Act¹ requires that Federal agencies publish inflation adjustments to their civil monetary penalties in the **Federal Register** not later than January 15 annually.² Public Law 114-74, sec. 701(b)(1). The purposes behind these inflation adjustments are to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes. Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101-410, sec. 2 (codified at 28 U.S.C. 2461 note).

II. Background

BOEM implemented the 2019 inflation adjustment for its civil monetary penalties through a final rule published in the **Federal Register** on March 26, 2019, which accounted for

¹ The FCPIA Improvements Act amended the Federal Civil Penalties Inflation Adjustment Act of 1990. Public Law 101-410 (codified at 28 U.S.C. 2461 note).

² Under the FCPIA Improvements Act, Federal agencies were required to adjust their civil monetary penalties for inflation with an initial "catch-up" adjustment through an interim final rulemaking in 2016 and are required to make subsequent inflation adjustments not later than January 15 annually, beginning in 2017. Public Law 114-74, sec. 701(b)(1).

inflation through October 2018. Oil and Gas and Sulfur Operations in the Outer Continental Shelf-Civil Penalties Inflation Adjustments, 84 FR 11,222 (Mar. 26, 2019).³

For 2020, OMB issued guidance that explains agency statutory responsibilities for identifying applicable civil monetary penalties and performing the annual adjustment; publishing revisions to regulations to implement the adjustment in the **Federal Register**; applying adjusted penalty levels; and performing agency oversight of inflation adjustments. Implementation of Penalty Inflation Adjustments for 2020, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, OMB Memorandum M–20–05, December 16, 2019 (OMB M–20–05), available at <https://www.whitehouse.gov/wp-content/uploads/2019/12/M-20-05.pdf>.

BOEM is implementing the 2020 inflation adjustments to the OCSLA and OPA maximum daily civil monetary penalties through this final rule pursuant to the FCPIA Improvements Act and OMB M–20–05. A proposed

rule is unnecessary. The FCPIA Improvements Act expressly exempts annual civil penalty inflation adjustments from the Administrative Procedure Act's (APA) notice of proposed rulemaking, public comment, and standard effective date provisions. FCPIA Improvements Act, Public Law 114–74, sec. 701(b)(1)(D); APA, 5 U.S.C. 553.⁴

III. Calculation of 2020 Adjustments

OMB issued guidance to Federal agencies on implementing the 2020 annual civil monetary penalties inflation adjustments, including the adjustment multiplier: 1.01764. OMB M–20–05; FCPIA Improvements Act, sec. 701(b)(4).⁵ In accordance with the FCPIA Improvements Act and OMB M–20–05, BOEM determined that the OCSLA and OPA maximum daily civil monetary penalties require annual inflation adjustments and is issuing this final rule adjusting those penalty amounts for inflation through October 2019.

For 2020, BOEM multiplied the current OCSLA maximum daily civil penalty of \$44,675 by the multiplier

1.01764 to equal \$45,463.07 rounded to nearest cent ($\$44,675 \times 1.01764 = \$45,463.07$). The FCPIA Improvements Act requires the resulting amount be rounded to the nearest dollar.

Accordingly, the 2020 adjusted OCSLA maximum daily civil penalty is \$45,463.

For 2020, BOEM multiplied the current OPA maximum daily civil penalty amount of \$47,357 by the multiplier 1.01764 to equal \$48,192.38 rounded to nearest cent ($\$47,357 \times 1.01764 = \$48,192.38$). The FCPIA Improvements Act requires that the resulting amount be rounded to the nearest dollar. Accordingly, the 2020 adjusted OPA maximum daily civil penalty is \$48,192.

The adjusted penalty amounts take effect immediately upon publication of this rule. Under the FCPIA Improvements Act, the adjusted amounts apply to civil penalties assessed after the date the increase takes effect, even if the associated violation predates the increase.

This table summarizes BOEM's 2020 maximum daily civil monetary penalties for each OCSLA and OPA violation:

CFR citation	Description of the penalty	Current maximum penalty	Multiplier	Adjusted maximum penalty
30 CFR 550.1403 (OCSLA)	Failure to comply per day per violation	\$44,675	1.01764	\$45,463
30 CFR 553.51(a) (OPA)	Failure to comply per day per violation	\$47,357	1.01764	48,192

IV. Procedural Requirement

A. Statutes

1. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) is not required because, as a regulation of an administrative nature, this rule is covered by a categorical exclusion. See 43 CFR 46.210(i). BOEM also has determined that the rule does not implicate any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA. Therefore, a detailed statement under NEPA is not required.

2. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, 5 U.S.C. 601 *et seq.*) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). The FCPIA Improvements Act expressly exempts these annual inflation adjustments from the requirement to publish a proposed rule for notice and comment. FCPIA Improvements Act, Public Law 114–74, sec. 701(b)(1)(D); OMB M–20–05 at 4. Thus, the RFA does not apply to this rulemaking.

3. Paperwork Reduction Act

This rule does not contain information collection requirements, and, therefore, a submission to OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required.

4. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on state, local, or tribal governments, or the private sector, of more than \$164 million per year. The rule does not have a significant or unique effect on state, local, or tribal governments or the private sector. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

³ The delayed publication resulted from a lapse of Federal government funding from December 22, 2018, until January 25, 2019. 84 FR 11,222, 11,222 (Mar. 26, 2019).

⁴ Specifically, Congress directed that agencies adjust civil monetary penalties “notwithstanding section 553 of title 5, United States Code [Administrative Procedure Act (APA)],” which generally requires prior notice of proposed rulemaking, opportunity for public comment on

proposed rulemaking, and publication of a final rule at least 30 days before its effective date. FCPIA Improvements Act, sec. 4(b)(2); APA, 5 U.S.C. 553. OMB confirmed this interpretation of the FCPIA Improvements Act. OMB M–20–05 at 4 (“This means that the public procedure the APA generally requires—notice, an opportunity for comment, and a delay in effective date—is not required for agencies to issue regulations implementing the annual adjustment.”).

⁵ The annual inflation adjustment is based on the percent change between the Consumer Price Index for All Urban Consumers (CPI-U) for the October preceding the date of the adjustment and the prior year's October CPI-U. Consistent with OMB M–20–05, the 2020 multiplier can be calculated by dividing the October 2019 CPI-U by the October 2018 CPI-U. In this case, October 2019 CPI-U (257.346)/October 2018 CPI-U (252.885) = 1.01764.

5. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2). This rule:

- (a) Will not have an annual effect on the economy of \$100 million or more;
- (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and
- (c) Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

6. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*) and OMB guidance,⁶ the Office of Information and Regulatory Affairs (OIRA) designated this rule as not a major rule as defined by that act.⁷ Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, *Fall 2019 Unified Agenda of Regulatory and Deregulatory Actions*, Dep't of the Interior, RIN 1010-AE03 (note the RIN for this rule is listed in error, the correct RIN is 1010-AE05), available at <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=1010-AE03>.

B. Executive Orders (E.O.)

1. Governmental Actions and Interference with Constitutionally Protected Property Rights (E.O. 12630)

This rule does not effect a taking of private property or otherwise have takings implications under E.O. 12630. Therefore, a takings implication assessment is not required.

2. Regulatory Planning and Review (E.O. 12866); Improving Regulation and Regulatory Review (E.O. 13563); and Reducing Regulation and Controlling Regulatory Costs (E.O. 13771)

E.O. 12866 provides that OIRA will review all significant rules. OIRA has determined that this rule is not significant. See OMB M-20-05 at 3.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to reduce uncertainty and to promote predictability and the use of the best, most innovative, and least burdensome tools for achieving regulatory ends. E.O. 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of

choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 further emphasizes that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. However, there is no science being used in this rulemaking, as Congress directed agencies to adjust the maximum daily civil penalty amounts using a particular equation and BOEM does not have discretion to use any other factor in the adjustment. BOEM has developed this rule in a manner consistent with these requirements, to the extent relevant and feasible given the limited discretion provided agencies under the FCPIA Improvements Act.

E.O. 13771 directs Federal agencies to reduce the regulatory burden on regulated entities and control regulatory costs. E.O. 13771, however, applies only to significant regulatory actions, as defined in section 3(f) of E.O. 12866. OIRA has determined this rule is not significant. This final rule exclusively implements the annual inflation adjustments consistent with OMB's guidance and its determination that this rule is not a significant regulatory action. OMB M-20-05 at 3. Thus, this rule is not considered an E.O. 13771 regulatory action. *Id.*

3. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

- (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and
- (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

4. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. To the extent State and local governments have a role in outer continental shelf activities, this rule will not affect that role. Therefore, a federalism summary impact statement is not required.

5. Consultation and Coordination With Indian Tribal Governments (E.O. 13175)

The Department of the Interior and BOEM strive to strengthen their government-to-government relationships with Indian tribes through

a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. BOEM has evaluated this rule under the Department of the Interior's consultation policy, under Departmental Manual part 512, chapters 4 and 5, and under the criteria in E.O. 13175. BOEM has determined that this rule has no substantial direct effects on Federally-recognized Indian tribes or Alaska Native Claims Settlement Act (ANCSA) Corporations, and that consultation under the Department of the Interior's and BOEM's tribal and ANCSA consultation policies is not required.

6. Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. Therefore, a Statement of Energy Effects is not required.

List of Subjects

30 CFR Part 550

Administrative practice and procedure, Continental shelf, Environmental impact statements, Environmental protection, Federal lands, Government contracts, Investigations, Mineral resources, Oil and gas exploration, Outer continental shelf, Penalties, Pipelines, Reporting and recordkeeping requirements, Rights-of-way, Sulfur.

30 CFR Part 553

Administrative practice and procedure, Continental shelf, Financial responsibility, Liability, Limit of liability, Oil and gas exploration, Oil pollution, Outer continental shelf, Penalties, Pipelines, Reporting and recordkeeping requirements, Rights-of-way, Surety bonds, Treasury securities.

Dated: January 28, 2020.

Casey Hammond,

Acting Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, BOEM amends title 30, chapter V, subchapter B, parts 550 and 553 of the Code of Federal Regulations as follows:

PART 550—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

- 1. The authority citation for part 550 continues to read as follows:

Authority: 30 U.S.C. 1751; 31 U.S.C. 9701; 43 U.S.C. 1334.

- 2. Revise § 550.1403 to read as follows:

⁶ Office of Mgmt. & Budget, Exec. Office of the President, OMB M-19-14, Guidance on Compliance with the Congressional Review Act (2019).

⁷ 5 U.S.C. 804(2).

§ 550.1403 What is the maximum civil penalty?

The maximum civil penalty is \$45,463 per day per violation.

PART 553—OIL SPILL FINANCIAL RESPONSIBILITY FOR OFFSHORE FACILITIES

■ 3. The authority citation for part 553 continues to read as follows:

Authority: 33 U.S.C. 2704, 2716; E.O. 12777, as amended.

■ 4. Revise § 553.51(a) to read as follows:

§ 553.51 What are the penalties for not complying with this part?

(a) If you fail to comply with the financial responsibility requirements of OPA at 33 U.S.C. 2716 or with the requirements of this part, then you may be liable for a civil penalty of up to \$48,192 per COF per day of violation (that is, each day a COF is operated without acceptable evidence of OSFR).

* * * * *

[FR Doc. 2020-02059 Filed 2-6-20; 8:45 am]

BILLING CODE 4310-MR-P

DEPARTMENT OF THE INTERIOR**Office of Natural Resources Revenue****30 CFR Part 1241**

[Docket No. ONRR-2017-0003; DS63644000 DRT000000.CH7000 201D1113RT]

RIN 1012-AA25

Inflation Adjustments to Civil Monetary Penalty Rates for Calendar Year 2020

AGENCY: Office of the Secretary, Office of Natural Resources Revenue, Interior.

ACTION: Final rule.

SUMMARY: The Office of Natural Resources Revenue (ONRR) publishes this final rule to increase our maximum civil monetary penalty (CMP) rates for inflation occurring between October 2018 and October 2019.

DATES: This rule is effective on February 7, 2020.

FOR FURTHER INFORMATION CONTACT: For questions on procedural issues, contact Luis Aguilar, Regulatory Specialist, by telephone at (303) 231-3418 or email to Luis.Aguilar@onrr.gov. For questions on technical issues, contact Michael Marchetti, Chief of Enforcement, by telephone at (303) 231-3125 or email to Michael.Marchetti@onrr.gov. You may obtain a paper copy of this rule by contacting Mr. Aguilar by phone or email.

SUPPLEMENTARY INFORMATION:**I. Background****II. Inflation-Adjusted Maximum Rates****III. Procedural Requirements**

A. Regulatory Planning and Review (E.O. 12866)

B. Regulatory Flexibility Act

C. Small Business Regulatory Enforcement Fairness Act

D. Unfunded Mandates Reform Act

E. Takings (E.O. 12630)

F. Federalism (E.O. 13132)

G. Civil Justice Reform (E.O. 12988)

H. Consultation With Indian Tribes (E.O. 13175)

I. Paperwork Reduction Act

J. National Environmental Policy Act

K. Effects on the Energy Supply (E.O. 13211)

L. Clarity of This Regulation

M. Administrative Procedure Act

I. Background

The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by

the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (collectively, “the Act”), codified at 28 U.S.C. 2461 (specifically, see the notes for more information), requires Federal agencies to adjust their civil monetary penalty (CMP) rates for inflation every year.

In accordance with sections 4 and 5 of the Act, the annual CMP inflation adjustment for 2020 is based on the percent change in the Consumer Price Index for all Urban Consumers (CPI-U) between October 2018 and October 2019. The CPI-U for October 2018 was 252.885, and for October 2019 was 257.346, for an increase of 1.764%. In accordance with section 5(a) of the Act, the new maximum CMP rates must be rounded to the nearest whole dollar. In accordance with section 6 of the Act, the new maximum penalty rates will apply only to CMPs, including those which are associated with violations predating the increase, that are assessed after the date the increase takes effect.

ONRR assesses CMPs under the Federal Oil and Gas Royalty Management Act, 30 U.S.C. 1719, and our regulations at 30 CFR part 1241. We calculate and assess CMPs per violation, at the applicable rate, for each day such violation continues.

II. Inflation-Adjusted Maximum Rates

This final rule increases the maximum CMP rates for each of the four categories of violations identified in 30 U.S.C. 1719(a)–(d) and 30 CFR part 1241. The following list identifies the existing ONRR regulations containing CMP rates and shows those rates before and after this increase.

30 CFR citation	Current penalty rate	2020 inflation adjustment multiplier	2020 adjusted penalty rate
1241.52(a)(2)	\$1,251	1.01764	\$1,273
1241.52(b)	12,519	1.01764	12,740
1241.60(b)(1)	25,037	1.01764	25,479
1241.60(b)(2)	62,595	1.01764	63,699

III. Procedural Requirements**A. Regulatory Planning and Review**
(Executive Orders 12866 and 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in OMB will review all significant rules. OIRA has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 12866, while calling for improvements in the Nation’s regulatory

system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. E.O. 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that

the rulemaking process must allow for public participation and an open exchange of ideas. We developed this rule in a manner consistent with these requirements.

B. Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601, *et seq.*, because the rule only makes adjustments for inflation. The Federal