

**DEPARTMENT OF TRANSPORTATION****Office of the Secretary****49 CFR Part 40**

[Docket DOT–OST–2021–0093]

RIN 2105–AE94

**Procedures for Transportation Workplace Drug and Alcohol Testing Programs****AGENCY:** Office of the Secretary, Department of Transportation (DOT).**ACTION:** Direct final rule.

**SUMMARY:** The U.S. Department of Transportation (DOT) is taking direct final action to revise DOT’s drug testing procedures rule, which became effective on June 1, 2023, to provide temporary qualification requirements for mock oral fluid monitors, provide for consistent privacy requirements by identifying which individuals may be present during an oral fluid collection, and clarify how collectors are to specify that a sufficient volume of oral fluid was collected.

**DATES:** This final rule is effective on August 5, 2024, without further notice unless DOT receives adverse comment by July 22, 2024. If DOT receives adverse comment on any of the provisions in this direct final rule, it will publish a timely withdrawal in the *Federal Register* informing the public that the provisions of the rule on which adverse comment were received will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. DOT–OST–2021–0093, at <https://www.regulations.gov/>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. DOT may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. For additional submission methods and general guidance on making effective comments, please visit <https://www.transportation.gov/regulations/rulemaking-process>.

**FOR FURTHER INFORMATION CONTACT:** Bohdan Baczara, Deputy Director, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone number 202–366–3784; [ODAPCwebmail@dot.gov](mailto:ODAPCwebmail@dot.gov).

**SUPPLEMENTARY INFORMATION:****I. Why is DOT using a direct final rule?**

DOT is publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment on any of the provisions of the rule. However, in the “Proposed Rules” section of this issue of the *Federal Register*, we are publishing a separate document containing the same amendments that serves as the proposed rule to amend the procedures for DOT’s drug testing program (49 CFR part 40) if adverse comments are received on any of the provision in this direct final rule. Any parties interested in commenting must do so at this time. We will not institute a second comment period on this action. For further information about commenting on this rule, see the **ADDRESSES** section.

If DOT receives adverse comment on any of the provisions, we will publish in the *Federal Register* a timely withdrawal of the provision or provisions that are the subject of the comments, informing the public that the provision(s) of the direct final rule on which DOT received adverse comment will not take effect unless and until DOT addresses public comments in any subsequent final rule.

**II. What is DOT including in this direct final rule?**

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 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 program. We have determined instances in which the text of various aspects of the procedures as amended by the final rule need to be further amended due to unforeseen circumstances rendering it impossible to comply with requirements for mock oral fluid collection observers, consistency with regard to privacy during testing, and a need to clarify the means by which oral fluid collectors specify that a sufficient volume of oral fluid was collected.

*Section 40.35 What training requirements must a collector meet for oral fluid collection?*

The May 2023 final rule established qualification requirements for oral fluid collector qualifications in § 40.35 that mirrored as closely as possible existing urine collector qualifications in § 40.33. All the qualification training requirements (*i.e.*, basic information,

qualification training, initial proficiency demonstration, refresher training, error correction training, and documentation) are identical. Regarding the mock collections specified in § 40.35(c), we required oral fluid collectors to demonstrate proficiency in collections by completing five consecutive error-free mock collections for each device they will use. These mock collections must be monitored and evaluated by a ‘qualified collector’ who has demonstrated the necessary knowledge, skills, and abilities by—(i) regularly conducting DOT drug test collections for a period of at least one year; (ii) conducting collector training under this part for at least one year; or (iii) successfully completing a “train the trainer” course.

Once the Department of Human and Health Services (HHS) certifies its first oral fluid laboratory, oral fluid testing devices will be available, but individuals wanting to be oral fluid collectors will not be able to be qualified because there are no currently qualified oral fluid collectors per § 40.35(c)(2) with the additional qualifications at § 40.35(c)(2)(i), (ii) or (iii) to monitor and evaluate the trainee’s mock collections. We did not intend to create a factual impossibility. We meant for the oral fluid monitors for the mock proficiency demonstrations to be proficient as oral fluid collectors.

The regulatory flexibility we provide in this direct final rule will allow individuals sufficiently knowledgeable in part 40’s oral fluid collection requirements and familiar with an oral fluid testing device of their choosing to observe the mock collections and attest in writing that the mock collections are ‘error free’. As a reminder, individuals meeting the criteria in § 40.35(c)(2)(ii) or (iii) should be prepared to provide any course material and/or certificates of successful completion to an employer or DOT representative upon request.

To facilitate the training of oral fluid collectors, we have amended the regulation to authorize individuals to monitor mock oral fluid collections without meeting the requirement of being a qualified oral fluid collector specified in § 40.35. To ensure the proficiency of the collection monitor, however, this regulatory flexibility will apply only to those individuals meeting the knowledge, skills, and abilities in § 40.35(c)(2)(ii) or (iii).<sup>1</sup> With regard to

<sup>1</sup> We note that the knowledge, skills, and abilities in § 40.35(c)(i) require regularly conducting DOT drug test collections (in this case, for oral fluids) for at least one year. This is not possible because until HHS certifies an oral fluid laboratory(ies), oral fluid is not a permissible means of collection. We have determined that, in contrast to paragraphs (c)(ii)

the knowledge, skills, and abilities in § 40.35(c)(2)(ii), we are waiving the requirement that individuals conducting oral fluid collector training have at least one year of experience conducting collector training, but we expect those individuals to have a thorough understanding of part 40 and to be well versed in the course content they are teaching. The course content must meet the requirements in § 40.35(b), and individuals conducting training should maintain good records (for example, the course content for the instructor and student, the duration of the training, the dates the course was taught, who attended the course and any certificate of successful completion you may have provided students, etc.) to demonstrate that they conducted the training. This is no different than what would be expected of those conducting urine collection training today. Individuals conducting this training would be eligible to observe oral fluid mock collections during the period of regulatory relief.

This regulatory flexibility will sunset one year after HHS publishes a **Federal Register** notice that it certified the first oral fluid drug testing laboratory. So that all are aware of the effective date of the regulatory flexibility, we will publish a **Federal Register** document specifying the date the first oral fluid laboratory is certified by HHS and the effective date that individuals observing mock collections (*i.e.*, monitors) will need to comply with the qualified collector requirements in § 40.35(c)(2) established in the May 2023 final rule.

We want to emphasize that while individuals may become qualified as oral fluid collectors after the first laboratory is HHS certified for oral fluid drug testing, oral fluid specimens cannot be collected and DOT oral fluid testing cannot be implemented until HHS certifies at least two laboratories (one to serve as a primary laboratory, and a second to serve as a split specimen laboratory). As of the publication of this direct final rule, HHS has not yet certified any laboratories for oral fluid drug testing. Upon certification, oral fluid laboratories will be added to the list of HHS-certified laboratories at <https://www.samhsa.gov/workplace/drug-testing-resources/certified-lab-list>.

and (c)(iii), there is no way for an individual to otherwise possess the knowledge, skills, and abilities in paragraph (c)(i) such that the individual could competently observe mock collections. As a result, those who want to act as monitors specified in subparagraph (c)(2)(i) must still become qualified collectors and meet the one-year requirement of regularly conducting DOT oral fluid drug test collections before they can act as monitors.

*Section 40.73 How is an oral fluid specimen collected? (persons allowed in testing room)*

DOT intended in the May 2023 final rule that the procedures for oral fluid testing parallel the alcohol testing procedure found in § 40.223(b), which requires the breath alcohol technician (BAT) or screening test technician (STT) to prohibit anyone other than the BAT or STT, the employee, or a DOT representative to witness the testing process. Such a provision also affords privacy to the employee being tested. In this direct final rule, DOT is correcting the inadvertent omission of this provision from its oral fluid testing requirements.

Thus, we are adding a new paragraph to the regulation instructing the oral fluid collector not to allow anyone other than the collector, the employee being tested, or a DOT agency representative to witness the testing process. This instruction will afford the employee privacy during testing and parallels the alcohol testing procedure found in § 40.223(b).

*Section 40.73 How is an oral fluid specimen collected? (specification of the collection of a sufficient amount of oral fluid)*

The current § 40.73(c)(2) requires the oral fluid collector to ensure that a sufficient specimen volume is collected. To be more specific and provide our interpretation of how collectors ensure that a sufficient volume is collected, we are requiring the collector to also check the 'volume indicator(s) observed' box in Step 2 of the CCF. To do so, in this direct final rule we are adding language to § 40.73(c)(2) to instruct the collector to document in Step 2 of the CCF that they observed the volume indicator(s) during the collection.

### III. Regulatory Notices and Analyses

This rule is a non-significant rule for purposes of Executive Order (E.O.) 12886, as supplemented by E.O. 13563 and amended by E.O. 14094 and will not impose any significant costs or have impacts beyond those analyzed in the May 2, 2023, final rule. DOT has determined that the regulatory analyses conducted for the May 2, 2023, final rule remain applicable to this direct final rule. DOT makes these statements on the basis that, as technical amendments that correct or clarify existing regulatory provisions, specifically to establish temporary requirements to qualify an initial group of mock oral fluid collection observers, establish privacy requirements during an oral fluid collection, and clarify how

collectors are to specify that a sufficient volume of oral fluid was collected, this direct final rule will not impose any significant costs or have impacts beyond those analyzed in the May 2, 2023, final rule.

DOT concludes that it has good cause to waive prior opportunity for notice and comment to 5 U.S.C. 553(b)(B) as unnecessary unless adverse comment is received by July 22, 2024. These amendments correct a factual impossibility with regard to mock collection observers, incorporate privacy considerations consistent with DOT regulations on alcohol testing, and clarify how collectors are to demonstrate compliance with the existing regulation that requires collection of a sufficient amount of oral fluid. DOT believes these amendments merely clarify and operationalize the final rule published on May 2, 2023, and are noncontroversial. The amendments do not make significant substantive changes to Part 40.

With regard to the added language in § 40.35 for monitors of mock oral fluid collections, DOT explained that the final rule published in May 2023 inadvertently created a factual impossibility. The temporary allowance in this direct final rule will be in effect until one year after HHS certifies an oral fluid laboratory, during which time individuals could become qualified oral fluid collectors. DOT believes that individuals monitoring collections under this final rule will be able to monitor collections with the same level of proficiency as qualified collectors meeting the knowledge, skills, and abilities set forth in § 40.35.

With regard to the added instruction in § 40.73 to the oral fluid collector not to allow anyone other than the collector, the employee being tested, or a DOT agency representative to witness the testing process, DOT is correcting the inadvertent omission of this provision from its oral fluid testing requirements to afford a commensurate level of privacy to all employees subject to testing.

With regard to the requirement for the collection of a sufficient specimen volume, the requirement established in this direct final rule to check the 'volume indicator(s) observed' box in Step 2 of the collection form is intended only to clarify how collectors ensure that a sufficient volume is collected as required by the regulation.

Based on the preceding discussion and the description of the measures in this direct final rule, DOT determined that the opportunity for prior notice and comment is unnecessary and contrary to the public interest, and DOT publishes

the amendments in this direct final rule. For these same reasons, DOT waives the 30-day delay in effective date for this rule pursuant to 5 U.S.C. 553(d)(3).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. DOT will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. This rule does not constitute a major rule as defined in 5 U.S.C. 804(2).

**List of Subjects in 49 CFR Part 40**

Administrative practice and procedures, 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 and the specified DOT agency regulations as follows:

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

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

**Authority:** 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

■ 2. In § 40.35, revise paragraph (c)(2) and add paragraph (c)(3) to read as follows:

**§ 40.35 What training requirements must a collector meet for oral fluid collection?**

\* \* \* \* \*

(c) \* \* \*

(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between you and the qualified collector, who must attest in writing that the mock collections are “error-free.” Except as provided in paragraph (c)(3) of this section, this person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by—

(i) Regularly conducting DOT drug test collections for a period of at least one year;

(ii) Conducting collector training under this part for at least one year; or

(iii) Successfully completing a “train the trainer” course.

(3) As the person monitoring and evaluating the collector’s five mock collections pursuant to paragraphs (c)(1) and (2) of this section, you need not be a qualified oral fluid collector to do so if you meet the necessary knowledge, skills, and abilities in paragraph (c)(2)(ii) or (iii) until otherwise specified (one year after HHS publishes a **Federal Register** notification of the first certified oral fluid drug testing laboratory (HHS notification)). Furthermore, the one-year requirement in (c)(2)(ii) is not applicable until otherwise specified (one year after the HHS notification).

\* \* \* \* \*

■ 3. In § 40.73, add paragraph (a)(1) and a reserved paragraph (a)(2) and revise paragraph (c)(2) to read as follows:

**§ 40.73 How is an oral fluid specimen collected?**

\* \* \* \* \*

(a) \* \* \*

(1) As the oral fluid collector, you must not allow any person other than you, the employee, or a DOT agency representative to actually witness the testing process.

(2) [Reserved]

\* \* \* \* \*

(c) \* \* \*

(2) The collector must ensure the collection is performed correctly (*i.e.*, using the oral fluid device in the manner described by its manufacturer), that the collection device is working properly, and that a sufficient specimen volume is collected. Check the “Volume indicator(s) Observed” box in Step 2 of the Federal CCF to document that you observed the volume indicator(s) during the collection.

\* \* \* \* \*

Signed pursuant to authority delegated at 49 CFR 1.27(c) in Washington, DC.

**Subash Iyer,**

*Acting General Counsel.*

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**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 648**

**[Docket No. 231215–0305; RTID 0648–XE044]**

**Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer From Virginia to Rhode Island**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; quota transfer.

**SUMMARY:** NMFS announces that the Commonwealth of Virginia is transferring a portion of its 2024 commercial summer flounder quota to the State of Rhode Island. This adjustment to the 2024 fishing year quota is necessary to comply with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) quota transfer provisions. This announcement informs the public of the revised 2024 commercial quotas for Virginia and Rhode Island.

**DATES:** Effective June 20, 2024, through December 31, 2024.

**FOR FURTHER INFORMATION CONTACT:** Laura Deighan, Fishery Management Specialist, (978) 281–9184.

**SUPPLEMENTARY INFORMATION:** Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.111. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102, and the final 2024 allocations were published on December 21, 2023 (88 FR 88266).

The final rule implementing amendment 5 to the FMP, as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: (1) the transfers or combinations would not preclude the overall annual quota from being fully harvested; (2) the transfers address an unforeseen variation or contingency in the fishery; and (3) the transfers are consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Regional Administrator has determined these three criteria have been met for the transfer approved in this notification.

Virginia is transferring 3,799 pounds (lb; 1,723 kilograms (kg)) to Rhode Island through a mutual agreement between the states. This transfer was requested to repay landings made by an