

intended clinical sites, or an alternative study design determined to be appropriate by FDA.

(ii) Information demonstrating that the outcomes measured and the length of followup are clinically relevant for the progression of the specified liver disease.

(iii) Information demonstrating that the clinical criteria for determining whether the target disease is present and that the exclusion and inclusion criteria for subjects who have the target disease are appropriate.

(iv) Information demonstrating test performance of the complete test system, including any sample collection and processing steps.

(v) Information, provided or referenced, generated in samples from non-diseased individuals, that demonstrate the upper and lower reference intervals for the output provided by the device.

(2) The labeling required under 21 CFR 809.10(b) must include:

(i) A warning statement that test results are not intended to diagnose disease or for monitoring the effect of any therapeutic product.

(ii) A warning statement that test results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, including information obtained by alternative methods, and clinical evaluation, as appropriate.

(iii) A warning statement that describes any limitations on the clinical interpretation(s) of the test results.

(iv) Detailed information on device performance, including any limitations to the data generated in the clinical study(ies) and information on device performance in relevant subgroups (e.g., severity of liver disease at the beginning of the observation period) observed in the clinical study(ies).

(v) Information on the analytical performance of the device, including demonstration of reproducibility across multiple sites and multiple reagent lots, or an alternative reproducibility study design determined to be appropriate by FDA.

Dated: January 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-00480 Filed 1-13-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

30 CFR Part 1241

[Docket No. ONRR-2022-0003; DS63644000 DR2000000.CH7000 234D1113RT]

RIN 1012-AA35

2023 Civil Monetary Penalty Inflation Adjustments

AGENCY: Office of Natural Resources Revenue ("ONRR"), Interior.

ACTION: Final rule.

SUMMARY: Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (codified at 28 U.S.C. 2461 note), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (referred to herein as the "Inflation Adjustment Acts"), and Office of Management and Budget ("OMB") guidance, ONRR is adjusting for inflation the civil monetary penalty ("CMP") amounts it assesses under the Federal Oil and Gas Royalty Management Act of 1982 ("FOGRMA").

DATES: This rule is effective on January 13, 2023.

FOR FURTHER INFORMATION CONTACT: For questions on procedural issues, contact Luis Aguilar, Regulatory Specialist, by telephone at (303) 231-3418 or by email to Luis.Aguilar@onrr.gov. For questions on technical issues, contact Michael Marchetti, Enforcement Program Manager, by telephone at (303) 231-3125 or by email to Michael.Marchetti@onrr.gov.

SUPPLEMENTARY INFORMATION:

I. Background

II. ONRR's Inflation-Adjusted Maximum Rates

III. Procedural Matters

- A. Regulatory Planning and Review (Executive Orders 12866 and 13563)
- B. Regulatory Flexibility Act
- C. Small Business Regulatory Enforcement Fairness Act
- D. Unfunded Mandates Reform Act
- E. Takings (Executive Order 12630)
- F. Federalism (Executive Order 13132)
- G. Civil Justice Reform (Executive Order 12988)
- H. Consultation With Indian Tribes (Executive Order 13175)
- I. Paperwork Reduction Act
- J. National Environmental Policy Act
- K. Effects on the Energy Supply (Executive Order 13211)

L. Clarity of This Regulation

M. Administrative Procedure Act

I. Background

FOGRMA, at 30 U.S.C. 1719(a)–(d), authorizes the Secretary of the Interior ("Secretary") to assess CMPs for royalty reporting and other violations. Pursuant to authority delegated to it by the Secretary, ONRR published regulations at 30 CFR part 1241 implementing the Secretary's CMP authority. The Inflation Adjustment Acts (Pub. L. 114–74) require Federal agencies to publish annual CMP inflation adjustments in the **Federal Register** by January 15th of each year.

The Inflation Adjustment Acts and OMB Memorandum No. M-23-05, December 15, 2022 ("OMB Memorandum") specify that the annual inflation adjustments are based on the percent change between the Consumer Price Index for all Urban Consumers ("CPI-U") published by the Department of Labor for the month of October in the year of the previous adjustment, and the October CPI-U for the preceding year. The OMB Memorandum further specifies that the cost-of-living adjustment multiplier for 2023, not seasonally adjusted, is 1.07745 for CY 2023 (the October 2022 CPI-U (298.012) divided by the October 2021 CPI-U (276.589) = 1.07745). ONRR used this guidance to calculate required inflation adjustments. Pursuant to the Inflation Adjustment Acts, any increases in CMPs are rounded to the nearest whole dollar and the new maximum penalty rates apply to CMPs assessed after the date the increase takes effect.

II. ONRR's Inflation-Adjusted Maximum Rates

This final rule increases the maximum CMP dollar amounts for each of the four violation categories identified in 30 U.S.C. 1719(a)–(d) and implemented by 30 CFR part 1241. The following table identifies the applicable ONRR regulations, the dollar amounts set forth in the regulations, and the adjusted amounts.

30 CFR citation	Current maximum penalty	2023 inflation adjustment multiplier	2023 adjusted maximum penalty
1241.52(a)(2)	\$1,368	1.07745	\$1,474
1241.52(b)	13,693	1.07745	14,754
1241.60(b)(1)	27,384	1.07745	29,505

30 CFR citation	Current maximum penalty	2023 inflation adjustment multiplier	2023 adjusted maximum penalty
1241.60(b)(2)	68,462	1.07745	73,764

III. Procedural Matters

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 the OMB will review all significant rules. OIRA has determined that agency regulations intended only to implement the annual inflation adjustments are not significant, provided they are consistent with the OMB Memorandum. Because ONRR is only implementing the annual inflation adjustments in this final rule, this rule is not significant under E.O. 12866.

E.O. 13563 reaffirms the principles of E.O. 12866, while calling for improvements in the United States’ regulatory system to promote predictability, to reduce uncertainty, and to use the 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 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. ONRR 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 an adjustment for inflation. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 requires agencies to adjust civil penalties with an annual inflation adjustment. Therefore, the RFA does not apply to this rulemaking.

C. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does 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, local government agencies; or geographic regions; and

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

D. 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 \$100 million per year. This rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. Therefore, ONRR is not required to provide a statement containing the information that the Unfunded Mandates Reform Act (2 U.S.C. 1531, *et seq.*) requires because this rule is not an unfunded mandate.

E. Takings (E.O. 12630)

This rule does not result in a taking of private property or otherwise have takings implications under E.O. 12630. Therefore, this rule does not require a takings implication assessment.

F. 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.

G. 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), which requires that ONRR review all regulations to eliminate errors and ambiguity and to write them to minimize litigation; and
(b) Meets the criteria of section 3(b)(2), which requires that ONRR write all regulations in clear language, using clear legal standards.

H. Consultation With Indian Tribal Governments (E.O. 13175)

The Department of the Interior (“DOI”) strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian

Tribes and recognition of their right to self-governance and Tribal sovereignty. Under the DOI’s consultation policy and the criteria in E.O. 13175, ONRR evaluated this rule and determined that it will have no substantial, direct effects on Federally recognized Indian Tribes and does not require consultation.

I. Paperwork Reduction Act

This rule:

(a) Does not contain any new information collection requirements; and

(b) Does not require a submission to OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). See 5 CFR 1320.4(a)(2).

J. National Environmental Policy Act of 1969 (“NEPA”)

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. ONRR is not required to provide a detailed statement under NEPA because this rule qualifies for categorical exclusion under 43 CFR 46.210(i) in that this rule is “. . . of an administrative, financial, legal, technical, or procedural nature” ONRR also has determined that this rule is not involved in any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

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

This rule is not a significant energy action under the definition in E.O. 13211 and, therefore, does not require a Statement of Energy Effects.

L. Clarity of This Regulation

ONRR is required by E.O. 12866 (section 1(b)(12)), E.O. 12988 (section 3(b)(1)(B)), and E.O. 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule ONRR publishes must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that ONRR has not met these requirements, send your

comments to *ONRR RegulationsMailbox@onrr.gov*. Your comments should be as specific as possible. For example, you should identify the number of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

M. Administrative Procedure Act

The Act requires agencies to publish annual inflation adjustments by January 15 of each year, notwithstanding section 553 of the Administrative Procedure Act. OMB has interpreted this direction to mean that the usual APA public procedure for rulemaking—which includes public notice of a proposed rule, an opportunity for public comment, and a delay in the effective date of a final rule—is not required when agencies issue regulations to implement the annual adjustments to civil penalties that the 2015 Act requires. See OMB Memorandum, M–23–05, at pages 3–4. Accordingly, ONRR is issuing the 2023 annual adjustments as a final rule without prior notice or an opportunity for comment and with an effective date immediately upon publication in the **Federal Register**.

List of Subjects in 30 CFR Part 1241

Administrative practice and procedure, Coal, Geothermal energy, Indian-lands, Mineral royalties, Natural gas, Oil and gas exploration, Penalties, Public lands—mineral resources.

Howard M. Cantor,

Acting Director for the Office of Natural Resources Revenue.

Authority and Issuance

For the reasons discussed in the preamble, ONRR amends 30 CFR part 1241 as set forth below:

PART 1241—PENALTIES

- 1. The authority citation for part 1241 continues to read as follows:

Authority: 25 U.S.C. 396 *et seq.*, 396a *et seq.*, 2101 *et seq.*; 30 U.S.C. 181 *et seq.*, 351 *et seq.*, 1001 *et seq.*, 1701 *et seq.*; 43 U.S.C. 1301 *et seq.*, 1331 *et seq.*, 1801 *et seq.*

§ 1241.52 [Amended]

- 2. Amend § 1241.52 by:

- a. In paragraph (a)(2), removing “\$1,368” and adding in its place “\$1,474”.

- b. In paragraph (b) introductory text, removing “\$13,693” and adding in its place “\$14,754”.

§ 1241.60 [Amended]

- 3. Amend § 1241.60 by:

- a. In paragraph (b)(1) introductory text, removing “\$27,384” and adding in its place “\$29,505”.

- b. In paragraph (b)(2), removing “\$68,462” and adding in its place “\$73,764”.

[FR Doc. 2023–00737 Filed 1–13–23; 8:45 am]

BILLING CODE 4335–30–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 583

Publication of Global Magnitsky Sanctions Regulations Web General Licenses 3 and 4

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury’s Office of Foreign Assets Control (OFAC) is publishing two general licenses (GLs) issued pursuant to the Global Magnitsky Sanctions Regulations: GLs 3 and 4, each of which was previously made available on OFAC’s website.

DATES: GLs 3 and 4 were issued on December 9, 2022. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC’s website: www.treas.gov/ofac.

Background

On December 9, 2022, OFAC issued GLs 3 and 4 to authorize certain transactions otherwise prohibited by the Global Magnitsky Sanctions Regulations, 31 CFR part 583. Each GL was made available on OFAC’s website (www.treas.gov/ofac) when it was issued. Both GLs have an expiration date of March 9, 2023. The text of these GLs is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Global Magnitsky Sanctions Regulations

31 CFR Part 583

GENERAL LICENSE NO. 3

Authorizing Transactions Related to Debt or Equity of Pingtan Marine Enterprise Ltd.

(a) Except as provided in paragraphs (d) and (e) of this general license, all transactions prohibited by the Global Magnitsky Sanctions Regulations, 31 CFR part 583 (GMSR), that are ordinarily incident and necessary to the divestment or transfer, or facilitation of the divestment or transfer, of debt or equity of Pingtan Marine Enterprise Ltd. (PME) to a non-U.S. person are authorized through 12:01 a.m. eastern standard time, March 9, 2023.

(b) Except as provided in paragraph (e) of this general license, all transactions prohibited by the GMSR that are ordinarily incident and necessary to facilitating, clearing, and settling trades of debt or equity of PME that were placed prior to 4:00 p.m. eastern standard time, December 9, 2022, are authorized through 12:01 a.m. eastern standard time, March 9, 2023.

(c) Except as provided in paragraph (e) of this general license, all transactions prohibited by the GMSR that are ordinarily incident and necessary to the wind down of financial contracts or other agreements linked to the debt or equity of PME and entered into prior to 4:00 p.m. eastern standard time, December 9, 2022 are authorized through 12:01 a.m. eastern standard time, March 9, 2023, provided that any payments to a blocked person are made into a blocked account in accordance with the GMSR.

NOTE TO PARAGRAPH (C). The wind down of financial contracts or other agreements linked to the debt or equity of PME includes the delisting of PME from a U.S. securities exchange.

(d) Paragraph (a) of this general license does not authorize:

(1) U.S. persons to sell, or to facilitate the sale of debt or equity of PME to, directly or indirectly, any person whose property and interests in property are blocked; or

(2) U.S. persons to purchase or invest in, or to facilitate the purchase of or investment in, directly or indirectly, debt or equity of PME, other than purchases of or investments in debt or equity of PME that are ordinarily incident and necessary to the divestment or transfer of debt or equity of PME as described in paragraph (a) of this general license.