

thereafter be continuously published in the Chart Supplement.

\* \* \* \* \*

#### ACE KS E2 Manhattan, KS [Amended]

Manhattan Regional Airport, KS

(Lat. 39°08'28" N, long. 96°40'19" W)

That airspace extending upward from the surface within a 4.3-mile radius of Manhattan Regional Airport excluding that airspace within the Fort Riley, KS, Class D airspace and Class E surface airspace areas and excluding that airspace within Restricted Area R-3602B. This Class E airspace area is effective during the specific dates and times established in advanced by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

*Paragraph 6004. Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.*

\* \* \* \* \*

#### ACE KS E4 Manhattan, KS [Amended]

Manhattan Regional Airport, KS

(Lat. 39°08'28" N, long. 96°40'19" W)

Manhattan VOR/DME

(Lat. 39°08'44" N, long. 96°40'07" W)

That airspace extending upward from the surface within 1.3 miles each side of the 042° radial from the Manhattan VOR/DME extending from the 4.3-mile radius of the Manhattan Regional Airport to 5.2 miles northeast of the airport, and within 2.4 miles each side of the 211° radial from the Manhattan VOR/DME extending from the 4.3-mile radius of the Manhattan Regional Airport to 7 miles southwest of the Manhattan VOR/DME excluding that airspace within the Fort Riley, KS, Class D airspace and Class E surface airspace areas and excluding that airspace within Restricted Area R-3602B.

*Paragraph 6005. Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

\* \* \* \* \*

#### ACE KS E5 Fort Riley, KS [Establish]

Marshall AAF, KS

(Lat. 39°03'10" N, long. 96°45'52" W)

Freeman Field, KS

(Lat. 39°02'36" N, long. 96°50'36" W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Marshall AAF, and within a 6.4-mile radius of Freeman Field excluding that airspace within Restricted Areas R-3602A and R-3602B.

\* \* \* \* \*

#### ACE KS E5 Manhattan, KS [Amended]

Manhattan Regional Airport, KS

(Lat. 39°08'28" N, long. 96°40'19" W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the Manhattan Regional Airport, and within 4 miles each side of the 040° bearing from the Manhattan Regional Airport extending from the 6.8-mile radius of the airport to 10.6 miles northeast of the airport

excluding that airspace within Restricted Areas R-3602A and R-3602B.

Issued in Fort Worth, Texas, on January 13, 2021.

**Martin A. Skinner,**

*Acting Manager, Operations Support Group, ATO Central Service Center.*

[FR Doc. 2021-01020 Filed 1-19-21; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2020-0459]

RIN 1625-AA00

#### Safety Zone; Tanapag Harbor, Saipan, CNMI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is establishing a annually recurring safety zone for navigable waters within Tanapag Harbor, Saipan. This safety zone will encompass the designated swim course for the Escape from Managaha swim event in the waters of Tanapag Harbor, Saipan, Commonwealth of the Northern Mariana Islands. This action is necessary to protect all persons and vessels participating in this marine event from potential safety hazards associated with vessel traffic in the area. Race participants, chase boats, and organizers of the event will be exempt from the safety zone. Entry of persons or vessels into the safety zone is prohibited unless authorized by the Captain of the Port (COTP) Guam.

**DATES:** This rule is effective February 22, 2021.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2020-0459 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 rule, call or email Chief Petty Officer Robert Davis, Sector Guam, U.S. Coast Guard, by telephone at (671) 355-4866, or email at [WWMGuam@uscg.mil](mailto:WWMGuam@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

#### I. Table of Abbreviations

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 purpose of this rule is to ensure the safety of the participants and the navigable waters in the safety zone before, during, and after the scheduled swim event. In response, on November 20, 2020, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Tanapag Harbor, Saipan, CNMI (85 FR 74304-74306). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this safety zone. During the comment period that ended December 21, 2020, we received no comments.

## III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under its authority in 46 U.S.C 70034 (previously 33 U.S.C. 1231). The Captain of the Port (COTP) Guam has determined that potential hazards exist, and the purpose of this rule is to protect all persons and vessels participating in this marine event from potential safety hazards associated with vessel traffic in the area.

## IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published November 20, 2020. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a annual recurring safety zone from 5:00 a.m. until 8:30 a.m. on a Saturday or Sunday between February and April. The safety zone will cover all navigable waters within 100-yard radius of race participants in Tanapag Harbor, Saipan. This rulemaking would prohibit persons and vessels not involved in the event from being in the safety zone unless authorized by the COTP or a designated representative.

## 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone, which will impact a small designated area of Tanapag Harbor for 3.5 hours. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

#### 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 received 00 comments from the Small Business Administration on this rulemaking. 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 safety zone lasting 3.5 hours that will prohibit entry within 100-yards of swim participants. It is categorically excluded from further review under paragraph L60(a) 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 protesters. 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 part 165 as follows:

#### **PART 165—SAFETY ZONE; TANAPAG HARBOR, SAIPAN, CNMI**

■ 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. 0170.1.

■ 2. Add § 165.1417 to read as follows:

#### **165.1417 Safety Zone; Tanapag Harbor, Saipan, CNMI.**

(a) *Location.* The following area, within the Guam Captain of the Port (COTP) Zone (See 33 CFR 3.70–15), all navigable waters within a 100-yard radius of race participants for Escape for Managaha Swim in Tanapag Harbor, Saipan. Race participants, chase boats, and organizers of the event will be exempt from the safety zone.

(b) *Definitions.* As used in this section, 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 (COTP) Sector Guam in the enforcement of the safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in section § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or a designated on-scene representative.

(2) This safety zone is closed to all persons and vessel traffic, except as may be permitted by the COTP or a designated on-scene representative.

(3) The “on-scene representative” of the COTP is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on his or her behalf.

(4) Persons and Vessel operators desiring to enter or operate within the safety zone must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or an on-scene representative.

(d) *Enforcement period.* This safety zone will be enforced at a specified date between February and April. The Coast Guard will provide advance notice of enforcement and a broadcast notice to mariners to inform public of specific date.

Dated: January 12, 2021.

**Christopher M. Chase,**

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

[FR Doc. 2021-01084 Filed 1-19-21; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

#### 42 CFR Part 100

RIN 0906-AB24

### National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

**AGENCY:** Public Health Service, Health Resources and Services Administration (“HRSA”), Department of Health and Human Services (“HHS” or the “Department”).

**ACTION:** Final rule.

**SUMMARY:** The Secretary finalizes the proposed rule to amend the Vaccine Injury Table (Table) by regulation. This

final rule will have effect only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after this final rule become effective. This final rule does not impact COVID-19 vaccines or PREP Act immunity for Covered Persons (as defined in the PREP Act) who manufacture, distribute, order, or administer COVID-19 vaccines.

**DATES:** This final rule is effective on February 22, 2021.

**FOR FURTHER INFORMATION CONTACT:** Please visit the National Vaccine Injury Compensation Program’s website, <https://www.hrsa.gov/vaccinecompensation/>, or contact Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Room 08N146B, 5600 Fishers Lane, Rockville, MD 20857; by email at [vaccinecompensation@hrsa.gov](mailto:vaccinecompensation@hrsa.gov); or by telephone at (855) 266-2427.

**SUPPLEMENTARY INFORMATION:** This is a final rule by which HHS amends the provisions of 42 CFR 100.3 by removing Shoulder Injury Related to Vaccine Administration, vasovagal syncope, and Item XVII from the Vaccine Injury Table.

#### I. Background and Purpose

Vaccination is one of the best ways to protect against potentially harmful diseases that can be very serious, may require hospitalization, or even be deadly. Almost all individuals who are vaccinated have no serious reactions.<sup>1</sup> Nonetheless, in the 1980s, Congress became concerned that a small number of children who received immunizations had serious reactions to them, and it was not always possible to predict which children would have reactions, or what reactions they would have.<sup>2</sup> Claimants alleging vaccine-related injuries in civil litigation encountered a time-consuming, expensive, and often inadequate system.<sup>3</sup> Moreover, increased litigation against vaccine manufacturers resulted in difficulties in their ability to secure affordable product liability insurance,

<sup>1</sup> National Vaccine Injury Compensation Program, Health Resources & Servs. Admin., <https://www.hrsa.gov/vaccine-compensation/index.html> (last reviewed Jan. 2020).

<sup>2</sup> H.R. Rep. No. 99-908, pt. 1, at 6 (1986). Even though in rare instances individuals may have adverse reactions to vaccines, the Centers for Disease Control and Prevention (CDC) recommends that individuals be vaccinated against a wide range of illnesses and diseases. See Recommended Vaccines by Age, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/vaccines/vpd/vaccines-age.html> (last reviewed Nov. 22, 2016).

<sup>3</sup> H.R. Rep. No. 99-908, at 6.

stabilize vaccine prices and supply, and enter the market.<sup>4</sup>

Therefore, Congress enacted the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660 (42 U.S.C. 300aa-1 *et seq.*) (“Vaccine Act” or “the Act”), which established the National Vaccine Injury Compensation Program (VICP). The objectives of the VICP are to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines to be federally compensated. Petitions for compensation under the VICP are filed in the United States Court of Federal Claims (Court), rather than the civil tort system, with a copy served on the Secretary, who is the Respondent. The U.S. Department of Justice (DOJ) represents HHS in Court, and the Court, acting through judicial officers called Special Masters, makes the final decision as to eligibility for, and the type and amount of, compensation.

To gain entitlement to compensation under this Program, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating what is referred to as a “Table injury.” That is, a petitioner may show that the vaccine recipient (1) received a vaccine covered under the Act; (2) suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the “Vaccine Injury Table” (Table)—corresponding to the vaccination in question; and (3) that the onset of such injury took place within the time period specified in the Table. If so, the injury is presumed to have been caused by the vaccine, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless the respondent affirmatively shows that the injury was caused by some factor unrelated to the vaccination (*see* 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)(B), and 300aa-14(a)).

42 U.S.C. 300aa-14(c) and (e) permit the Secretary to revise the Table. The Table currently includes 17 vaccine categories, with 16 categories for specific vaccines, as well as the corresponding illnesses, disabilities, injuries, or conditions covered, and the requisite time period when the first symptom or manifestation of onset or of significant aggravation after the vaccine administration must begin to receive the Table’s legal presumption of causation. The final category of the Table, “Item

<sup>4</sup> *See id.* at 4-6.