

characteristics as well as the stability claims.

(xi) All stability protocols, including acceptance criteria.

(xii) Appropriate and acceptable procedure(s) for addressing complaints and other device information that determines when to submit a medical device report.

(xiii) Premarket notification submissions must include the information contained in paragraphs (b)(2)(i) through (xii) of this section.

Dated: October 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23868 Filed 11–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

[Docket No. USPC–2020–04]

RIN 1104–AA09

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences Under the United States and District of Columbia Codes

AGENCY: United States Parole Commission, Justice.

ACTION: Final rule.

SUMMARY: The U.S. Parole Commission is modifying a rule that permits it to reopen a case and rescind a parole date when the prisoner has committed a violation of institutional rules. This modification will permit findings by a Residential Reentry Center's Disciplinary Committee, as well as findings by the Disciplinary Hearing Officer, as conclusive evidence of misconduct for the United States Parole Commission to rescind an established parole date.

DATES: This regulation is effective November 4, 2022.

FOR FURTHER INFORMATION CONTACT: Helen H. Krapels, General Counsel, U.S. Parole Commission, 90 K Street NE, Third Floor, Washington, DC 20530, telephone (202) 346–7000. Questions about this publication are welcome, but inquiries concerning individual cases cannot be answered over the telephone.

SUPPLEMENTARY INFORMATION: In 2021, the United States Parole Commission issued an interim rule revising 28 CFR 2.34(a) (86 FR 51271, September 15, 2021). The comment period expired on November 15, 2021, and the Parole

Commission did not receive any comments on the change. On October 13, 2022, the Parole Commission voted to

After the U.S. Parole Commission has granted a prisoner a parole effective date, but before the prisoner has signed the parole certificate, if the prisoner violates the rules of the institution, the Parole Commission may reopen the case and schedule a rescission hearing. 28 CFR 2.34(a). At that hearing, the Parole Commission may consider the report of the Bureau of Prisons (“BOP”) Disciplinary Hearing Officer (“DHO”) following a disciplinary hearing, that a prisoner has violated disciplinary rules as “conclusive evidence of institutional misconduct,” and does not need to conduct a full hearing to consider witnesses and evidence. 28 CFR 2.34(c). The disciplinary hearing conducted by the DHO complies with the procedural due process requirements established by the Supreme Court in *Wolff v. McDonnell*, *i.e.*, the prisoner has notice of the alleged violations at least 24 hours in advance of hearing, a statement of factfinding, the right to call witnesses and present documentary evidence. Thus, the Parole Commission may rely on the findings and conclusions of the DHO to take action in response to the information.

For prisoners who are housed at a Residential Reentry Center (“RRC”) prior to their release and violate the rules, the in-person disciplinary hearing is conducted before the RRC's Center Disciplinary Committee (“CDC”). Under the BOP's Program Statement 7300.09, the CDC then refers its findings to the DHO for review, final action, and sanctions. Every court which has examined the procedures established by Program Statement 7300.09 has held that hearing procedures used by the CDC satisfy the procedural due process requirements established by the Supreme Court in *Wolff v. McDonnell*.

This rule permits the U.S. Parole Commission to rely on the CDC's findings to promote the smooth transition to the community or to return a prisoner who has demonstrated that he or she is not ready to be released to the community without requiring a second hearing by the DHO or a fully contested disciplinary hearing conducted by the U.S. Parole Commission.

The Parole Commission has added a phrase to clarify that parole may also be rescinded without a hearing for DC Code prisoners for up to 120 days. The interim rule only referenced the 90-day rescission of parole that pertains to US Code prisoners and the rule will apply correspondingly to US Code prisoner

and DC Code prisoners under the Parole Commission's jurisdiction. The Parole Commission is publishing the revised rule at § 2.34(a) as a final rule without seeking public comment because this does not create a substantive change to parole decision-making.

Executive Orders 12866 and 13563

This regulation has been drafted and reviewed in accordance with Executive Order 12866, “Regulation Planning and Review,” section 1(b), Principles of Regulation, and in accordance with Executive Order 13565, “Improving Regulation and Regulatory Review,” section 1(b), General Principles of Regulation. The Commission has determined that this rule is not a “significant regulatory action” under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 13132

This rule will not have substantial direct effects 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. Under Executive Order 13132, this rule does not have sufficient federalism implications requiring a federalism assessment.

Regulatory Flexibility Act

This rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local, or tribal governments, or the private sector, to spend \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. No action under the Unfunded Mandates Reform Act of 1995 is necessary.

Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E—Congressional Review Act)

This rule is not a “major rule” as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 Subtitle E—Congressional Review Act, now codified at 5 U.S.C. 804(2). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on the ability

of United States-based companies to compete with foreign-based companies. Moreover, this is a rule of agency practice or procedure that does not substantially affect the rights or obligations of non-agency parties, and does not come within the meaning of the term "rule" as used in Section 804(3)(C), now codified at 5 U.S.C. 804(3)(C). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Prisoners, Probation and Parole.

The Interim Rule

Accordingly, the interim rule amending 28 CFR part 2 which was published at 86 FR 51271 on September 15, 2021, is adopted as final with the following change:

PART 2—[AMENDED]

1. The authority citation for 28 CFR part 2 continues to read as follows:

Authority: 18 U.S.C. 4203(a)(1) and 4204(a)(6).

2. Section 2.34 is amended by revising paragraphs (a) and (c) to read as follows:

§ 2.34 Rescission of parole.

(a) When an effective date of parole has been set by the Commission, release on that date is conditioned upon continued satisfactory conduct by the prisoner. If a prisoner granted such a date has been found in violation of institution rules by a Discipline Hearing Officer, or the Center Disciplinary Committee, or is alleged to have committed a new criminal act at any time prior to the delivery of the certificate of parole, the Commissioner shall be advised promptly of such information. The prisoner shall not be released until the institution has been notified that no change has been made in the Commission's order to parole. Following receipt of such information, the Commissioner may reopen the case and retard the parole date for up to 90 days without a hearing, or 120 days for a DC Code sentenced prisoner, or schedule a rescission hearing under this section on the next available docket at the institution or on the first docket following return to a federal institution from a community corrections center or a state or local halfway house.

* * * * *

(c) A hearing before a Discipline Hearing Officer, or the Center Disciplinary Committee, resulting in a finding that the prisoner has committed a violation of disciplinary rules may be

relied upon by the Commission as conclusive evidence of institutional misconduct. However, the prisoner will be afforded an opportunity to explain any mitigating circumstances, and to present documentary evidence in mitigation of the misconduct at the rescission hearing.

* * * * *

Patricia K. Cushwa,
Chairman (Acting), U.S. Parole Commission.
[FR Doc. 2022-23793 Filed 11-3-22; 8:45 am]

BILLING CODE 4410-31-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2022-0882]

Safety Zone; Fireworks Displays Within the Fifth Coast Guard District

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

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for fireworks at The Wharf DC on December 3, 2022 to provide for the safety of life on navigable waterways during this event. Our regulation for Fireworks Displays within the Fifth Coast Guard District identifies the safety zone for this event in Washington, DC. During the enforcement period, the operator of any vessel in the safety zone must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulation in 33 CFR 165.506 will be enforced for the location identified as item (1) of table 2 to paragraph (h)(2) from 7 until 9 p.m. on December 3, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email MST2 Courtney Perry, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410-576-2596, email Courtney.E.Perry@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone regulation for fireworks at The Wharf DC from 7 to 9 p.m. on December 3, 2022. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for Fireworks Displays within the Fifth Coast Guard District, 33 CFR 165.506, specifies the location of

the safety zone for the fireworks show which encompasses portions of the Washington Channel in the Upper Potomac River as item 1 to table 2 to paragraph (h)(2). During the enforcement period, as reflected in § 165.506(d), if you are the operator of a vessel in the safety zone you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the Federal Register, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: October 28, 2022.

David E. O'Connell,
Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2022-23999 Filed 11-3-22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0880]

RIN 1625-AA00

Safety Zone; Head of the South Regatta, Savannah River, Augusta, GA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Savannah River near Augusta, GA for the Head of the South Regatta. This temporary safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the rowing regatta. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Savannah or a designated representative.

DATES: This rule is effective from noon until 5 p.m. on November 11, 2022 through November 12, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to https://www.regulations.gov, type USCG-2022-0880 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 about this notification of enforcement, call or