of Food and Drugs, 21 CFR part 864 is amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for part 864 continues to read as follows:

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

■ 2. Add § 864.1865 to subpart B to read as follows:

§ 864.1865 Cervical intraepithelial neoplasia (CIN) test system.

(a) *Identification.* A cervical intraepithelial neoplasia (CIN) test system is a device used to detect a biomarker associated with CIN in human tissues. The device is indicated as an adjunct test and not to be used as a stand-alone device. The test results must be interpreted in the context of the patient's clinical history including, but not limited to, prior and current cervical biopsy results, Papanicolaou (Pap) test results, human papillomavirus (HPV) test results, and morphology on hematoxylin and eosin (H&E) stained sections. This device is not intended to detect the presence of HPV.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Premarket notification submissions must include the following information:

(i) The indications for use must specify the biomarker that is intended to be identified and its adjunct use (*e.g.,* adjunct to examination of H&E stained slides) to improve consistency in the diagnosis of CIN.

(ii) Summary of professional society recommendations, as applicable.

(iii) A detailed device description including:

(A) A detailed description of all test components, including all provided reagents and required, but not provided, ancillary reagents.

(B) A detailed description of instrumentation and equipment, including illustrations or photographs of non-standard equipment or manuals.

(C) If applicable, detailed documentation of the device software, including, but not limited to, stand-alone software applications and hardware-based devices that incorporate software.

(D) A detailed description of appropriate positive and negative controls that are recommended or provided.

(E) Detailed specifications for sample collection, processing, and storage.

(F) A detailed description of methodology and assay procedure.

(G) A description of the assay cutoff (the medical decision point between positive and negative) or other relevant criteria that distinguishes positive and negative results, including the rationale for the chosen cutoff or other relevant criteria and results supporting validation of the cutoff.

(H) Detailed specification of the criteria for test results interpretation and reporting.

(iv) Detailed information demonstrating the performance characteristics of the device, including:

(A) Analytical specificity studies such as, but not limited to, antibody characterization (*e.g.,* Western Blot, peptide inhibition analysis), studies conducted on panels of normal tissues and neoplastic tissues, interference by endogenous and exogenous substances as well as cross-reactivity, as applicable.

(B) Device analytical sensitivity data generated by testing an adequate number of samples from individuals with the target condition including limit of blank, limit of detection, and limit of quantification, as applicable.

(C) Device precision/reproducibility data to evaluate within-run, between-run, between-day, between-lot, between-site, between-reader, within-reader and total precision, as applicable, using a panel of samples covering the device measuring range and/or the relevant disease categories (*e.g.* No CIN, CIN1, CIN2, CIN3, cervical cancer) and testing in replicates across multiple, nonconsecutive days.

(D) Device robustness/guardbanding studies to assess the tolerance ranges for various critical test and specimen parameters.

(E) Device stability data, including real-time stability and shipping stability under various storage times, temperatures, and freeze-thaw conditions.

(F) Data from a clinical study demonstrating clinical validity using well-characterized prospectively or retrospectively obtained clinical specimens, as appropriate, representative of the intended use population. The study must evaluate the consistency of the diagnosis of CIN, for example, by comparing the levels of agreements of diagnoses rendered by community pathologists to those rendered by a panel of expert pathologists. Agreement for each CIN diagnostic category (*e.g.,* No CIN, CIN1, CIN2, CIN3, cancer) and for alternate diagnostic categories (*e.g.,* No CIN, low grade squamous intraepithelial lesion (LSIL)-histology, high grade squamous intraepithelial lesion (HSIL)-histology, cancer) between reference diagnosis by expert pathologist and community pathologist must be evaluated, as applicable. In addition, agreements for CIN binary categories as ≥CIN2 (*i.e.,* CIN2 or CIN3 or cancer) and ≤CIN1 (*i.e.,* No CIN or CIN1) between reference diagnosis by expert pathologist with H&E staining and community pathologist with H&E staining and agreements for alternate CIN binary categories as ≥HSIL-histology (*i.e.,* HSIL-histology or cancer) and ≤LSIL-histology (*i.e.,* No CIN or LSIL-histology) between reference diagnosis by an expert pathologist with H&E + [biomarker specified in paragraph (b)(1)(i) of this section] and a community pathologist with H&E + [biomarker specified in paragraph (b)(1)(i) of this section] must be evaluated and compared, as applicable.

(G) The staining performance of the device as determined by the community pathologists during review of the study slides must be evaluated. The staining performance criteria assessed must include overall staining acceptability, background staining acceptability, and morphology acceptability, as applicable.

(H) Appropriate training requirements for users, including interpretation manual, as applicable.

(I) Identification of risk mitigation elements used by the device, including a description of all additional procedures, methods, and practices incorporated into the instructions for use that mitigate risks associated with testing.

(2) The device's 21 CFR 809.10(b) compliant labeling must include a detailed description of the protocol, including the information described in paragraph (b)(1)(ii) of this section, as applicable, and a detailed description of the performance studies performed and the summary of the results, including those that relate to paragraph (b)(1)(ii) of this section, as applicable.

Dated: December 27, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28342 Filed 1–2–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Parts 35, 103, 127, and 138

[Public Notice 10236]

RIN 1400–AE50

Department of State 2018 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 2017 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 3, 2018.

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 on June 8, 2016, to implement the ''catch-up'' provisions. *See* 81 FR 36791. The Department published its first annual update to its CMPs in January 2017. *See* 82 FR 3168.

On December 15, 2017, OMB notified agencies that the annual cost-of-living adjustment multiplier for 2018, based on the Consumer Price Index, is 1.02041. Additional information may be found in OMB Memorandum M–18–03, at: *https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-03.pdf.* This final rule amends Department CMPs for fiscal year 2018.

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 all previous adjustments in accordance with the 2015 Act, the maximum liabilities under the PFRCA were $10,957, up to a maximum of $328,734. Applying the 2018 multiplier (1.02041) provided by OMB, the new maximum liabilities are as follows: $11,181 up to a maximum of $335,443.

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 all previous adjustments in accordance with the 2015 Act, the maximum amounts were as follows: *Prohibited acts related to inspections,* $36,849; for *Recordkeeping violations,* $7,370.

Applying the 2018 multiplier (1.02041) provided by OMB, the new maximum amounts are as follows: *Prohibited acts related to inspections,* $37,601; for *Recordkeeping violations,* $7,520.

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 all previous adjustments in accordance with the 2015 Act, the maximum penalty under 22 U.S.C. 2778(e), or Section 38(e) of the AECA, was $1,111,908. Applying the 2018 multiplier (1.02041) provided by OMB, the new maximum penalty under 22 U.S.C. 278(e) is $1,134,602.

(2) *AECA section 39A(c):*

Applying all previous adjustments in accordance with the 2015 Act, the maximum penalty for 22 U.S.C. 2779a(c), or Section 39A(c) of the AECA, was $808,458. Applying the 2018 multiplier (1.02041) provided by OMB, the new maximum penalty for 22 U.S.C. 2779a(c) is $824,959.

(3) *AECA section 40(k):*

Applying all previous adjustments in accordance with the 2015 Act, the maximum penalty for 22 U.S.C. 2780(k), or Section 40(k) of the AECA, was $962,295 per violation. Applying the 2018 multiplier (1.02041) provided by OMB, the new maximum penalty per violation is $981,935.

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 all previous adjustments in accordance with the 2015 Act, the maximum penalties for both improper expenditures and failure to disclose, was: For first offenders, a penalty of $18,936; for others, not less than $19,246, and not more than $192,459. Applying the 2018 multiplier (1.02041) provided by OMB, the new maximums are: For first offenders, $19,322; for others, not less than $19,639, and not more than $196,387.

Summary

Citation in 22 CFR	Old penalty	2018 penalty
§ 35.3	$10,957 up to $328,734	$11,181 up to $335,443.
§ 103.6 Prohibited Acts	$36,849	$37,601.
§ 103.6 Recordkeeping Violations	$7,370	$7,520.
§ 127.10(a)(1)(i)	$1,111,908	$1,134,602.
§ 127.10(a)(1)(ii)	$808,458	$824,959.
§ 127.10(a)(1)(iii)	$962,295	$981,935.
§ 138.400 First Offenders	$18,936	$19,322.
§ 138.400	$19,246 up to $192,459	$19,639 up to $192,549.
2018 multiplier: 1.02041		

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; it implements Public Law 114–74. In addition, the Department of State finds good cause for this rule to be effective upon publication, as Congress has mandated that the penalty adjustments be effective on or before January 15th. *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. It is the Department's position that this rulemaking is not an economically significant rule under the criteria of Executive Order 12866, and is consistent with the provisions of Executive Order 13563. This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Executive Order 12988

The Department of State has reviewed the proposed 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 ''$10,957'' and add in its place ''$11,181'', wherever it occurs.

■ b. In paragraph (f), remove ''$328,734'' and add in its place ''$335,443''.

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. Amend § 103.6 by removing ''$36,849'' and adding in its place $37,601'' in paragraph (a)(1), and removing ''$7,370'' and adding in its place ''$7,520'' 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. Section 127.10 is amended as follows:

■ a. In paragraph (a)(1)(i), remove ''$1,111,908'' and add in its place ''$1,134,602'';

■ b. In paragraph (a)(1)(ii), remove ''$808,458'' and add in its place ''$824,959''; and

■ c. In paragraph (a)(1)(iii), remove ''$962,295'' and add in its place ''$981,935.''

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 ''$19,246'' and ''$192,459'' and add in their place ''$19,639'' and ''$196,387'', respectively, wherever they occur.

■ b. In paragraph (e), remove ''$18,936'' and add in its place ''$19,322''.

Jerry C. Drake,

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

[FR Doc. 2017–28395 Filed 1–2–18; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100, 117, 147, and 165

[USCG–2017–1008]

2016 Quarterly Listings; Safety Zones, Security Zones, Special Local Regulations, Drawbridge Operation Regulations and Regulated Navigation Areas

AGENCY: Coast Guard, DHS.

ACTION: Notification of expired temporary rules issued.

SUMMARY: This document provides notification of substantive rules issued by the Coast Guard that were made temporarily effective but expired before they could be published in the **Federal Register.** This document lists temporary safety zones, security zones, special local regulations, drawbridge operation regulations and regulated navigation areas, all of limited duration and for which timely publication in the **Federal Register** was not possible.

DATES: This document lists temporary Coast Guard rules that became effective, primarily between April 2016 and June 2016, unless otherwise indicated, and were terminated before they could be published in the **Federal Register.**

ADDRESSES: Temporary rules listed in this document may be viewed online, under their respective docket numbers, using the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this document contact Yeoman First Class David Hager, Office of Regulations and Administrative Law, telephone (202) 372–3862.

SUPPLEMENTARY INFORMATION: Coast Guard District Commanders and Captains of the Port (COTP) must be immediately responsive to the safety and security needs within their jurisdiction; therefore, District Commanders and COTPs have been delegated the authority to issue certain local regulations. *Safety zones* may be established for safety or environmental purposes. A safety zone may be stationary and described by fixed limits or it may be described as a zone around a vessel in motion. *Security zones* limit access to prevent injury or damage to vessels, ports, or waterfront facilities. *Special local regulations* are issued to enhance the safety of participants and spectators at regattas and other marine events. *Drawbridge operation regulations* authorize changes to drawbridge schedules to accommodate bridge repairs, seasonal vessel traffic, and local public events. *Regulated Navigation Areas* are water areas within a defined boundary for which regulations for vessels navigating within the area have been established by the regional Coast Guard District Commander.

Timely publication of these rules in the **Federal Register** may be precluded when a rule responds to an emergency, or when an event occurs without sufficient advance notice. The affected public is, however, often informed of these rules through Local Notices to Mariners, press releases, and other means. Moreover, actual notification is provided by Coast Guard patrol vessels enforcing the restrictions imposed by the rule. Because **Federal Register** publication was not possible before the end of the effective period, mariners were personally notified of the contents of these safety zones, security zones, special local regulations, regulated navigation areas or drawbridge operation regulations by Coast Guard officials on-scene prior to any enforcement action. However, the Coast Guard, by law, must publish in the **Federal Register** notice of substantive rules adopted. To meet this obligation without imposing undue expense on the public, the Coast Guard periodically publishes a list of these temporary safety zones, security zones, special local regulations, regulated navigation areas and drawbridge operation regulations. Permanent rules are not included in this list because they are published in their entirety in the **Federal Register**. Temporary rules are also published in their entirety if sufficient time is available to do so before they are placed in effect or terminated.

The following unpublished rules were placed in effect temporarily during the period between June 2014–June 2016 unless otherwise indicated. To view copies of these rules, visit *www.regulations.gov* and search by the docket number indicated in the list below.