

## PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

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

■ 2. Add § 870.2345 to subpart C to read as follows:

### § 870.2345 Electrocardiograph software for over-the-counter use.

(a) *Identification.* An electrocardiograph software device for over-the-counter use creates, analyzes, and displays electrocardiograph data and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis.

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

(1) Clinical performance testing under anticipated conditions of use must demonstrate the following:

(i) The ability to obtain an electrocardiograph of sufficient quality for display and analysis; and

(ii) The performance characteristics of the detection algorithm as reported by sensitivity and either specificity or positive predictive value.

(2) Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

(3) Non-clinical performance testing must validate detection algorithm performance using a previously adjudicated data set.

(4) Human factors and usability testing must demonstrate the following:

(i) The user can correctly use the device based solely on reading the device labeling; and

(ii) The user can correctly interpret the device output and understand when to seek medical care.

(5) Labeling must include:

(i) Hardware platform and operating system requirements;

(ii) Situations in which the device may not operate at an expected performance level;

(iii) A summary of the clinical performance testing conducted with the device;

(iv) A description of what the device measures and outputs to the user; and

(v) Guidance on interpretation of any results.

Dated: January 7, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF THE INTERIOR

### National Indian Gaming Commission

#### 25 CFR Part 575

#### Annual Adjustment of Civil Monetary Penalty To Reflect Inflation

**AGENCY:** National Indian Gaming Commission.

**ACTION:** Final rule.

**SUMMARY:** In compliance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the Act) and Office of Management and Budget (OMB) guidance, the National Indian Gaming Commission (NIGC or Commission) is amending its civil monetary penalty rule to reflect an annual adjustment for inflation in order to improve the penalty's effectiveness and maintain its deterrent effect. The Act provides that the new penalty level must apply to penalties assessed after the effective date of the increase, including when the penalties whose associated violation predate the increase.

**DATES:** This rule is effective January 18, 2022. This final rule is applicable beginning on January 15, 2022.

**FOR FURTHER INFORMATION CONTACT:** Armando J. Acosta, Senior Attorney, Office of General Counsel, National Indian Gaming Commission, at (202) 632–7003; fax (202) 632–7066 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74). Beginning in 2017, the Act requires agencies to make annual inflationary adjustments to their civil monetary penalties by January 15th of each year, in accordance with annual OMB guidance.

##### II. Calculation of Annual Adjustment

In December of every year, OMB issues guidance to agencies to calculate the annual adjustment. According to OMB, the cost-of-living adjustment multiplier for fiscal year 2022 is 1.06222, based on the Consumer Price Index for the month of October 2021, not seasonally adjusted.

Pursuant to this guidance, the Commission has calculated the annual adjustment level of the civil monetary penalty contained in 25 CFR 575.4 (“The Chairman may assess a civil fine, not to exceed \$54,157 per violation, against a tribe, management contractor, or individual operating Indian gaming for each notice of violation . . .”). The 2022 adjusted level of the civil monetary penalty is \$57,527 (\$54,157 × 1.06222).

### III. Regulatory Matters

#### *Regulatory Planning and Review*

This final rule is not a significant rule under Executive Order 12866.

(1) This rule will not have an effect of \$100 million or more on the economy or will not adversely affect, in a material way, the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This rule does not involve entitlements, grants, user fees, or loan programs or the rights or obligations of recipients.

(4) This regulatory change does not raise novel legal or policy issues.

#### *Regulatory Flexibility Act*

The Commission certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because the rule makes annual adjustments for inflation.

#### *Small Business Regulatory Enforcement Fairness Act*

This final rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. It will not result in the expenditure by state, local, or tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year. The rule will not result in a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions. Nor will this rule have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the U.S.-based enterprises to compete with foreign-based enterprises.

#### *Unfunded Mandates Reform Act*

This final rule does not impose an unfunded mandate of more than \$100 million per year on state, local, or tribal

governments or the private sector. The rule also 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.

#### Takings

Under the criteria in Executive Order 12630, this final rule does not affect individual property rights protected by the Fifth Amendment nor does it involve a compensable “taking.” Thus, a takings implication assessment is not required.

#### Federalism

Under the criteria in Executive Order 13132, this final rule has no 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.

#### Civil Justice Reform

This final rule complies with the requirements of Executive Order 12988. Specifically, this rule has been reviewed to eliminate errors and ambiguity and written to minimize litigation. It is written in clear language and contains clear legal standards.

#### Consultation With Indian Tribes

In accordance with the President’s memorandum of April 29, 1994, *Government-to-Government Relations with Native American Tribal Governments*, Executive Order 13175 (59 FR 22951, November 6, 2000), the Commission has determined that consultations with Indian gaming tribes is not practicable, as Congress has mandated that annual civil penalty adjustments in the Act be implemented no later than January 15th of each year.

#### Paperwork Reduction Act

This final rule does not affect any information collections under the Paperwork Reduction Act.

#### National Environmental Policy Act

This final rule does not constitute a major Federal action significantly affecting the quality of the human environment.

#### Information Quality Act

In developing this final rule, the Commission did not conduct or use a study, experiment, or survey requiring peer review under the Information Quality Act (Pub. L. 106–554).

#### Effects on the Energy Supply

This final rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

#### Clarity of This Regulation

The Commission is required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule that the Commission publishes must:

- (a) Be logically organized;
- (b) use the active voice to address readers directly;
- (c) use clear language rather than jargon;
- (d) be divided into short sections and sentences; and
- (e) use lists and tables wherever possible.

#### Required Determinations Under the Administrative Procedure Act

In accordance with the Act, agencies are to annually adjust civil monetary penalties without providing an opportunity for notice and comment, and without a delay in its effective date. Therefore, the Commission is not required to complete a notice and comment process prior to promulgation.

#### List of Subjects in 25 CFR Part 575

Administrative practice and procedure, Gaming, Indian lands, Penalties.

For the reasons set forth in the preamble, the Commission amends 25 CFR part 575 as follows:

#### PART 575—CIVIL FINES

- 1. The authority citation for part 575 continues to read as follows:

**Authority:** 25 U.S.C. 2705(a), 2706, 2713, 2715; and Sec. 701, Pub. L. 114–74, 129 Stat. 599.

##### § 575.4 [Amended]

- 2. Amend the introductory text of § 575.4 by removing “\$54,157” and adding in its place “\$57,527”.

Dated: January 12, 2022.

**E. Sequoyah Simermeyer,**  
*Chairman.*

**Jeannie C. Hovland,**  
*Vice Chair.*

[FR Doc. 2022–00835 Filed 1–14–22; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG–2022–0006]

RIN 1625–AA00

#### Safety Zone; St. Clair Icy Bazaar Fireworks, St. Clair River, MI

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for navigable waters within a 50-yard radius of a portion of the St. Clair River, St. Clair, MI. This zone is necessary to protect spectators and vessels from potential hazards associated with the St. Clair Icy Bazaar Fireworks.

**DATES:** This temporary final rule is effective from 6 p.m. on January 22, 2022, through 6:30 p.m. on January 23, 2022.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2022–0006 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, call or email Tracy Girard, Prevention Department, Sector Detroit, Coast Guard; telephone 313–568–9564, or email [Tracy.M.Girard@uscg.mil](mailto:Tracy.M.Girard@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
COTP Captain of the Port Detroit  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking  
§ Section  
U.S.C. United States Code

##### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b) (B), the Coast Guard finds that