

§ 892.1001 Liver iron concentration imaging companion diagnostic for deferasirox.

(a) *Identification.* The liver iron concentration imaging companion diagnostic for deferasirox is an image processing device intended to aid in the identification and monitoring of non-transfusion-dependent thalassemia patients receiving therapy with deferasirox. The device calculates a numeric value for liver iron concentration based on magnetic resonance images acquired under controlled conditions. The calculated numeric value is used to assess the need for deferasirox treatment and for monitoring treatment in patients with non-transfusion-dependent thalassemia. The liver iron concentration imaging companion diagnostic for deferasirox is essential to the safe and effective use of deferasirox in patients with non-transfusion-dependent thalassemia.

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

(1) Design verification and validation must include nonclinical and clinical performance testing demonstrating the bias, precision, repeatability, and reproducibility of liver iron concentration measurements.

(2) Labeling must include specifying:

- (i) Instructions for acceptance testing of images prior to processing;
- (ii) Data processing quality assurance protocols; and
- (iii) The sensitivity and specificity of liver iron concentration measurements.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 630

[Docket No. FHWA-2025-0019]

RIN 2125-AG26

Rescinding Regulations on Procedures for Advance Construction of Federal-Aid Projects

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

ACTION: Final rule.

SUMMARY: FHWA rescinds a specific labeling provision of the rule issued on March 30, 1990, on Advance Construction of Federal-aid Projects.

DATES: This final rule is effective September 22, 2025.

FOR FURTHER INFORMATION CONTACT: For questions about this rulemaking, please contact Mr. Anthony DeSimone, FHWA Office of Infrastructure, 317-226-5307, or via email at Anthony.DeSimone@dot.gov. For legal questions, please contact Mr. Michael Harkins, FHWA Office of Chief Counsel, 202-366-1523, or via email at Michael.Harkins@dot.gov. Office hours for FHWA are from 8:00 a.m. to 4:30 p.m., eastern time (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 a specific provision of its rule on Advance Construction of Federal-Aid Projects, which was originally promulgated on December 8, 1983, at 48 FR 54972, and later amended on March 30, 1990, at 55 FR 11902. This provision is part of FHWA regulations, codified at 23 CFR part 630, subpart G, that prescribe procedures for advancing the construction of Federal-aid highway projects without obligating Federal funds apportioned or allocated to the State, known as Advance Construction (AC). 23 CFR 630.701. AC is authorized under 23 U.S.C. 115. Under the statute, FHWA¹ may authorize a State to proceed with a project authorized under Title 23 of the U.S. Code without the use of Federal funds while preserving eligibility for future Federal-aid funds. After an AC project is authorized, the State may convert the project to regular Federal-aid funding provided eligible Federal funds are made available for the project. For the reasons explained below, FHWA is rescinding a specific provision of those regulations, 23 CFR 630.705(b), as FHWA has determined it is unnecessary.

On December 8, 1983, FHWA issued a regulation revising FHWA's

regulations concerning AC projects that existed at the time. Among the changes made, FHWA revised 23 CFR 630.703 to state: "Project designations [for advance construction projects] shall be the same as for regular Federal-aid projects except that until the project is converted to a regular Federal-aid project, the prefix letters 'AC' for advance construction shall be used as the first letters of each project designation." See 48 FR at 54974. In issuing this provision, the preamble only stated that "[p]rovisions for submitting programs and making project designations for advance construction projects now comprise § 630.703." On March 30, 1990, FHWA revised its AC regulations, moving the contents of what was previously 23 CFR 630.703 to 23 CFR 630.705, while only noting that regular AC procedures would then be contained in 23 CFR 630.705. See 55 FR at 11902. Through this 1990 rule, FHWA modified 23 CFR 630.705(b) to read: "Project numbers shall be identified by the letters 'AC' preceding the regular project number prefix." See 55 FR at 11903. This provision, 23 CFR 630.705(b), has not been changed subsequently.

The requirements in 23 CFR 630.705(b) are not required by 23 U.S.C. 115. In addition, FHWA's current process of determining which projects are advance construction projects, versus Federal-aid projects where Federal-aid funds have already been obligated, does not require the use of the prefix "AC." Accordingly, FHWA is eliminating this regulatory provision.

On May 30, 2025, at 90 FR 22872, FHWA published an NPRM proposing to rescind 23 CFR 630.705(b) and sought comment on all aspects of that proposal. The FHWA did not receive any public comments on its proposal and now adopts the proposal without change.

II. Rulemaking Analyses and Notices

A. Executive Order 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 regulations that are not in alignment with current FHWA process. For that reason, FHWA does not believe there are any costs to this rulemaking. FHWA anticipates some unquantified cost-savings associated

¹ Authority to administer 23 U.S.C. 115 is delegated to the FHWA under 49 CFR 1.85.

with the removal of unnecessary provisions from the CFR.

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. E.O. 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 rule would not have a significant economic impact on a substantial number of small entities; therefore, an analysis is not included. This rule removes an outdated provision that is not consistent with current FHWA processes.

D. Unfunded Mandates Reform Act

This rule would 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 rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. E.O. 13132 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in E.O. 13132. The FHWA has determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. The 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 rule would rescind regulations not in accordance with current FHWA processes. FHWA does not anticipate any adverse environmental impacts from this rule, and no unusual circumstances are present under 23 CFR 771.117(b).

H. E.O. 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 rule would not have Tribal implications that require consultation under E.O. 13175.

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

regulations.gov, under the docket number.

List of Subjects in 23 CFR Part 630

Government contracts, Grant programs—transportation, Highway safety, Highways and roads, Reporting and recordkeeping requirements, Traffic regulations.

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

Gloria M. Shepherd,

Executive Director, Federal Highway Administration.

For the reasons stated in the preamble, FHWA amends 23 Code of Federal Regulations Part 630, as set forth below:

PART 630—PRECONSTRUCTION PROCEDURES

■ 1. The authority citation for Part 630 continues to read as follows:

Authority: 23 U.S.C. 106, 109, 112, 115, 315, 320, and 402(a); Sec. 1110, 1501, and 1503 of Pub. L. 109–59, 119 Stat. 1144; Pub. L. 105–178, 112 Stat. 193; Pub. L. 104–59, 109 Stat. 582; Pub. L. 97–424, 96 Stat. 2106; Pub. L. 90–495, 82 Stat. 828; Pub. L. 85–767, 72 Stat. 896; Pub. L. 84–627, 70 Stat. 380; 23 CFR 1.32 and 49 CFR 1.81 and 1.85, and Pub. L. 112–141, 126 Stat. 405, sections 1303 and 1405.

§ 630.705 [Amended]

■ 2. Amend § 630.705 by removing and reserving paragraph (b).

[FR Doc. 2025–16008 Filed 8–20–25; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2025–0052; FRL–12541–01–R10]

Adequacy Status of the Klamath Falls, Oregon Submitted 2006 24-Hour PM_{2.5} NAAQS Redesignation Request and Maintenance Plan Budgets for Transportation Conformity Purposes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Determination of adequacy.

SUMMARY: The EPA is notifying the public that we have found the motor vehicle emissions budgets for the Klamath Falls, Oregon 2006 24-hour fine particulate matter standard nonattainment area adequate for transportation conformity purposes. The budgets were submitted on August 20, 2024, as part of Oregon's Klamath Falls Redesignation Request and Maintenance