

TABLE 1—SUMMARY OF BENEFITS AND COSTS ASSOCIATED WITH THE VACATUR OF THE RULE—Continued
[Millions of 2024 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Other Annualized Monetized (\$millions/year).	7	
	3	
From:				To:			

Effects:
State, Local or Tribal Government:
Small Business:
Wages:
Growth:

Note: Values in parentheses denote negative values.

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. For this analysis, we assume that the costs of the Rule in years 21 and beyond would be equal to the costs of the Rule in year 20. When estimating the cost savings of the vacatur of the Rule, we include cost savings that will similarly extend in perpetuity. We estimate that this action is associated with \$1,423.23 million in annualized net cost savings at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

TABLE 2—EXECUTIVE ORDER 14192 SUMMARY TABLE
[Millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate]

	Primary estimate	Low estimate	High estimate
Present Value of Costs	\$0	\$0	\$0
Present Value of Cost Savings	20,331.91	12,675.63	44,468.47
Present Value of Net Costs	(20,331.91)	(12,675.63)	(44,468.47)
Annualized Costs	0	0	0
Annualized Cost Savings	1,423.23	887.29	3,112.79
Annualized Net Costs	(1,423.23)	(887.29)	(3,112.79)

Note: Values in parentheses denote net negative costs (i.e., net cost savings).

List of Subjects in 21 CFR Part 809

Labeling, 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 809 is amended as follows:

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

■ 1. The authority citation for part 809 continues to read as follows:

Authority: 21 U.S.C. 321(h)(1), 331, 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 371, 372, 374, 381, and 42 U.S.C. 262.

■ 2. In § 809.3, revise the last sentence of paragraph (a) to read as follows:

§ 809.3 Definitions.

(a) * * * These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological

products subject to section 351 of the Public Health Service Act.

* * * * *

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services

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BILLING CODE 4164-01-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 972

[Docket Number FHWA-2025-0017]

RIN 2125-AG23

Rescinding Regulations Regarding Management Systems Pertaining to the Fish and Wildlife Service and the Refuge Roads Program

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FHWA is rescinding the regulations issued on February 27, 2004 on the Fish and Wildlife Service (FWS) Management Systems.

DATES: This final rule is effective October 20, 2025.

FOR FURTHER INFORMATION CONTACT: Corey Bobba, Office of Federal Lands Highways, (202) 366-9489, *corey.bobba@dot.gov*; or James Esselman, Office of the Chief Counsel, (202) 366-6181, *James.Esselman@dot.gov*, Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, as well as the notice of proposed rulemaking (NPRM), and all comments received may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic

retrieval assistance and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of Federal Register's website at www.federalregister.gov and the U.S. Government Publishing Office's website at www.GovInfo.gov.

I. General Discussion

FHWA is rescinding the rule, issued on February 27, 2004 at 69 FR 9483 that established regulations at Title 23 of the Code of Federal Regulations (CFR) part 972 concerning FWS Management Systems. The rule provided for the development and implementation of safety, bridge, pavement, and congestion management systems for transportation facilities serving the National Wildlife Refuge System (Refuge System) funded under the Federal Lands Highway Program (FLHP), as required by the Transportation Equity Act for the 21st Century (TEA-21) (Pub. L. 105-178) (1998). For the reasons explained below, FHWA has determined that this part is unnecessary and will rescind it in full.

Section 1115(d)(1) of TEA-21 amended the version of 23 U.S.C. 204 that existed at the time to add a paragraph (a)(6) stating: "The Secretary and the Secretary of each appropriate Federal land management agency shall, to the extent appropriate, develop by rule safety, bridge, pavement, and congestion management systems for roads funded under the Federal lands highway program." The roads funded under FLHP included Refuge Roads. Through 23 CFR part 972, FHWA addressed the management systems for the Fish and Wildlife and the Refuge Roads programs. See 69 FR 9484.

On July 6, 2012, Congress enacted the Moving Ahead for Progress in the 21st Century Act (MAP-21) (Pub. L. 112-141). Section 1119(a) of MAP-21 removed FLHP under 23 U.S.C. 204, replacing that program with the Tribal Transportation Program (TTP) (23 U.S.C. 202), the Federal Lands Transportation Program (FLTP) (23 U.S.C. 203), and the Federal Lands Access Program (FLAP) (23 U.S.C. 204). In doing so, Congress repealed the previous version of 23 U.S.C. 204(a)(6) and replaced it with a similar provision at 23 U.S.C. 201(c)(5), which has remained unchanged. Under that provision, FHWA "and the Secretary of each appropriate Federal land management agency shall, to the extent appropriate, implement safety, bridge, pavement, and congestion management systems for facilities funded under the tribal transportation program and the

Federal lands transportation program in support of asset management."

FHWA first notes that the current regulations have become outdated due to subsequent statutory changes, and FHWA has issued more up-to-date guidance.¹ FHWA also finds it significant that Congress, in enacting MAP-21, retained the same general requirements for asset management in 23 U.S.C. 201(c)(5) but replaced the phrase "develop by rule" with the word "implement." To the extent that FHWA and Federal land management agencies agree that safety, bridge, pavement, and congestion management systems are appropriate for certain facilities, such systems can be implemented without the need for regulations.

On May 30, 2025, at 90 FR 22887, FHWA published an NPRM to rescind 23 CFR part 972 in full and sought comments on all aspects of that proposal. FHWA received one public comment, urging FHWA to retain certain elements of the rule in updated guidance to ensure continued standardization, accountability, and data-driven planning. As outlined above, FHWA believes that the statutory provisions for TTP (23 U.S.C. 202), FLTP (23 U.S.C. 203), and FLAP (23 U.S.C. 204), in addition to existing guidance, provide the necessary framework to ensure these goals. As such, this final rule adopts the proposal without change.

II. Rulemaking Analyses and Notices

A. Executive Orders 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

This rule does not meet the criteria of a "significant regulatory action" under Executive Order (E.O.) 12866, as amended by E.O. 14215 and E.O. 13563. Therefore, the Office of Management and Budget (OMB) has not reviewed this rule under those orders.

This rule rescinds outdated regulations regarding management systems pertaining to FWS and the Refuge Roads Program. FHWA does not believe there are any costs to this rulemaking. FHWA anticipates some unquantified cost-savings associated with removal of unnecessary provisions from the CFR. In addition, it could result in some cost savings for FWS, but FHWA does not have the data to estimate the reduction in costs that would result from this final rule. The Agency requested comment on any impacts that could result from removing

the provisions identified in its NPRM but did not receive any additional information.

These changes would not adversely affect, in a material way, any sector of the economy. In addition, these changes would not interfere with any action taken or planned by another agency and would not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. Consequently, a full regulatory evaluation is not required.

B. Executive Order 14192 (Unleashing Prosperity Through Deregulation)

This final rule is an E.O. 14192 deregulatory action. Cost-savings are not quantified.

C. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by the Small Business Regulatory Enforcement Fairness Act of 1996; 5 U.S.C. 601 *et seq.*), agencies must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). No regulatory flexibility analysis is required; however, if the head of an agency or an appropriate designee certifies that the rule will not have a significant economic impact on a substantial number of small entities. FHWA has concluded and hereby certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities; therefore, an analysis is not included. This rule would only remove obsolete regulations that had provided for the development and implementation of management systems for transportation facilities serving the Refuge System funded under FLHP, as required by an outdated and superseded statutory provision.

D. Unfunded Mandates Reform Act

This rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4, 109 Stat. 48) for State, local and Tribal governments, or the private sector of \$100 million or more in any one year. Thus, the rulemaking is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in E.O. 13132. FHWA has determined that this action does not have sufficient federalism implications

¹ <https://highways.dot.gov/federal-lands/transportation>.

to warrant the preparation of a federalism assessment. FHWA has also determined that this action does not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions.

F. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number. This rule is deregulatory and so would not impose any additional information collection requirements.

G. National Environmental Policy Act

FHWA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA) and has determined that it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Categorically excluded actions meet the criteria for categorical exclusions under 23 CFR 771.117(a) and normally do not require any further NEPA approvals by FHWA. This rulemaking would remove requirements regarding management systems that are currently outdated. FHWA does not anticipate any adverse environmental impacts from this rule, and no unusual circumstances are present under 23 CFR 771.117(b).

H. Executive Order 13175 (Tribal Consultation)

E.O. 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects 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. FHWA has assessed the impact of this rule on Indian Tribes and determined that this rulemaking would not have Tribal implications that require consultation under E.O. 13175. This rule would only remove obsolete regulations, previously required by an outdated and superseded statutory provision. To the extent that FHWA and Federal land management agencies agree that safety, bridge, pavement, and congestion management systems are appropriate for certain facilities, such systems can be implemented without

the need for regulations under the authorities provided by TTP (23 U.S.C. 202), FLTP (23 U.S.C. 203), and FLAP (23 U.S.C. 204).

I. Regulation Identifier Number

A Regulation Identifier Number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in the spring and fall of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

J. Rulemaking Summary, 5 U.S.C. 553(b)(4)

As required by 5 U.S.C. 553(b)(4), a summary of this rule can be found at www.regulations.gov, under the docket number.

List of Subjects in 23 CFR Part 972

Bridges, Congestion management, Grant programs—transportation, Highways and roads, Management systems, Pavement management, Public lands, Safety management, Transportation, Wildlife refuge roads.

Issued in Washington, DC, under authority delegated in 49 CFR 1.85.

Gloria M. Shepherd,
Executive Director, Federal Highway Administration.

PART 972—[REMOVED AND RESERVED]

■ For the reasons stated in the preamble, under the authority of 23 U.S.C. 315 FHWA removes 23 CFR part 972.

[FR Doc. 2025–18194 Filed 9–18–25; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2025–0651]

RIN 1625–AA08

Special Local Regulation; Tennessee River, Florence, Alabama

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for certain waters of the Tennessee River. This action is necessary to provide for the safety of life on these navigable waters near Florence, AL,

during a rowing event on September 27, 2025. This regulation prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective from 8 a.m. through 4 p.m. on September 27, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0651 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 rule, call or email Petty Officer, Zachary T. Epps, and MSD Nashville, Waterways division, U.S. Coast Guard; telephone (206) 815–7006, email MSDNashville@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 Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists to waive prior notice and public comment for this temporary final rule. A permanent annual special local regulation for this event has already been published in the Code of Federal Regulations at 33 CFR 100.801 Table 1, Line 95. However, this action is necessary to accommodate the event’s shift to an earlier date in September, rather than the event’s usual date in October, making it impracticable to conduct a full notice and comment period before the event’s scheduled occurrence this year.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with Shoals Scholar Dollar occurring on September 27, 2025, will be a safety concern for anyone