

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order. FDA supports the principles of the “3Rs,” to replace, reduce, and/or refine animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider whether such an alternative method could be assessed for equivalency to an animal test method.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for focused ultrasound systems for non-thermal, mechanical tissue ablation. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under

OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

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, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

- 1. The authority citation for part 878 continues to read as follows:

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

- 2. Add § 878.4405 to subpart E to read as follows:

§ 878.4405 Focused ultrasound system for non-thermal, mechanical tissue ablation.

(a) *Identification.* This device uses focused ultrasound to mechanically ablate soft tissue. The device is not intended to thermally ablate tissue.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must document the adverse event profile and characterize tissue destruction.

(2) Animal performance testing must demonstrate that the device mechanically destroys targeted tissue while characterizing the chronic safety profile, including thermal and mechanical injury to adjacent, non-target tissue.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

- (i) Acoustic characterization at clinically relevant settings;
- (ii) Determination of the minimum drive voltages necessary to sustain a bubble cloud in the target tissue;
- (iii) Validation of mechanisms to prevent energy delivery that would result in adverse thermal effects;
- (iv) Availability of real-time monitoring during the procedure;
- (v) Validation that the treatment zone is limited to the defined target tissue; and

(vi) Validation of mechanisms to prevent, pause, and terminate ablation in the event of device failure.

(4) Performance data must support the electrical safety and electromagnetic compatibility of the device.

(5) All patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Software validation, verification, and hazard analysis must be performed.

(7) Human factors testing must demonstrate that the user can safely and correctly use the device.

(8) Labeling must include the following:

(i) A warning that focused ultrasound ablation should only be considered in patients with sufficient functional reserve to withstand the destruction of the planned volume of tissue;

(ii) A statement that the device has not been evaluated for the treatment of any specific disease or condition; and

(iii) A detailed summary of the clinical testing with the device.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of the Secretary

31 CFR Part 1

Privacy Act Exemptions

AGENCY: Department of the Treasury.

ACTION: Final rule.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Department of the Treasury (Treasury) is issuing a final rule, exempting a new system of records entitled “Department of the Treasury, Treasury .032—Federal Program Waste, Fraud, and Abuse Tip Intake and Referral Records” from certain provisions of the Privacy Act. This system of records is established to support the receipt, maintenance, review, triage, and referral of tips, complaints, allegations, leads, supporting information, and related correspondence concerning suspected waste, fraud, abuse, improper payments, misuse of Federal funds, or other misconduct affecting Federal programs. The exemption is intended to protect investigatory material compiled for law enforcement purposes.

DATES: This rule is effective on November 5, 2026.

FOR FURTHER INFORMATION CONTACT: For general questions and questions regarding privacy issues, please contact: Ryan Law, Deputy Assistant Secretary for Privacy, Transparency, and Records, Department of the Treasury, 1500 Suite #8100, JBAB, 250 Murray Lane SW, BLDG 410/Door 123, Washington, DC 20222; telephone: (202) 622-5710.

SUPPLEMENTARY INFORMATION:

Background

Treasury published a notice of proposed rulemaking (Systems Exemption NPRM) in the **Federal Register**, 91 FR 36550 (June 17, 2026), proposing to exempt portions of the system of records from one or more provisions of the Privacy Act.

Executive Order 14249, “Protecting America’s Bank Account Against Fraud, Waste, and Abuse,” states that it is the policy of the United States to defend against financial fraud and improper payments and directs Treasury-related activity to support fraud prevention and payment integrity. Executive Order 14395, “Establishing the Task Force To Eliminate Fraud,” directs a comprehensive national strategy to stop fraud, waste, and abuse in Federal benefit programs and includes Treasury, the Department of Justice, inspectors general, and other agencies in coordinated anti-fraud work.

Treasury intends to receive and maintain tips, complaints, allegations, referrals, supporting information, and related correspondence submitted by members of the public, Federal agencies, law enforcement entities, contractors, and grant recipients concerning suspected fraud, waste, abuse, improper payments, misuse of Federal funds, and related misconduct affecting Federal programs. Treasury will review, assess, validate, categorize, de-duplicate, triage, and refer such information to appropriate Federal agencies, Offices of Inspector General, law enforcement agencies, or other authorized entities in support of fraud detection, investigative, enforcement, and recovery activities. Treasury’s review and referral activities are intended to facilitate the coordination and referral of matters that may warrant further review, investigation, enforcement action, or recovery efforts by authorized governmental entities.

To the extent that records maintained within this system constitute investigatory material compiled for law-enforcement purposes, including information supporting investigative, enforcement, and fraud-detection activities conducted by authorized agencies, such records may be exempt

from certain provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2).

Public Comments

Treasury received two comments on the proposed rule. One commenter opposed the proposed exemptions, arguing they were overly broad, expressing concerns regarding transparency, oversight, and the handling of personal information. Another commenter generally supported protecting legitimate investigatory material but urged Treasury to narrow the scope of the exemption to qualifying investigatory records and preserve certain Privacy Act protections for non-law-enforcement records.

The system of records is established to support the receipt, maintenance, review, triage, and referral of tips, complaints, allegations, leads, supporting information, and related correspondence concerning suspected waste, fraud, abuse, improper payments, misuse of Federal funds, or other misconduct affecting Federal programs. After careful consideration of the comments received, Treasury continues to conclude that the exemptions adopted in this final rule are authorized by 5 U.S.C. 552a(k)(2) and are necessary to protect the integrity of investigatory material compiled for law enforcement purposes. The exemptions do not apply broadly to all records maintained in the system merely because those records are contained in the system. Rather, the exemptions apply only to records, or portions of records, that constitute investigatory material compiled for law enforcement purposes and otherwise qualify for exemption under 5 U.S.C. 552a(k)(2). Records maintained in the system that do not meet the statutory criteria for exemption remain subject to the applicable provisions of the Privacy Act. This limitation addresses the commenters’ concerns that the proposed exemptions could extend to non-law-enforcement records or otherwise apply more broadly than permitted by the statute. Accordingly, Treasury is adopting the proposed rule without change.

Treasury is hereby promulgating a final rule to exempt the Federal Program Waste, Fraud, and Abuse Tip Intake and Referral Records system from certain provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2) and the authority vested in the Secretary of the Treasury by 31 CFR 1.23(c).

Under 5 U.S.C. 552a(k)(2), the head of a Federal agency may promulgate rules to exempt a system of records from certain provisions of 5 U.S.C. 552a if the system of records contains investigatory material compiled for law enforcement

purposes that are not within the scope of subsection (j)(2) of the Privacy Act (which applies to agencies and components thereof that perform as their principal function any activity pertaining to the enforcement of criminal laws).

To the extent that this system of records contains investigatory materials compiled for law enforcement purposes protected by 5 U.S.C. 552a(k)(2), Treasury exempts the following system of records from various provisions of the Privacy Act:

Treasury .032—Federal Program Waste, Fraud, and Abuse Tip Intake and Referral Records.

Under 5 U.S.C. 552a(k)(2), Treasury is promulgating a final rule to exempt certain records in the above-referenced system of records be exempt from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) of the Privacy Act. See 31 CFR 1.36.

The following are the reasons why investigatory materials contained in the above-referenced system of records may be exempted from various provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2).

(1) 5 U.S.C. 552a(c)(3) requires an agency to make any accounting of disclosures of records required by 5 U.S.C. 552a(c)(1) available to the individual named in the record upon his or her request. Exemption from this requirement is appropriate because release of the accounting of disclosures could alert individuals that they are the subject of a tip, complaint, allegation, referral, inquiry, or law enforcement-related review or analysis. Disclosure of the accounting could reveal the existence, scope, nature, or status of an inquiry or referral and could impede law enforcement or program-integrity efforts by allowing individuals to evade detection, influence witnesses, alter conduct, destroy evidence, fabricate information, or otherwise interfere with lawful investigative, enforcement, or recovery activities.

(2) 5 U.S.C. 552a(d) grants individuals access to records containing information about them and permits them to request amendment of records pertaining to them. Exemption from these requirements is appropriate because access to or amendment of records contained in this system could reveal the existence, nature, scope, or status of investigatory or law enforcement-related materials and could interfere with ongoing or prospective investigations, activities, recovery efforts, or other law enforcement purposes. Providing access or permitting amendment could enable subjects of tips or investigations to avoid detection, intimidate or influence

witnesses, destroy evidence, conceal assets, coordinate testimony, or otherwise impede lawful activities. In addition, investigatory material may include information obtained from third parties or other agencies, the disclosure of which could compromise confidentiality, investigative techniques, or sensitive law enforcement information.

(3) 5 U.S.C. 552a(e)(1) requires an agency to maintain only such information about an individual as is relevant and necessary to accomplish a purpose required by statute or executive order. Exemption from this requirement is appropriate because, during the receipt, assessment, triage, referral, and review of tips and allegations, Treasury may obtain information whose relevance or accuracy is not immediately apparent. In the interests of effective fraud prevention, payment integrity, law enforcement coordination and program-integrity activities, it is appropriate to retain information that may aid in identifying patterns, relationships, schemes, trends, or other indicators relevant to suspected waste, fraud, abuse, improper payments, or related misconduct.

(4) 5 U.S.C. 552a(e)(4)(G), (H), and (I) and 5 U.S.C. 552a(f) require an agency to publish procedures whereby individuals can determine whether a system contains records pertaining to them, gain access to such records, contest their contents, and identify categories of sources of records in the system. Exemption from these requirements is appropriate because this system is exempt from the access and amendment provisions of subsection (d). Publication of such procedures could undermine the purpose of the exemption by revealing investigatory interests, law enforcement-sensitive information, or the existence of ongoing referral or investigatory activities.

Any records from another Treasury system of records or another Executive Branch agency's system of records for which an exemption is claimed under 5 U.S.C. 552a(j) or (k) that may also be included in this system of records retain the same exempt status as such records have in the system for which the exemption is claimed.

Regulatory Analysis

This final rule is not a "significant regulatory action" under Executive Order 12866.

Pursuant to the requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, it is hereby certified that this final rule will not have a significant economic impact on a substantial number of small entities.

This rule, issued pursuant to 5 U.S.C. 552a(k)(2), is to exempt certain information maintained by Treasury in the above-referenced system of records from certain provisions of the Privacy Act. Small entities, as defined in the RFA, are not provided rights under the Privacy Act and are outside the scope of this regulation.

List of Subjects in 31 CFR Part 1

Courts, Freedom of Information, Government Employees, Privacy.

For the reasons stated in the preamble, part 1 of title 31 of the Code of Federal Regulations is amended as follows:

PART 1—DISCLOSURE OF RECORDS

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

Authority: 5 U.S.C. 301, 552, 552a, 553; 31 U.S.C. 301, 321; 31 U.S.C. 3717.

■ 2. Amend § 1.36 in table 10 to paragraph (g)(1)(i) by adding, in alphanumeric order, an entry for "Treasury .032" to read as follows:

§ 1.36 Systems exempt in whole or in part from provisions of the Privacy Act and this part.

(g) * * *
(1) * * *
(i) * * *

TABLE 10 TO PARAGRAPH (g)(1)(i)

No.	Name of system
Treasury .032 ..	Federal Program Waste, Fraud, and Abuse Tip Intake and Referral Records.

Ryan Law,

Deputy Assistant Secretary for Privacy, Transparency, and Records.

[FR Doc. 2026–20469 Filed 10–5–26; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2026–1287]

RIN 1625-AA87

Security Zone; Patapsco River, Baltimore, MD

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone for certain navigable waters of the Patapsco River. The security zone is needed to protect persons, including those under the protection of the United States Secret Service (USSS), and property from terrorist acts and incidents and to prevent terrorist acts or incidents during a high-ranking public official visit. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Maryland-National Capital Region or a designated representative.

DATES: This rule is effective from 1 p.m. until 7 p.m. on October 6, 2026.

ADDRESSES: To view available documents, go to <https://www.regulations.gov> and search for USCG–2026–1287.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact Lieutenant Commander Randy Johnston, Sector Maryland-National Capital Region, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2519, or email Randy.L.johnston@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
MD Maryland
NCR National Capital Region
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
USSS United States Secret Service

II. Background Information and Authority

The Coast Guard received notification that persons under the protection of the United States Secret Service (USSS) will conduct a visit to Baltimore, MD, during the afternoon of October 6, 2026. The nationally publicized event is being held in Baltimore, MD, in close proximity to navigable waterways within the Captain of the Port (COTP) Maryland-National Capital Region's (MD-NCR) Area of Responsibility, as set forth at 33 CFR 3.25–15. The COTP MD-NCR has determined that potential hazards associated with the high-ranking official public visit are a safety and security concern for anyone within 1,000 yards of their location. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70051 and 70124, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the security zone.