regulatory-information/search-fda-guidance-documents/recommendations-premarket-notification-510k-submissions-nucleic-acid-based-human-leukocyte-antigen.

5. FDA, ''Medical Devices; Immunology and Microbiology Devices; Classification of Human Leukocyte, Neutrophil and Platelet Antigen and Antibody Tests,'' Preliminary Regulatory Impact Analysis Initial Regulatory Flexibility Analysis Unfunded Mandates Reform Act Analysis,'' 2019 (available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 866 be amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

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

■ 2. Add § 866.5960 to subpart F to read as follows:

§ 866.5960 Human Leukocyte, Human Neutrophil, and Human Platelet antigen and antibody devices.

(a) *Identification.* Human Leukocyte, Human Neutrophil, and Human Platelet antigen and antibody devices consist of Human Leukocyte Antigen (HLA), Human Platelet Antigen (HPA), and Human Neutrophil Antigen (HNA) typing and antibody detection devices.

(1) HLA typing devices are used to determine HLA types, to aid in transfusion or transplantation donor and recipient matching, or to aid in the diagnosis of diseases.

(2) HLA antibody detection devices are used to detect antibodies to HLA antigens to aid in donor and recipient matching in transfusion or transplantation.

(3) HPA typing devices are used for the detection of human platelet antigens to aid in donor and recipient matching in blood transfusion or to aid in the diagnosis of diseases.

(4) HPA antibody detection devices are used to detect autoantibodies and alloantibodies against platelet glycoproteins to aid in donor and recipient matching in blood transfusion or to aid in the diagnosis of diseases.

(5) HNA typing devices are used for the detection of human neutrophil antigens to aid in donor and recipient matching in blood transfusion or to aid in the diagnosis of diseases.

(6) HNA antibody detection devices are used to detect autoantibodies and alloantibodies against neutrophil antigens to aid in donor and recipient matching in blood transfusion or to aid in the diagnosis of diseases.

(b) *Classification.* Class II (special controls). HLA, HPA, and HNA typing devices must comply with the following special controls:

(1) Premarket submissions must include detailed documentation of the following:

(i) Device accuracy study using well-characterized samples representing as many targets as possible.

(ii) Precision studies to evaluate possible sources of variation that may affect test results.

(iii) Comparison studies to evaluate the device's performance compared to a predicate.

(iv) Specific information that addresses or mitigates risks associated with false positive antibody reactivity, *e.g.,* reactivity with denatured/cryptic epitopes, if applicable.

(v) Description of how the assay cutoff was established and validated as well as supporting data.

(vi) Documentation for device software, including, but not limited to, software requirement specifications, software design specifications, *e.g.,* algorithms, alarms, and device limitations; hazard analysis, traceability matrix, verification and validation testing, unresolved anomalies, hardware and software specifications; electromagnetic compatibility and wireless testing.

(vii) Design specifications that are in place to prevent incorrect reactivity assignment or multiplex assays in which large numbers of probes and/or primers are handled during manufacturing process.

(viii) Description of a plan on how to ensure the performance characteristics of the device remain unchanged over time when new HLA alleles are identified and/or reactivity assignments are changed from the assignments at the time the device was evaluated.

(2) The device labeling must include:

(i) A limitation statement that reads, ''The results should not be used as the sole basis for making a clinical decision.''

(ii) A warning that reads ''The device has not been cleared or approved for use as a companion diagnostic.''

Dated: January 11, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–01156 Filed 1–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

[COE–2021–0006]

Eagle River From Bravo Bridge to Eagle Bay in Knik Arm, Richardson Training Area on Joint Base Elmendorf-Richardson, Alaska; Restricted Area

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 revise its regulations to establish a restricted area within the Richardson Training Area on Joint Base Elmendorf-Richardson (JBER), at Eagle River. The United States Army, Alaska (USARAK) G3/5/7 Training and Support Activity-Alaska (TSA–AK) requested establishment of a restricted area which would be located in the area of navigable waters extending from the span on Bravo Bridge across Eagle River to the mouth of Eagle River Knik Arm (Eagle River channel). Establishment of the restricted area would prevent all watercraft navigations and individuals from entering an active military range munitions impact area at all times, except for authorized vessels and individuals engaged in support of military training and management activities. This restricted area is necessary to avoid inadvertent entry into the impact area during live-fire weapons training, exposure to hazardous noise, and inadvertent encounters with unexploded ordnance.

DATES: Written comments must be submitted on or before February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number COE–2021–0006, 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–2021–0006, 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–2021–0006. 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* or email. The *regulations.gov* website 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,* 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 compact disk 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, U.S. Army Corps of Engineers, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922.

SUPPLEMENTARY INFORMATION:

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 amend the regulations at 33 CFR part 334 by establishing a restricted area in the Eagle River channel. The amendment to this regulation will allow the USARAK Commander to prevent all watercraft navigations and individuals from entering an active military range (Richardson Training Area, Joint Base Elmendorf-Richardson) munitions impact area at all times, except for authorized vessels and individuals engaged in support of military training and management activities. This restricted area will be in place as a precautionary measure to protect the public from inadvertently entering the impact area during live-fire weapons training, encountering hazardous noise in the vicinity of the impact area, and encountering unexploded ordnance.

Procedural Requirements

a. *Regulatory Planning and Review.* This proposed rule is not a ''significant regulatory action'' under Executive Order 12866 (58 FR 51735, October 4, 1993) and it was not submitted to the Office of Management and Budget for review.

b. *Regulatory Flexibility Act, as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 et seq.* This rule has been reviewed under the Regulatory Flexibility Act (Pub. L. 96–354). The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (*i.e.,* small businesses and small governments).

The Corps certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. The restricted area is necessary to protect public safety. This restricted regulation would prevent all watercraft and individuals from entering an activity military range munitions impact area at all times, except for authorized vessels and individuals engaged in support of military training and management activities. The regulation would allow people, watercraft, or vessels to enter or remain in the waters in the restricted area as long as they are authorized by the enforcing agency. Small entities can utilize navigable waters outside of the restricted area. Unless information is obtained to the contrary during the comment period, the Corps expects that the economic impact of the proposed restricted area would have practically no impact on the public, any anticipated navigational hazard or interference with existing waterway traffic. After considering the economic impacts of this restricted area regulation on small entities, I certify that this proposed rule would not have a significant impact on a substantial number of 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 on 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.

d. *Unfunded Mandates Act.* This proposed rule does not contain a federal mandate that may result in expenditures of $100 million or more for tribal, state, and local governments, in the aggregate, or the private sector in any one year. Therefore, this proposed rule is not subject to the requirements of Sections 202 and 205 of the Unfunded Mandates Reform Act (UMRA). The proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. Therefore, the proposed rule is not subject to the requirements of Section 203 of UMRA.

List of Subjects in 33 CFR Part 334

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

For the reasons set forth in the summary above, 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 § 334.1305 to read as follows:

§ 334.1305 Eagle River from Bravo Bridge to its mouth at Eagle Bay in Knik Arm, Richardson Training Area on Joint Base Elmendorf-Richardson, Alaska; restricted area.

(a) *Restricted area.* The restricted area consists of navigable waters within an area defined as beginning a point on shore at latitude 61°19′40.1″ N, longitude 149°44′20.336″ W; thence easterly to latitude 61°19′41.59″ N, longitude 149°44′6.825″ W; 3.06 nautical miles southerly along the river to latitude 61°18′40.13″ N, longitude

149°41′16.12″ W; thence southerly to latitude 61°18′38.404″ N, to longitude 149°41′14.73″ W. The datum for these coordinates is NAD–83.

(b) *The regulation.* The restricted area is permanently closed for public use at all times. No persons, watercraft, or vessels shall enter, or remain, in the area except for those authorized by the enforcing agency.

(c) *Enforcement.* This regulation will be enforced by the Commander, United States Army-Alaska.

Thomas P. Smith,

Chief, Operations and Regulatory Division.

[FR Doc. 2022–01011 Filed 1–20–22; 8:45 am]

BILLING CODE 3720–58–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2021–0854; FRL–9381–01–R3]

Air Plan Approval; Delaware; Philadelphia Area 2017 Base Year Inventory for the Ozone National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision formally submitted by the State of Delaware. This revision consists of the base year inventory for the Delaware portion of the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE marginal nonattainment area (Philadelphia Area) for the 2015 ozone national ambient air quality standards (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before February 22, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2021–0854 at *https://www.regulations.gov,* or via email to *Gordon.Mike@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Adam Yarina, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2103. Mr. Yarina can also be reached via electronic mail at *Yarina.Adam@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 9, 2020, the Delaware Department of Natural Resources and Environmental Control (DNREC) on behalf of the State of Delaware, submitted a revision to the Delaware SIP entitled, ''2017 Base Year Emissions Inventory State Implementation Plan for VOC, NO_X, and CO for Areas of Marginal Nonattainment of the 2015 Ozone NAAQS in Delaware.'' New Castle County comprises Delaware's portion of the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE 2015 ozone NAAQS nonattainment area. This SIP revision, referred to in this rulemaking action as the ''New Castle County base year inventory SIP,'' addresses Delaware's base year inventory requirement for the 2015 ozone NAAQS.

I. Background

On October 1, 2015, EPA strengthened the 8-hour ozone NAAQS, lowering the level of the NAAQS from 0.075 ppm parts per million (ppm) to 0.070 ppm. See 80 FR 65292 (October 26, 2015). Effective August 3, 2018, EPA designated the Philadelphia Area, which consists of New Castle County in Delaware and counties in Maryland, New Jersey, and Pennsylvania, as marginal nonattainment for the 2015 ozone NAAQS. See 83 FR 25776 (June 4, 2018). CAA section 182(a)(1) requires ozone nonattainment areas classified as marginal or above to submit a comprehensive, accurate, current inventory of actual emissions from all emissions sources in the nonattainment area, known as a ''base year inventory.'' The New Castle County base year inventory SIP addresses a base year inventory requirement for the Philadelphia Area.

II. Summary of SIP Revision and EPA Analysis

A. EPA Evaluation of the New Castle County Base Year Inventory SIP

EPA's review of Delaware's base year inventory SIP indicates that it meets the base year inventory requirements for the 2015 ozone NAAQS. As required by 40 CFR 51.1315(a), DNREC selected 2017 for the base year inventory, which is consistent with the baseline year for the RFP because it is the year of the most recent triennial inventory. DNREC included actual ozone season emissions, pursuant to 40 CFR 51.1315(c).

EPA prepared a Technical Support Document (TSD) in support of this rulemaking. In that TSD, EPA reviewed the results, procedures, and methodologies for the SIP base year, and found them to be acceptable and developed in accordance with EPA's technical guidance. The TSD is available online at *http://www.regulations.gov,* Docket ID No. EPA–R03–OAR–2021–0854.

B. Base Year Inventory Requirements

In EPA's December 6, 2018 (83 FR 62998) rulemaking, ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements,'' known as the ''SIP Requirements Rule,'' EPA set out nonattainment area requirements for the 2015 ozone NAAQS. SIP Requirements Rule established base year inventory requirement, which were codified at 40 CFR 51.1315. As per 40 CFR 51.1315(a), each 2015 ozone nonattainment area is required to submit a base year inventory within 2 years of designation (*i.e.,* no later than August 3, 2020).

Also, 40 CFR 51.1315(a) requires that the inventory year be selected consistent with the baseline year for the reasonable further progress (RFP) plan as required by 40 CFR 51.1310(b), which states that the baseline emissions inventory shall be the emissions inventory for the most recent calendar year for which a complete triennial inventory is required to be submitted to the EPA under the provisions of subpart A of 40 CFR part 51, Air Emissions Reporting Requirements, 40 CFR 51.1 through 51.50. The most recent triennial inventory year conducted for the National Emissions Inventory (NEI) pursuant to the Air Emissions Reporting Requirements (AERR) rule is 2017. See