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List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

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

■ 2. Section 878.4635 is revised to read as follows:

§ 878.4635 Sunlamp product.

(a) *Identification.* An electronic product that includes one or more ultraviolet (UV) lamps and a fixture intended for irradiation of any part of the living human body, by UV radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning. This definition includes tanning beds, tanning booths, and UV lamps (bulbs) sold separately.

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

(1) Conduct performance testing that demonstrates the following:

(i) Sunlamp products meet appropriate output performance specifications such as wavelengths, energy density, and lamp life; and

(ii) Safety features, such as timers to limit UV exposure and alarms, function properly.

(2) Demonstrate that sunlamp products are mechanically safe to prevent user injury.

(3) Demonstrate software verification, validation, and hazard analysis.

(4) Demonstrate that sunlamp products are biocompatible.

(5) Demonstrate that sunlamp products are electrically safe and electromagnetically compatible in their intended use environment.

(6) Labeling must bear all information required for the reasonable assurance of safe and effective use of the device.

(i) The warning statement below must appear on all sunlamp product fixtures. This statement must be permanently affixed or inscribed on the product when fully assembled for use so as to be legible and readily accessible to view by the person who will be exposed to UV radiation immediately before the use of the product. It shall be of sufficient durability to remain legible throughout the expected lifetime of the product. It shall appear on a part or panel displayed prominently under normal conditions of use so that it is readily accessible to view whether the tanning bed canopy (or tanning booth door) is open or closed when the person who will be exposed approaches the equipment and the text shall be at least 10 millimeters (height). Labeling on the device must include the following statement:

"Attention: This sunlamp product should not be used on persons under the age of 18 years."

(ii) Manufacturers of sunlamp products shall provide or cause to be provided in the user instructions for a sunlamp product as well as all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed Web pages on which sunlamp products are offered for sale, the following contraindication and warning statements:

(A) "Contraindication: This sunlamp product is contraindicated for use on persons under the age of 18 years."

(B) "Contraindication: This sunlamp product must not be used if skin lesions or open wounds are present."

(C) "Warning: This sunlamp product should not be used on individuals who have had skin cancer or have a family history of skin cancer."

(D) "Warning: Persons repeatedly exposed to ultraviolet sunlamp products should be regularly evaluated for skin cancer."

(iii) Manufacturers of sunlamp products shall provide validated instructions on cleaning and disinfection of sunlamp products between uses in the user instructions.

(c) Sunlamp products are subject to the electronic product performance standard at § 1040.20 of this chapter.

Dated: May 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10982 Filed 5–6–13; 4:15 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Pacific Ocean Off the Kekaha Range Facility at Barking Sands, Island of Kauai, Hawaii; Danger Zone

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Corps of Engineers is proposing to amend its regulations to establish a new danger zone in waters of the Pacific Ocean off the Kekaha Range Facility, Barking Sands, Island of Kauai, Hawaii. The proposed amendment is necessary for the Hawaii Army National Guard to continue small arms training operations at the Kekaha Range Facility and to protect the public from potentially hazardous conditions which may exist as a result of that use. The proposed amendment would prohibit, on an intermittent basis, vessels from entering a six mile wide section of the Pacific Ocean that narrows to a 0.7 mile wide section along the shoreline fronting the Kekaha Range Facility without first obtaining permission from the Commanding Officer of Kekaha Range Facility.

DATES: Written comments must be submitted on or before June 10, 2013.

ADDRESSES: You may submit comments, identified by docket number COE–2013–0004, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Email: david.b.olson@usace.army.mil. Include the docket number COE–2013–0004, in the subject line of the message.

Mail: U.S. Army Corps of Engineers, Attn: CECW–CO–R (David B. Olson), 441 G Street NW., Washington, DC 20314–1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Direct your comments to docket number COE–2013–0004. All

comments received will be included in the public docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the commenter indicates that the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) Web site is an anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to the Corps without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, we recommend that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If we cannot read your comment because of technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

Docket: For access to the docket to read background documents or comments received, go to www.regulations.gov. All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202-761-4922, or Mr. Farley Watanabe, Corps of Engineers, Honolulu District, Regulatory Branch, at 808-835-4305 or by email at farley.k.watanabe@usace.army.mil.

SUPPLEMENTARY INFORMATION:

Executive Summary

The purpose of this regulatory action is to establish a new danger zone in waters of the Pacific Ocean off the Kekaha Range Facility at Barking Sands, Island of Kauai, Hawaii.

The Corps authority to establish this danger zone is Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat 892; 33 U.S.C. 3).

Background

Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps of Engineers is proposing to amend the regulations at 33 CFR part 334 to establish a new danger zone in the waters of the Pacific Ocean off the Kekaha Range Facility at Barking Sands, Island of Kauai, Hawaii.

Procedural Requirements

a. Review Under Executive Order 12866

This proposed rule is issued with respect to a military function of the Defense Department and the provisions of Executive Order 12866 do not apply.

b. Review Under the Regulatory Flexibility Act

This proposed rule has been reviewed under the Regulatory Flexibility Act (Pub. L. 96-354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (i.e., small businesses and small governments). Unless information is obtained to the contrary during the public notice comment period, the Corps expects that the establishment of this danger zone would have practically no economic impact on the public, no anticipated navigational hazard, or interference with existing waterway traffic. This proposed rule if adopted, will have no significant economic impact on small entities.

c. Review Under the National Environmental Policy Act

Due to the administrative nature of this action and because there is no intended change in the use of the area, the Corps expects that this regulation, if adopted, will not have a significant impact to the quality of the human environment and, therefore, preparation of an environmental impact statement will not be required. An environmental assessment will be prepared after the public notice period is closed and all comments have been received and considered. After it is prepared, it may be reviewed at the District office listed at the end of the **FOR FURTHER INFORMATION CONTACT** section, above.

d. Unfunded Mandates Act

This proposed rule does not impose an enforceable duty among the private sector and, therefore, it is not a Federal private sector mandate and it is not subject to the requirements of either Section 202 or Section 205 of the Unfunded Mandates Act. We have also found under Section 203 of the Act, that small governments will not be significantly and uniquely affected by this rulemaking.

List of Subjects in 33 CFR Part 334

Danger zones, Marine safety, Navigation (water), Restricted areas, Waterways.

For the reasons set out in the preamble, the Corps proposes to amend 33 CFR part 334 as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

■ 1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

■ 2. Add § 334.1395 to read as follows:

§ 334.1395 Pacific Ocean off the Kekaha Range Facility at Barking Sands, Island of Kauai, Hawaii; danger zone.

(a) *The danger zone.* All waters within the area bounded by a line connecting the following coordinates: beginning at a point on the shore at latitude 21°58'45" N, longitude 159°45'32" W; thence easterly along the shoreline (shoreline is defined as the mean high water line and is coterminous with the federal property line) to a point at latitude 21°58'33" N, longitude 159°44'57" W; thence southeasterly to a point at latitude 21°55'39" N, longitude 159°43'36" W; thence northwesterly to a point at latitude 21°57'50" N, longitude 159°48'54" W; thence to point of beginning. All coordinates reference 1983 North American Datum (NAD 83).

(b) *The regulations.* (1) Weapons firing at the Kekaha Range Facility (KRF) may occur at any time between 7 a.m. and 6 p.m., Monday through Sunday. Specific dates and hours for weapons firing, along with information regarding onshore warning signals, will be promulgated by the U.S. Coast Guard's Local Notice to Mariners. Information on weapons firing schedules may also be obtained by calling the KRF Facility Manager, NCHI-OPS-TNG (G3) at 808-844-6731.

(2) Whenever live firing is in progress during daylight hours, two large red triangular warning pennants will be flown at each of two highly visible and

widely separated locations on the shore at the KRF.

(3) Whenever any weapons firing is scheduled and in progress during periods of darkness, flashing red warning beacons will be displayed on the shore at the KRF.

(4) Boaters will have complete access to the danger zone whenever there is no weapons firing scheduled, which will be indicated by the absence of any warning flags, pennants, or beacons displayed ashore.

(5) The danger zone is not considered safe for boaters whenever weapons firing is in progress. Boaters shall expeditiously vacate the danger zone at best speed and by the most direct route whenever weapons firing is in progress. Weapons firing will be suspended as long as there is a vessel in the danger zone. Whenever a boater disregards the publicized warning signals that hazardous weapons firing is in progress, the boater will be personally requested to expeditiously vacate the danger zone by KRF personnel hailing the vessel on VHF channel 16 or contacting the vessel directly by surface craft.

(6) Observation posts will be manned whenever any weapons firing is scheduled and in progress. Visibility will be sufficient to maintain visual surveillance of the entire danger zone and for an additional distance of 5 miles in all directions whenever weapons firing is in progress.

(c) *The enforcing agency.* The regulations shall be enforced by the Commanding Officer, Kekaha Range Facility, Hawaiian Area, Barking Sands, Kauai, Hawaii and such agencies or persons as he or she may designate.

Dated: May 3, 2013.

Approved:

James R. Hannon,

Chief, Operations and Regulatory, Directorate of Civil Works.

[FR Doc. 2013-11037 Filed 5-8-13; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

East Bay, St. Andrews Bay and the Gulf of Mexico at Tyndall Air Force Base, Florida; Restricted Areas

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The U.S. Army Corps of Engineers (Corps) is proposing to amend its regulations by revising an existing restricted area regulation and establishing six new restricted areas along the Tyndall Air Force Base (AFB) facility shoreline. Tyndall AFB is surrounded on three sides by water with approximately 129 miles of unprotected coastline. This includes several areas where the lack of security or lack of restriction on access to these areas leaves Tyndall AFB personnel and resources vulnerable to unauthorized activities. This amendment is necessary to implement an enhanced security plan for Tyndall AFB, which includes four new permanent restricted areas and the ability to activate two additional restricted areas as local and national intelligence threat evaluations dictate.

DATES: Written comments must be submitted on or before June 10, 2013.

ADDRESSES: You may submit comments, identified by docket number COE-2013-0003, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Email: david.b.olson@usace.army.mil. Include the docket number, COE-2013-0003, in the subject line of the message.

Mail: U.S. Army Corps of Engineers, Attn: CECW-CO (David B. Olson), 441 G Street NW., Washington, DC 20314-1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Direct your comments to docket number COE-2013-0003. All comments received will be included in the public docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the commenter indicates that the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) Web site is an anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to the Corps without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic

comment, we recommend that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If we cannot read your comment because of technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

Docket: For access to the docket to read background documents or comments received, go to www.regulations.gov. All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202-761-4922 or Mr. Jon M. Griffin, U.S. Army Corps of Engineers, Jacksonville District, Regulatory Division, at 904-232-1680.

SUPPLEMENTARY INFORMATION:

Executive Summary

The purpose of this regulatory action is to establish four new permanent restricted areas in the waters surrounding Tyndall AFB to counter postulated threats against their personnel and equipment at those sites. Additionally, this regulatory action would establish two additional restricted areas which would be activated under conditions of heightened security risks and provide an administrative correction to the existing regulation at 33 CFR 334.660.

The Corps authority to establish these restricted areas is Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3).

Background

Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat 892; 33 U.S.C. 3) the Corps is proposing to revise the regulations at 33 CFR part 334 by establishing a total of six new restricted areas in the waters surrounding Tyndall AFB. This amendment to the existing regulation will allow the Commander, Tyndall