

information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. In § 890.3690, revise paragraph (b) to read as follows:

§ 890.3690 Powered wheeled stretcher.

* * * * *

(b) *Classification.* Class II (performance standards). The powered wheeled stretcher is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to § 890.9, and the following conditions for exemption:

(1) Appropriate analysis and nonclinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure;

(2) Appropriate analysis and nonclinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety;

(3) Appropriate analysis and nonclinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide the user with an expected service life of the device;

(4) Appropriate analysis and nonclinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device;

(5) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate electromagnetic compatibility and electrical safety;

(6) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the skin-contacting components of the device are biocompatible;

(7) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented;

(8) Appropriate analysis and nonclinical testing must validate that the device components are found to be nonflammable;

(9) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the battery in the device performs as intended over the anticipated service life of the device;

(10) Adequate labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device in the intended use environment; and

(11) Appropriate risk assessment including, but not limited to, evaluating the dimensional limits of the gaps in hospital beds, and mitigation strategy to reduce entrapment.

Dated: January 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00295 Filed 1–13–20; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 35, 103, 127, and 138

[Public Notice: 10992]

RIN 1400–AF00

Department of State 2020 Civil Monetary Penalties Inflationary Adjustment

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This final rule is issued to adjust the civil monetary penalties (CMP) for regulatory provisions maintained and enforced by the Department of State. The revised CMP adjusts the amount of civil monetary penalties assessed by the Department of State based on the December 2019

guidance from the Office of Management and Budget. The new amounts will apply only to those penalties assessed on or after the effective date of this rule, regardless of the date on which the underlying facts or violations occurred.

DATES: This final rule is effective on January 14, 2020.

FOR FURTHER INFORMATION CONTACT: Alice Kottmyer, Attorney-Adviser, Office of Management, kottmyeram@state.gov. ATTN: Regulatory Change, CMP Adjustments, (202) 647–2318.

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, as amended by the Debt Collection Improvement Act of 1996, Public Law 104–134, required the head of each agency to adjust its CMPs for inflation no later than October 23, 1996 and required agencies to make adjustments at least once every four years thereafter. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Section 701 of Public Law 114–74 (the 2015 Act) further amended the 1990 Act by requiring agencies to adjust CMPs, if necessary, pursuant to a “catch-up” adjustment methodology prescribed by the 2015 Act, which mandated that the catch-up adjustment take effect no later than August 1, 2016. Additionally, the 2015 Act required agencies to make annual adjustments to their respective CMPs in accordance with guidance issued by the Office of Management and Budget (OMB).

Based on these statutes, the Department of State (the Department) published a final rule in June 2016 to implement the “catch-up” provisions; and annual updates to its CMPs in January 2017, January 2018, and March 2019 (delayed due to the government shutdown).

On December 16, 2019, OMB notified agencies that the annual cost-of-living adjustment multiplier for 2020, based on the Consumer Price Index, is 1.01764. Additional information may be found in OMB Memorandum M–20–05, at: <https://www.whitehouse.gov/wp-content/uploads/2019/12/M-20-05.pdf>. This final rule amends Department CMPs for fiscal year 2019.

Overview of the Areas Affected by This Rule

Within the Department of State (title 22, Code of Federal Regulations), this rule affects four areas:

(1) Part 35, which implements the Program Fraud Civil Remedies Act of 1986 (PFCRA), codified at 31 U.S.C. 3801–3812;

(2) Part 103, which implements the Chemical Weapons Convention Implementation Act of 1998 (CWC Act);

(3) Part 127, which implements the penalty provisions of sections 38(e), 39A(c), and 40(k) of the Arms Export Control Act (AECA) (22 U.S.C. 2778(e), 2779a(c), 2780(k)); and

(4) Part 138, which implements Section 319 of Public Law 101–121, codified at 31 U.S.C. 1352, and prohibits recipients of federal contracts, grants, and loans from using appropriated funds for lobbying the Executive or Legislative Branches of the federal government in connection with a specific contract.

Specific Changes to 22 CFR Made by This Rule

I. Part 35

The PFRCA, enacted in 1986, authorizes agencies, with approval from the Department of Justice, to pursue individuals or firms for false claims. Applying the 2020 multiplier, the new maximum liabilities are as follows: \$11,665 up to a maximum of \$349,969.

II. Part 103

The CWC Act provided domestic implementation of the Convention on

the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on Their Destruction. The penalty provisions of the CWC Act are codified at 22 U.S.C. 6761. Applying the 2020 multiplier, the new maximum amounts are as follows: *Prohibited acts related to inspections*, \$39,229; for *Recordkeeping violations*, \$7,846.

III. Part 127

The Assistant Secretary of State for Political-Military Affairs is responsible for the imposition of CMPs under the International Traffic in Arms Regulations (ITAR), which is administered by the Directorate of Defense Trade Controls (DDTC).

(1) AECA Section 38(e)

Applying the 2020 multiplier, the new maximum penalty under 22 U.S.C. 2778 (22 CFR 127.10(a)(1)(i)) is \$1,183,736.

(2) AECA Section 39A(c)

Applying the 2020 multiplier, the new maximum penalty under 22 U.S.C. 2779a (22 CFR 127.10(a)(1)(ii)) is \$860,683, or five times the amount of

the prohibited payment, whichever is greater.

(3) AECA Section 40(k)

Applying the 2020 multiplier, the new maximum penalty under 22 U.S.C. 2780 (22 CFR 127.10(a)(1)(iii)) is \$1,024,457.

IV. Part 138

Section 319 of Public Law 101–121, codified at 31 U.S.C. 1352, provides penalties for recipients of federal contracts, grants, and loans who use appropriated funds to lobby the Executive or Legislative Branches of the federal government in connection with a specific contract, grant, or loan. Any person who violates that prohibition is subject to a civil penalty. The statute also requires each person who requests or receives a federal contract, grant, cooperative agreement, loan, or a federal commitment to insure or guarantee a loan, to disclose any lobbying; there is a penalty for failure to disclose.

Applying the 2020 multiplier, the maximum penalties for both improper expenditures and failure to disclose, is: For first offenders, \$20,158; for others, not less than \$20,489, and not more than \$204,892.

SUMMARY

Citation in 22 CFR	2019 Max penalties	New max penalties
§ 35.3	\$11,463 up to \$343,903	\$11,665 up to \$349,969.
§ 103.6, <i>Prohibited Acts</i>	\$38,549	\$39,229.
§ 103.6, <i>Recordkeeping Violations</i>	\$7,710	\$7,846.
§ 127.10(a)(1)(i)	\$1,163,217	\$1,183,736.
§ 127.10(a)(1)(ii)	\$845,764 or 5 times the amount of the prohibited payment, whichever is greater.	\$860,683 or 5 times the amount of the prohibited payment, whichever is greater.
§ 127.10(a)(1)(iii)	\$1,006,699	\$1,024,457.
§ 138.400, <i>First Offenders</i>	\$19,809	\$20,158.
§ 138.400	\$20,134 up to \$201,340	\$20,489 up to \$204,892.

2020 Multiplier: 1.01764.

Effective Date of Penalties

The revised CMP amounts will go into effect on the date this rule is published. All violations for which CMPs are assessed on or after the effective date of this rule, regardless of whether the violation occurred before the effective date, will be assessed at the adjusted penalty level.

Future Adjustments and Reporting

The 2015 Act directed agencies to undertake an annual review of CMPs using a formula prescribed by the statute. Annual adjustments to CMPs are made in accordance with the guidance issued by OMB. As in this rulemaking, the Department of State will publish notification of annual inflation adjustments to CMPs in the **Federal**

Register no later than January 15 of each year, with the adjusted amount taking effect immediately upon publication.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is publishing this rule using the “good cause” exception to the Administrative Procedure Act (5 U.S.C. 553(b)), as the Department has determined that public comment on this rulemaking would be impractical, unnecessary, or contrary to the public interest. This rulemaking is mandatory and entirely without agency discretion; it implements Public Law 114–74. See 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because this rulemaking is exempt from 5 U.S.C. 553, a Regulatory Flexibility Analysis is not required.

Unfunded Mandates Reform Act of 1995

This rule does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This amendment will not have substantial direct effects 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. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement.

Executive Orders 12866, 13563, and 13771

The Department believes that benefits of the rulemaking outweigh any costs, and there are no feasible alternatives to this rulemaking. Pursuant to M–20–05, the Office of Information and Regulatory Affairs (OIRA) has determined that agency regulations that (1) exclusively implement the annual adjustment, (2) are consistent with this guidance, and (3) have an annual impact of less than \$100 million, are generally not significant regulatory actions under E.O. 12866. Therefore, agencies are generally not required to submit regulations satisfying those criteria to OIRA for review. Further, since those regulations are not significant regulatory actions under E.O. 12866, they are not considered E.O. 13771 regulatory actions. This regulation satisfies all of those criteria.

Executive Order 12988

The Department of State has reviewed the amendment in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. chapter 35.

List of Subjects

22 CFR Part 35

Administrative practice and procedure, Claims, Fraud, Penalties.

22 CFR Part 103

Administrative practice and procedure, Chemicals, Classified information, Foreign relations, Freedom of information, International organization, Investigations, Penalties, Reporting and recordkeeping requirements.

22 CFR Part 127

Arms and munitions, Exports.

22 CFR Part 138

Government contracts, Grant programs, Loan programs, Lobbying, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth above, 22 CFR parts 35, 103, 127, and 138 are amended as follows:

PART 35—PROGRAM FRAUD CIVIL REMEDIES

- 1. The authority citation for part 35 continues to read as follows:

Authority: 22 U.S.C. 2651a; 31 U.S.C. 3801 *et seq.*; Pub. L. 114–74, 129 Stat. 584.

§ 35.3 [Amended]

- 2. In § 35.3:
 - a. Remove “\$11,463” and add in its place “\$11,665”, wherever it occurs.
 - b. In paragraph (f), remove “\$343,903” and add in its place “\$349,969”.

PART 103—REGULATIONS FOR IMPLEMENTATION OF THE CHEMICAL WEAPONS CONVENTION AND THE CHEMICAL WEAPONS CONVENTION IMPLEMENTATION ACT OF 1998 ON THE TAKING OF SAMPLES AND ON ENFORCEMENT OF REQUIREMENTS CONCERNING RECORDKEEPING AND INSPECTIONS

- 3. The authority citation for part 103 continues to read as follows:

Authority: 22 U.S.C. 2651a; 22 U.S.C. 6701 *et seq.*; Pub. L. 114–74, 129 Stat. 584.

§ 103.6 [Amended]

- 4. In § 103.6:
 - a. Remove “\$38,549” and add in its place “\$39,229” in paragraph (a)(1); and
 - b. Remove “\$7,710” and add in its place “\$7,846” in paragraph (a)(2).

PART 127—VIOLATIONS AND PENALTIES

- 5. The authority citation for part 127 continues to read as follows:

Authority: Sections 2, 38, and 42, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2791); 22 U.S.C. 401; 22 U.S.C. 2651a; 22 U.S.C. 2779a; 22 U.S.C. 2780; E.O. 13637, 78 FR 16129; Pub. L. 114–74, 129 Stat. 584.

§ 127.10 [Amended]

- 6. In § 127.10:
 - a. In paragraph (a)(1)(i), remove “\$1,163,217” and add in its place “\$1,183,736”;
 - b. In paragraph (a)(1)(ii), remove “\$845,764” and add in its place “\$860,683”;
 - c. In paragraph (a)(1)(iii), remove “\$1,006,699” and add in its place “\$1,024,457”.

PART 138—RESTRICTIONS ON LOBBYING

- 7. The authority citation for part 138 continues to read as follows:

Authority: 22 U.S.C. 2651a; 31 U.S.C. 1352; Pub. L. 114–74, 129 Stat. 584.

§ 138.400 [Amended]

- 8. In § 138.400:
 - a. Remove “\$20,134” and “\$201,340” and add in their place “\$20,489” and “\$204,892”, respectively, wherever they occur.
 - b. In paragraph (e), remove “\$19,809” and add in its place “\$20,158”.

Dated: January 8, 2020.

Alicia Frechette,

Executive Director, Office of the Legal Adviser and Bureau of Legislative Affairs, Department of State.

[FR Doc. 2020–00443 Filed 1–13–20; 8:45 am]

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56 and 57

[Docket No. MSHA–2019–0007]

RIN 1219–AB88

Electronic Detonators

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Direct final rule; request for comments.

SUMMARY: The Mine Safety and Health Administration (MSHA) is revising certain safety standards for explosives at metal and nonmetal (MNM) mines. This rule updates existing provisions consistent with technological advancements involving electronic detonators. MSHA is publishing a direct final rule because the Agency expects that there will be no significant adverse