

holds. Under §§ 1.283(d) and 1.285(j), certain parties may, for the enumerated reasons, request reviews of the prior notice refusals and holds within 5 calendar days of the hold or refusal. The fourth edition clarifies that FDA considers the 5-calendar-day clock to begin when FDA provides notice of the refusal or hold to the submitter or transmitter.

Additionally, in 2016, CBP issued a notice announcing that ABI/ACE would replace ACS as the sole electronic data interchange system authorized by CBP for the processing of electronic entries of FDA-regulated products (see 81 FR 30320, May 16, 2016). ABI/ACE became the successor system to ACS. In 2017, we amended 21 CFR part 1, subpart I to replace references to ACS and successor system with ABI/ACE (see 82 FR 15627). As part of this rulemaking, we eliminated some requirements for submitting prior notice due to the expanded capabilities of ABI/ACE, such as the requirement to submit articles that have been refused under section 801(m)(1) of the FD&C Act or subpart I in FDA PNSI. Further, ABI/ACE can now accommodate entries it previously could not, such as articles of food arriving through international mail. Therefore, to reflect these changes that were implemented in the rulemaking and the expanded capabilities of ABI/ACE, we are replacing references in the prior notice guidance to ACS with the successor system ABI/ACE. In addition, we are providing clarification regarding how persons may submit prior notice for articles of food imported or offered for import by international mail.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on guidance for industry on the prior notice requirements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1.278 to 1.282 have been approved under OMB control number 0910–0520.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 10, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2023–0735]

RIN 1625–AA00

#### Safety Zone; Atlantic Ocean, Jacksonville Beach, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the waterways surrounding Jacksonville, Florida during the 2023 Jacksonville Beach Sea and Sky Air Show. The safety zone is necessary to ensure the safety of event participants and spectators. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Jacksonville or a designated representative.

**DATES:** This rule is effective from 7 a.m. until 5 p.m. on October 20, 2023, through October 22, 2023.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2023–0735 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Marine Science Technician First Class Anthony DeAngelo, Waterways Management Division, Sector Jacksonville, FL, U.S. Coast Guard; telephone 904–714–7631; email [Anthony.DeAngelo@uscg.mil](mailto:Anthony.DeAngelo@uscg.mil).

## SUPPLEMENTARY INFORMATION:

### I. Table of Abbreviations

COTP Captain of the Port  
CFR Code of Federal Regulations  
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 good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard was notified of the event without ample time for the NPRM process. We must establish the safety zone by October 20, 2023, and lack sufficient time to provide for a reasonable comment period and then consider those comments before issuing this rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to ensure the safety of the participants and vessels during the 2023 Jacksonville Beach Sea and Sky Air Show.

### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Jacksonville (COTP) has determined that potential hazards associated with the 2023 Jacksonville Beach Sea and Sky Air Show will be a safety concern for persons and vessels in the regulated area. This rule is needed to ensure the safety of the event participants, the general public, vessels and the marine environment in the navigable waters within the safety zone during the 2023 Jacksonville Beach Sea and Sky Air Show.

### IV. Discussion of the Rule

This rule establishes a safety zone on certain waters of Jacksonville, Florida, during the 2023 Jacksonville Beach Sea

and Sky Air Show. The safety zone will be enforced from 7 a.m. until 5 p.m. on October 20, 2023, through October 22, 2023. The safety zone will cover waters within the points starting at 30°18'00" N, 081°23'06" W, then proceeding to the East to point 30°17'54" N, 081°21'54" W, then to the Southeast to point 30°16'12" N, 081°21'34" W, then to the Southwest to point 30°16'06" N, 081°22'43" W, then proceeding to the first point.

No person or vessel will be permitted to enter, transit through, anchor in, or remain within the safety zone without first obtaining permission from the COTP or a designated representative. If authorization to enter, transit through, anchor in, or remain within the safety zone is granted by the COTP or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP or a designated representative. The Coast Guard will provide notice of the safety zone by Broadcast Notice to Mariners, and/or by on-scene designated representatives.

## V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

### A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a "significant regulatory action," under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on following reasons: (1) the temporary safety zone will only be enforced for a total of 10 hours per day, for 3 consecutive days; (2) although persons and vessels may not enter, transit through, anchor in, or remain within the safety zone without authorization from the COTP or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the areas during the enforcement period if authorized by the COTP or a designated representative.

### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

### C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have Tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

### E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a 1.7 nautical mile perimeter safety zone, lasting the duration of the marine event and thus limited in time and scope. This zone will prohibit entry while in effect. It is categorically excluded from further review under paragraph L60a of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

### G. Protest Activities

The Coast Guard respects the First Amendment rights of protestors. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to

coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR 165 as follows:

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T07–0735 to read as follows:

#### § 165.T07–0735 2023 Jacksonville Beach Sea and Sky Airshow.

(a) *Location.* The following area is a safety zone: All waters of the Atlantic Ocean off the coast of Jacksonville Beach, from surface to bottom, that are within the 1.7 nautical mile perimeter that begins at 30°18'00" N, 081°23'06" W, then proceeding to the East to point 30°17'54" N, 081°21'54" W, then to the Southeast to point 30°16'12" N, 081°21'34" W, then to the Southwest to point 30°16'06" N, 081°22'43" W, then proceeding to the first point.

(b) *Definitions.* As used in this section, the term “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Jacksonville (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the COTP Jacksonville or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the COTP Jacksonville by telephone at (904) 714–7557, or a designated representative via VHF–FM radio on channel 16 to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the

COTP Jacksonville or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast Notice to Mariners via VHF–FM channel 16, or the COTP’s designated representative.

(d) *Enforcement period.* This section will be enforced from 7 a.m. until 5 p.m. on October 20, 2023, through October 22, 2023.

Dated: October 6, 2023.

**J.D. Espino-Young,**

*Captain, U.S. Coast Guard, Captain of the Port Jacksonville.*

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**BILLING CODE 9110–04–P**

### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Part 20

[WT Docket No. 20–3; DA 23–914; FR ID 133942]

#### Wireless Telecommunications Bureau Conditionally Waives Certain Aspects of the Wireless Hearing Aid Compatibility Volume Control Testing Standard

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; limited waiver.

**SUMMARY:** The Wireless Telecommunications Bureau (Bureau) of the Federal Communications Commission (Commission) recently granted a limited waiver of the Commission’s wireless hearing aid compatibility rules with respect to the volume control technical standard that handset manufacturers use in part to certify handsets as hearing aid-compatible under the 2019 ANSI Standard. The Bureau took this step in response to a petition filed by the Alliance for Telecommunications Industry Solutions (ATIS) seeking waiver of certain aspects of these rules. By conditionally granting the waiver request, the Bureau ensures that handset manufacturers can continue to release new hearing aid-compatible handset models while a new volume control standard is developed that the Commission can adopt into its wireless hearing aid compatibility rules.

**DATES:** The waiver is effective as of September 29, 2023.

**ADDRESSES:** Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Eli Johnson, [Eli.Johnson@fcc.gov](mailto:Eli.Johnson@fcc.gov), of the Wireless Telecommunications Bureau,

Competition & Infrastructure Policy Division, (202) 418–1395.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission document, WT Docket No. 20–3, DA 23–914, released on September 29, 2023. The full text of this document is available for public inspection on the FCC’s website at: <https://docs.fcc.gov/public/attachments/DA-23-914A1.pdf>. The document is available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format, etc.), and reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) may be requested by sending an email to [FCC504@fcc.gov](mailto:FCC504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

#### Synopsis

1. The Bureau grants a limited waiver of § 20.19(b)(1) and (3) of the Commission’s wireless hearing aid compatibility rules with respect to the volume control technical standard that handset manufacturers use in part to certify handsets as hearing aid-compatible under the 2019 ANSI Standard. This action is prompted by a request filed by the Alliance for Telecommunications Industry Solutions (ATIS) seeking waiver of certain aspects of these rules. Under the terms of the time-limited waiver the Bureau grants, a handset may be certified as hearing aid-compatible under the 2019 ANSI Standard if it meets the volume control testing requirements described in this Order as well as all other aspects of the 2019 ANSI Standard.

2. Consistent with ATIS’s September 12, 2023, *ex parte* letter (ATIS Ex Parte Letter) and as a condition of this waiver, the Bureau requires a handset to pass the conversational gain test at the 2 Newton (N) force level on all available narrowband and wideband codecs and air interface combinations. With respect to the 8N force level test, the Bureau agrees with the ATIS Ex Parte Letter that this test should be performed, and the Bureau waives the requirement that a handset achieve at least an 18 dB conversational gain. This waiver is conditioned on manufacturers performing the 8N force level test using the same testing parameters that the Bureau is requiring for the 2N force level test and to place on the handset’s package label the resulting conversational gain (even if it is below 18 dB) in a manner consistent with the