



DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket DOT-OST-2021-0093]

RIN 2105-AF28

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, Department of Transportation (Department or DOT).

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: This action supplements an earlier notice of proposed rulemaking (NPRM) that DOT published on December 9, 2024. This supplemental proposal would update terminology in DOT's drug and alcohol testing regulations consistent with Executive Order 14168 (E.O. 14168), *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*. DOT continues to propose a provision to require a directly observed urine collection in situations where oral fluid tests are currently required, but oral fluid testing is not yet available.

DATES: Comments on this notice of proposed rulemaking should be submitted by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Bohdan Baczara, Deputy Director, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, S.E., Washington, D.C. 20590; telephone number 202-366-3784; ODAPCwebmail@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Purpose

DOT is issuing this supplemental notice of proposed rulemaking (SNPRM) following issuance of a 2024 notice of proposed rulemaking (NPRM) to amend its drug testing procedures rule. (*See* 89 FR 97579.) The NPRM proposed an interim provision to require the conduct of directly observed urine tests in the limited situations where the rule requires oral fluid tests, but oral fluid testing is not yet available. DOT continues to propose a directly observed urine collection in situations where oral fluid tests are currently required, but oral fluid testing is not yet available and supplements that proposal by updating language in its drug and alcohol testing regulations consistent with E.O. 14168 on Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government.

II. Authority for This Rulemaking

This rulemaking is promulgated pursuant to the Omnibus Transportation Employee Testing Act of 1991 (OTETA) (Pub. L. 102–143, Tit. V, 105 Stat. 952). DOT requires urine drug testing and authorizes oral fluid drug testing as an alternative methodology for the testing of safety-sensitive transportation industry employees subject to drug testing under part 40 of Title 49 of the Code of Federal Regulations (part 40). DOT’s part 40 regulations are, in turn, incorporated by reference in the drug and alcohol testing requirements of each of its operating administrations.¹

III. Background

DOT published a final rule amending the procedures for its drug testing program (49 CFR part 40) on May 2, 2023 (88 FR 27596) (May 2023 Final Rule). The May 2023 Final Rule went into effect on June 1, 2023. The May 2023 Final Rule authorized oral fluid drug testing as an additional methodology for employers to use as a means of achieving the safety goals of the

¹ *See* § 40.3 (defining “DOT, The Department, DOT Agency” to include each of the DOT operating administrations).

program. Because the Department of Health and Human Services (HHS) had determined that oral fluid drug testing, like urine drug testing, is both scientifically accurate and forensically defensible, DOT saw no reason to eliminate or mandate either methodology. As such, in the vast majority of collection scenarios, oral fluid testing is available to employers as an alternate methodology to choose, and not as a replacement for urine drug testing.

Importantly, for an employer to implement oral fluid testing, there must be at least two HHS-certified laboratories for oral fluid testing. There must be one HHS-certified laboratory to conduct the screening and confirmation drug testing on the primary specimen. There must be a different HHS-certified laboratory to conduct the split specimen drug testing on the secondary specimen if the employee requests split specimen testing for the Medical Review Officer (MRO) verified positive, adulterated, or substituted result. However, as of the date of the publication of this rule, there are no HHS-certified laboratories to conduct oral fluid testing.²

DOT regulations at § 40.67 require that a collection be directly observed in certain circumstances, *e.g.*, if the original sample was invalid without an adequate medical explanation or the test is for a return to duty. In the May 2023 Final Rule, and in response to comments received on the notice of proposed rulemaking (NPRM) that preceded that rule, we added a provision at § 40.67(g)(3) to require a directly observed collection to be an oral fluid test³ (as opposed to a urine test) in situations where an observer as required by the regulations cannot be easily provided and in certain other situations. These limited situations are the only ones in which Part 40 expressly requires an oral fluid test to be conducted as opposed to a urine test; in all other situations, an employer has the choice of whether a urine test or an oral fluid test will be conducted, including those conducted as directly observed collections.

² For a list of HHS-certified laboratories, please see <https://www.samhsa.gov/substance-use/drug-free-workplace/drug-testing-resources/lab-list>.

³ All oral fluid collections are directly observed because they are always conducted in front of the collector. See also the definition of “oral fluid specimen” in § 40.3: “A specimen that is collected from an employee’s oral cavity and is a combination of physiological fluids produced primarily by the salivary glands. **An oral fluid specimen is considered to be a direct observation collection for all purposes of this part.**” [Emphasis added]

Because there are no HHS-certified oral fluid laboratories, it is not yet possible to comply with the requirement in § 40.67(g)(3) that requires the directly observed collection to be an oral fluid test in the situations specified in that section. In the interim, and to preserve transportation safety by deterring illicit drug use, it is necessary to ensure that directly observed collections can still be conducted when required.

To correct the inadvertent factual impossibility created by the fact there are no HHS certified oral fluid laboratories, DOT published an NPRM on December 9, 2024, proposing to amend Part 40, for an interim period, to require directly observed urine collections in the situations specified in § 40.67(g)(3) if an oral fluid collection is not yet available (89 FR 97579). The proposed amendment would simply maintain the “status quo” wherein all directly observed collections are currently conducted as urine tests, because oral fluid testing is not yet available.

The Department stated that the amendment to require directly observed urine tests in situations where an oral fluid collection is required, but is not yet available, is intended to be a temporary, short-term solution, as there are currently no certified oral fluid laboratories. DOT proposed that the provision would sunset one year after HHS publishes a Federal Register notice that it certified the second oral fluid drug testing laboratory. To ensure all are aware of the date when this provision will sunset, DOT stated it will publish a *Federal Register* document specifying the date the second oral fluid laboratory is certified by HHS and the corresponding sunset date. Importantly, DOT was clear that if, during the interim period, a collection site is able to conduct an oral fluid collection (HHS has certified at least two oral fluid drug testing laboratories, and both a qualified oral fluid collector and a conforming oral fluid collection device are available at the collection site), an oral fluid collection would be required to be conducted as specified in § 40.67(g)(3).

III. Comments on the NPRM

DOT received 22 comments on the NPRM. Several commenters expressed concern and frustration that oral fluid testing is not yet available, given that the May 2023 Final Rule that

authorized the use of oral fluid testing in the DOT drug testing program became effective on June 1, 2023. DOT made it clear in the May 2023 Final Rule, and we have again noted above, there must be at least two HHS-certified laboratories for oral fluid testing for an employer to implement oral fluid testing under Part 40. HHS is the agency that establishes scientific and technical guidelines for Federal workplace drug testing programs and standards for certification of laboratories engaged in such drug testing. While DOT has discretion concerning many aspects of its regulations governing testing in the transportation industries' regulated programs, DOT is required, by statute (OTETA of 1991), to follow the HHS Mandatory Guidelines for the laboratory and specimen testing procedures. While DOT acknowledges the comments urging DOT to accelerate/expedite the certification of laboratories to conduct oral fluid testing, DOT has no authority or jurisdiction to do so because HHS is the agency that certifies laboratories that can be used in the DOT drug testing program. Similarly, DOT is not permitted to allow single-laboratory testing on a temporary basis as recommended by one commenter, as statutory law (again, OTETA of 1991) gives employees the right to request a test of the split specimen sample, which must be tested independently at a second HHS-certified laboratory. Because HHS certifies laboratories, comments related to laboratory certification are outside of the scope of this rulemaking.

Several commenters expressed concerns regarding various issues related to oral fluid testing, including the qualification of oral fluid collectors, the availability and cost of oral fluid collection devices, and other associated issues. In addition, some commenters seem to believe that the NPRM proposed to delay implementation of oral fluid testing in general, which is not the case. The scope of the NPRM was very narrow, and proposed to revert to directly observed urine collections in situations where a required oral fluid collection could not be done until two laboratories are certified for oral fluid testing by HHS. As such, these commenters' concerns about oral fluid testing are similarly outside of the scope of this rulemaking.

Several commenters supported the proposal to conduct directly observed urine collections in the limited situations where an observer as required by the regulations cannot be easily provided or in the circumstances identified in § 40.67(g)(3) but objected to the manner and timeline in which the provision was proposed to be implemented. Specifically, a commenter read the NPRM to “delay and/or make optional 49 CFR section § 40.67(g)(3) for one year from when HHS certifies the first two laboratories to conduct Federal testing.” Other commenters stated similar concerns, citing the comments submitted by this commenter.

In response, DOT notes that in situations where an observer as required by the regulations cannot be easily provided or in the circumstances identified in § 40.67(g)(3), and a directly observed collection is required, DOT was clear that an oral fluid collection must be conducted, if possible (*i.e.*, HHS has certified at least two oral fluid drug testing laboratories, and both a qualified oral fluid collector and a conforming oral fluid collection device are available at the collection site) during the period until one year after HHS publishes a Federal Register notification that a second oral fluid laboratory has been certified. Otherwise, if oral fluid testing is not available, a directly observed urine test must be conducted in these situations during the specified time period. After one year following the certification of the second oral fluid laboratory, an oral fluid test must be conducted as required in the May 2023 Final Rule. The above aligns directly with the commenter’s statement that collection sites with trained personnel prepared to offer oral fluid testing immediately should be allowed to proceed with oral fluid testing.

Several commenters stated that the proposed changes would have a significant economic impact on a number of small entities. These commenters stated that many companies have expended time and costs to revise their company policies to incorporate changes to facilitate oral fluid testing in their drug testing programs, and that these policies will need to be revised again to reflect the changes associated with the provisions to require the conduct of directly observed urine tests in the limited situations where the rule requires oral fluid tests, but oral fluid testing is

not yet available. As discussed above, this regulatory flexibility is very narrow in scope, and affects a very small percentage of collections (directly observed collections where an observer as required by the regulations cannot easily be provided or in the specific circumstances specified in § 40.67(g)(3)). As noted below, DOT stated in the May 2023 Final Rule that oral fluid testing is optional except in very rare cases. As such, DOT does not believe that widespread changes will need to be made to the company policies that have been developed to facilitate the implementation of oral fluid testing. Further, employers will not be faced with a “new choice” (*i.e.*, whether to conduct an oral fluid test or a urine test) in these limited scenarios because the rule requires that an oral fluid test be conducted, if possible, and that a urine test be conducted otherwise.

Finally, in the May 2023 Final Rule in § 40.67(g)(3), DOT included procedures on what to do when the required “observer” cannot be found but mistakenly used the term “collector” instead of “observer” in the regulatory text of that section. We proposed to correct the error in the NPRM and received no comments on this issue.

IV. Proposed supplement to the NPRM

In § 40.65 there are two scenarios, (b)(5) and (c)(1), that direct the collector to perform either a directly observed urine collection or an oral fluid collection. However, nothing in those sections tells the collector how or who makes that decision. We think it is important to remind the collector to check if the employer has standing orders or contact the Designated Employer Representative (DER) to receive instructions on how to proceed in each of those scenarios. We would do so in the proposed new paragraph (d).

On January 20, 2025, the President issued E.O. 14168 on Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government. E.O. 14168 stated, among other things, that it was the policy of the United States to recognize two sexes, male and female, that each Federal agency shall use the term “sex” and not “gender” in its policies and documents, that “sex” shall refer to an individual’s immutable biological

classification as either male or female and give meaning to the term “sex” as set forth in the E.O. when applying regulations, statutes or guidance. The Department has identified several instances in its regulation 49 CFR part 40 (*i.e.*, §§ 40.67, 40.69, and 40.147) where the word “gender” is used. In these sections, we propose to replace the word “gender” with the word “sex”. E.O. 14168 also states “sex” is not a synonym for and does not include the concept of “gender identity”.

The Department is proposing to amend § 40.67(g)(3) by retaining only the original instructions that require an oral fluid collection when a same sex observer cannot be found with a slight modification to the text in (g)(3)(ii) to say that the DER is to instruct the collector to perform an oral fluid test. The Department is retaining the originally proposed language that requires a directly observed urine collection when an oral fluid collection cannot be done for up to one year after two laboratories are HHS certified for oral fluid testing. This language was proposed to ensure that a urine collection would be done in the event the collection site was not ready to conduct oral fluid collections even after two laboratories were HHS-certified for oral fluid testing. To summarize the supplemental proposal to (g)(3), if a directly observed urine collection is required and a same sex observer cannot be provided, then an oral fluid test is to be performed. However, because oral fluid testing cannot be performed (because there are no two HHS-certified oral fluid laboratories), we have retained the originally proposed language that a directly observed urine collection be performed. This provision applies for one year after HHS certifies at least two oral fluid laboratories. In the interest of safety, if the employee initially provided a suspect urine specimen, we would want to ensure that a second urine collection is performed rather than not performing a second collection because oral fluid testing is not yet available.

V. Regulatory Notices and Analyses

Executive Orders 12866, 13563, and 14094

This rule is a non-significant rule for purposes of E.O. 12886, as supplemented by E.O. 13563 and amended by E.O. 14094 and will not impose any significant costs or have any significant impacts. Given the uncertainty of testing costs and lack of data on other aspects of testing, DOT did not estimate cost savings or other benefits for the May 2023 Final Rule which permitted oral fluid testing as an alternative to urine testing in most scenarios. In the regulatory analyses for the May 2023 Final Rule, DOT stated that oral fluid testing is optional except in very rare cases. This proposal amends the transportation industry drug testing program procedures regulation to comply with E.O. 14168 and proposes to require a directly observed urine collection be conducted when an oral fluid test is required but cannot because there are no two HHS-certified oral fluid drug testing laboratories. This proposal will not impose any significant costs or have any significant impacts on the DOT testing program, because the requirement of a directly observed urine collection existed before issuance of the May 2023 Final Rule, and oral fluid testing has not yet been able to be conducted since the May 2023 Final Rule in the absence of at least two HHS-certified oral fluid laboratories.

Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act (SBREFA)

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of their regulatory actions on small businesses and other small entities and minimize any significant economic impact. The term “small entities” comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with a population of less than 50,000. For this rulemaking, potentially affected small entities include drug testing companies (U.S. Small Business Administration (SBA) North American Industry Classification System (NAICS) Sector 54 (Professional, Scientific and Technical Services), Code 541380 (Testing Laboratories and Services)) as well as DOT-regulated entities (SBA NAICS Sectors 48–49 (Transportation and Warehousing)).

The Department does not expect that the rule will have a significant economic impact on a substantial number of small entities. This proposal amends the transportation industry drug testing program procedures regulation to revise language consistent with E.O. 14168 and proposes a requirement to conduct directly observed urine collections in situations when an oral fluid collection is required but not yet available. The requirement for directly observed urine collections was in existence before issuance of the May 2023 Final Rule, and regulated entities are therefore familiar with the procedure for directly observed urine tests. In addition, because oral fluid testing is not yet available, regulated entities are also likely to still have the collection devices and personnel to conduct urine testing. As a result, the proposed amendments will not impose significant costs. For these reasons, I certify that the rule does not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Unfunded Mandates

DOT has examined the impact of this rule under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104-4). This rule does not trigger the requirement for a written statement under sec. 202(a) of the UMRA because this rulemaking does not impose a mandate that results in an expenditure of \$206 million or more by either State, local, and Tribal governments in the aggregate or by the private sector in any one year.

Environmental Impact

DOT has analyzed the environmental impacts of this action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1D, “DOT’s Procedures for Considering Environmental Impacts” (July 1, 2025) (available at <https://www.transportation.gov/mission/dots-procedures-considering-environmental-impacts>). Categorical exclusions are actions identified in an agency’s NEPA implementing procedures that

do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). This proposal amends the transportation industry drug testing program procedures regulation to comply with E.O. 14168 and requires a directly observed urine collection when required by part 40 because oral fluid testing is not yet available. This action is covered by the categorical exclusion listed at 23 CFR 771.118(c)(4), “[p]lanning and administrative activities that do not involve or lead directly to construction, such as: . . . promulgation of rules, regulations, directives...” The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Executive Order 13132: Federalism

DOT has analyzed the rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies carefully to examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the order, “policies that have federalism implications” refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that 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.

Most of the regulated parties under the Department’s drug testing program are private entities. Some regulated entities are public entities (*e.g.*, transit authorities and public works departments); however, DOT has determined that this proposed rule, which would amend the transportation industry drug testing program procedures regulation to comply with E.O. 14168 and require the conduct of directly observed urine testing where employers are required to conduct an oral fluid test but such testing is not available, does not contain policies that have federalism implications.

Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires Federal agencies to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” as defined in the Executive Order, include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.” This rule does not have Tribal implications. The proposal does not have substantial direct effects on Tribal governments, 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, as specified in Executive Order 13175.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public. The information collection for DOT’s drug and alcohol testing program is approved under OMB control number 2105-0529. This rule does not require any new collection of information under the PRA. Notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a currently valid Office of Management and Budget (OMB) control number.

Privacy Act

Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT’s compliance with the Privacy Act, please visit <https://www.transportation.gov/privacy>.

Rule Summary

As required by 5 U.S.C. 553(b)(4), a summary of this rule can be found at regulations.gov, Docket DOT-OST-2021-0093, in the **SUMMARY** section of this document.

Pay-As-You-Go Act of 2023

In accordance with Compliance with Pay-As-You-Go Act of 2023 (Fiscal Responsibility Act of 2023, Pub. L. 118–5, div. B, title III) and OMB Memorandum (M–23–21) dated September 1, 2023, the Department has determined that this rule is not subject to the Pay-As-You-Go Act of 2023 because it will not increase direct spending beyond specified thresholds.

List of Subjects in 49 CFR Part 40

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons stated in the preamble, DOT amends 49 CFR part 40 as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

1. The authority for 49 CFR part 40 continues to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, 45101 and 60102 *et seq.*

2. In § 40.65, add a new paragraph (d) to read:

§ 40.65 What does the collector check for when the employee presents a urine specimen?

* * * * *

(d) **Direct observations.** If a new urine collection using direct observation procedures or an oral fluid collection is required under § 40.65(b)(5) or (c)(1), you must check if the employer has a standing order on which specimen collection to perform. If there is no standing order, you must contact the DER on whether to continue with a directly observed urine collection or an oral fluid collection.

3. In § 40.67 revise paragraph g and in paragraph (h) remove the word “gender” and add in its place “sex” to read as follows:

§ 40.67 When and how is a directly observed urine collection conducted?

* * * * *

(g) As the collector, you must ensure that the observer is the same sex (male or female) as the employee.

(1) You must never permit a person of the opposite sex to act as the observer.

(2) The observer can be a different person from the collector and need not be a qualified collector.

(3) If a same sex observer cannot be found:

(i) If the employer has a standing order to allow oral fluid testing in such situations, the collector will follow that order.

(ii) If there is no standing order from the employer, the collector must contact the DER and the DER will direct the collector to either conduct an oral fluid test if the collection site is able to do so or send the employee to a collection site acceptable to the employer for the oral fluid test.

(4) Notwithstanding paragraphs (g)(3)(i) and (ii) of this section, until otherwise specified (one year after HHS publishes a Federal Register notification of the second certified oral fluid drug testing laboratory), you must conduct an oral fluid collection if possible (*i.e.*, HHS has certified at least two oral fluid drug testing laboratories, and both a qualified oral fluid collector and a conforming oral fluid collection device are available at the collection site).

Otherwise, you must conduct a directly observed urine collection as required in this section.

* * * * *

4. In § 40.69 in paragraph (c), remove the word “gender” and add in its place “sex (male or female)”; in paragraph (d), remove the word “same-gender” and add in its place “same-sex”.

5. In § 40.145 in paragraph (h)(1)(ii), remove the word “gender” and add in its place “sex (male or female)”.

Issued in Washington, DC.

Sean P. Duffy,

Secretary of Transportation

[FR Doc. 2025-19119 Filed: 9/30/2025 8:45 am; Publication Date: 10/1/2025]