

the Captain of the Port Sector Columbia River or a designated representative.

DATES: The regulations in 33 CFR 165.1315 will be enforced from 7 p.m. until 8:30 p.m., each day on December 6 and 7, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Commander Jesse Wallace, Waterways Management Division, Sector Columbia River, Coast Guard; telephone 503-572-3524, email SCRWWM@USCG.MIL.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone in 33 CFR 165.1315 for the City of Richland Lighted Boat Parade Fireworks Display, in Richland, WA, from 7 p.m. until 8:30 p.m., each day on December 6 and 7, 2024 on the Columbia River. The safety zone will include all navigable waters within a 450-yard radius of the fireworks launch site location of approximately 46°16'29" N; 119°16'10" W.

The special requirements listed in 33 CFR 165.1315 apply to the activation and enforcement of the safety zone. During the enforcement period, as reflected in § 165.1315(e), no person may enter or remain in the safety zone unless authorized by the Captain of the Port Sector Columbia River or a designated representative. Additionally, each person in the safety zone must comply with the lawful order or directions of the Captain of the Port Sector Columbia River or designated representative.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: October 25, 2024

J.W. Noggle,

CAPTAIN, U.S. Coast Guard, Captain of the Port Sector Columbia River.

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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: Final rule.

SUMMARY: The U.S. Department of Transportation (DOT) revises its drug and alcohol testing procedures, as amended by a final rule published on May 2, 2023, to provide temporary qualification requirements for mock oral fluid monitors, provide for consistent requirements by identifying which individuals may be present during an oral fluid collection, and clarify how collectors are to document that a sufficient volume of oral fluid was collected.

DATES: This final rule is effective on December 5, 2024.

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.

SUPPLEMENTARY INFORMATION:

I. Authority for This Rulemaking

This rulemaking is promulgated under the authority originally enacted in the Omnibus Transportation Employee Testing Act (OTETA) of 1991, codified at 49 U.S.C. 45102 and 45104 (aviation industry testing), 49 U.S.C. 20140 (rail), 49 U.S.C. 31306 (motor carrier), and 49 U.S.C. 5331 (transit). OTETA requires that the Department incorporate the Department of Health and Human Services' (HHS) Mandatory Guidelines, including amendments, into the Department's regulations for testing and laboratory requirements for aviation, rail (except for rail post-accident testing), motor carrier, and transit testing. Additional authority at 5 U.S.C. 7301 note and Executive Order 12564, specify HHS as 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 follows the HHS Mandatory Guidelines for the laboratory and specimen testing procedures.

On October 25, 2019, HHS published a final rule establishing the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG), which became effective January 1, 2020. (84 FR 57554, Oct. 25, 2019). As of the time of the publication of this final rule, there have been no laboratories yet certified by HHS for oral fluid testing.

II. 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 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 May 2023 final rule need to be further amended due to unforeseen circumstances that have rendered it impossible to comply with requirements for mock oral fluid collection observers, for consistency with regard to privacy during the specimen collection, and to clarify the means by which collectors document that a sufficient volume of oral fluid was collected.

To address the issues identified above, DOT published a direct final rule (DFR) on June 21, 2024. (89 FR 5189) DOT published the DFR without a prior proposed rule because we viewed the DFR as a noncontroversial action and anticipated no adverse comments on any of the provisions of the rule. The DFR was to become effective on August 5, 2024, unless DOT received adverse comments on the provisions of the DFR. DOT noted that if adverse comments were received, it would publish a timely withdrawal in the **Federal Register** informing the public that the provisions of the rule on which adverse comments were received would not take effect.

On the same day, DOT published a notice of proposed rulemaking (NPRM) containing the same amendments in the DFR that served as the proposed rule to amend Part 40 if adverse comments were received on any of the provisions in the DFR (89 FR 52002). DOT noted that if adverse comments were received, DOT would address the public comments received in a subsequent final rule based on the NPRM. DOT stated that it would not institute a second comment period on the NPRM.

DOT received adverse comments to each of the provisions in the DFR and NPRM, and DOT published a notice withdrawing the DFR in the **Federal Register** on August 1, 2024 (89 FR 62665).

III. Comments to the DFR and NPRM

DOT received 15 unique comments to the DFR, and 18 unique comments to the NPRM.¹ These comments included

¹ There were duplicate comments filed for both the DFR and the NPRM that are included in the docket in www.regulations.gov.

three that expressed concerns about, or opposed the use of, oral fluid testing generally, and one that was not related to the subject rulemaking. DOT considered and responded to comments expressing the same concerns about and opposing oral fluid testing in the May 2023 final rule establishing oral fluid testing as an additional test methodology for employers. These comments are therefore outside of the scope of this rulemaking, which makes only technical corrections to the May 2023 final rule, and are not addressed in this final rule.

A. Comments in Support of the Amendments

The Substance Abuse Program Administrators Association (SAPAA), a nonprofit trade association with a membership encompassing third-party administrators, in-house program administrators, medical review officers (MROs), HHS-certified laboratories, substance abuse professionals (SAP), manufacturers of testing devices, and collection sites/collectors, supported each of the changes to Part 40 as outlined in the DFR and NPRM. SAPAA stated that the changes “emphasize the necessity of aligning the regulations with practical implementation realities and reflect the successful introduction of similar guidelines in the past,” and that “nothing in these changes would negatively impact the ability to train DOT oral fluid collectors once collection devices are commercially available; and, in fact, would facilitate that process.”

Airlines for America (A4A) commented, stating that it generally supports DOT’s efforts in the DFR and NPRM to address the issues identified regarding the May 2023 final rule. A4A suggested that DOT extend the sunset date for the regulatory relief under § 40.35(c)(3) to 18 months, instead of 12 months as proposed. A4A also requested that DOT clarify the intent of § 40.35(c)(2)(ii), specifically with respect to whether the qualified collector under that section is required to have conducted *oral fluid* training under Part 40 for a period of at least one year. Finally, A4A suggested that DOT permit an employee to orally waive the prohibition on others “actually witnessing the testing process.”

DOT received one comment supporting the clarifying language to § 40.73(c)(2) regarding how collectors are to specify that a sufficient volume of oral fluid was collected. That commenter stated that the amendment “brings uniformity to all collectors, maintains consistent results, and

promotes more efficient workflow and data from collectors.”

B. Comments in Opposition to the Amendments

DOT received comments from two individuals opposing the proposed amendment to § 40.73(a)(1) regarding who may witness the oral fluid testing process.

DOT received comments opposing the DFR and the NPRM from the National Drug and Alcohol Screening Association (NDASA), a nonprofit association with a membership that includes laboratories, employers’ substance abuse program administrators, compliance auditors, consortia/third party administrators (C/TPA), specimen collection facilities, collectors, breath alcohol technicians, screening test technicians, laboratories, MROs, and SAPs. In addition, several other organizations and individuals provided comments opposing the DFR and NPRM by either (1) citing to NDASA’s comments as the basis for their opposition, or (2) attaching a copy of NDASA’s comments as their docket submittal.

In discussing comments on this rule and our response to them, we focus on the substance of positions that commenters expressed, and on why we did or did not make changes in response. We address each of the substantive comments provided to the DFR and the NPRM in the discussion of the amendments to Part 40 in the following section.

IV. Amendments to Part 40

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

The May 2023 final rule established requirements for oral fluid collector qualifications in § 40.35 that mirrored as closely as possible existing urine collector qualifications in § 40.33. All of the qualification training requirement categories (*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 additionally: (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.

At this time, however, individuals wanting to be oral fluid collectors are not 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. In the NPRM, we stated that we did not intend to create a factual impossibility, and that we meant for the oral fluid monitors for the mock proficiency demonstrations to be proficient as oral fluid collectors.

To facilitate the training of oral fluid collectors, we proposed to amend 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, we proposed that this regulatory flexibility would apply only to those individuals meeting the knowledge, skills, and abilities in § 40.35(c)(2)(ii) or (iii).² With regard to the knowledge, skills, and abilities in § 40.35(c)(2)(ii), we proposed to waive the requirement that individuals conducting oral fluid collector training have at least one year of experience conducting collector training, but stated that 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 provided to students, etc.) to demonstrate that they conducted the training. We noted that this is no different than what would be expected of those conducting urine

² We noted 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) with a device that meets DOT’s requirements per appendix B of part 40, oral fluid is not a permissible means of collection. We determined that, in contrast to paragraphs (c)(ii) 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, we stated that 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.

collection training today. Individuals conducting this training would be eligible to observe oral fluid mock collections during the period of regulatory relief.

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

Comments

NDASA (and the other commenters that echoed NDASA's comments) objected to the proposed change to § 40.35(c), expressing concern that DOT was "lowering its standards" by not requiring the monitor of the mock oral fluid collections to be a qualified oral fluid collector under the requirements of § 40.35. Instead, NDASA recommended that DOT retain the language of § 40.35(c)(2) as currently written, which it contends would permit qualified urine collectors under § 40.33 to serve as monitors for the required mock oral fluid collections.

Specifically, NDASA recommended leaving § 40.35(c)(2) unchanged because, as it currently reads, a monitor must be a "qualified collector." Under the current Part 40, the only qualified collectors are urine collectors who meet the requirements of § 40.33. Therefore, if the Direct Final Rule does not become effective, current qualified urine collectors who have taken a train the trainer class would be able to be the monitors of the initial proficiency demonstrations required under § 40.35(c).

NDASA and others also objected to language in the preamble stating that individuals conducting oral fluid collector training under § 40.35(c)(2)(ii) "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." NDASA states that it is the responsibility of those receiving the training, and not of the trainer, to retain proof of their training and its sufficiency with Part 40. NDASA believes that the

preamble language imposes (1) new "processes and requirements," and (2) an "additional and arguably redundant record-keeping requirement for monitors or trainers" that were not properly evaluated through regulatory and cost analyses.

As noted above, A4A recommended that DOT extend the sunset date for the regulatory relief under § 40.35(c)(3) to 18 months, instead of 12 months as proposed.

DOT Response

While the training and qualification requirements for urine collectors and oral fluid collectors in Part 40 are similar, they are also unique because of the differences in the collection site, collection equipment and supplies used, and the collection process for urine and oral fluid specimens. The intent to have separate training and qualification requirements for urine collectors and oral fluid collectors is evident when looking at the manner in which Part 40 was amended in the May 2023 rule that authorized—for the first time—the use of a specimen other than urine in the DOT drug testing program. In the May 2023 final rule, DOT stated that it had "amended § 40.31 to *separately* specify the requirements for collectors of urine and oral fluid specimens, respectively." (88 FR at 27600) (emphasis added). Specifically, § 40.31(b) states that "A urine collector must meet training requirements of § 40.33," and § 40.31(c) states that "An oral fluid collector must meet training requirements of § 40.35."

In the May 2023 final rule, DOT established requirements for oral fluid collector qualifications in a new § 40.35 that mirrored the existing urine collector qualifications in § 40.33 as closely as possible. The qualification training requirements in the new § 40.35 for oral fluid collectors directly parallel those in the longstanding § 40.33 for urine collectors (*i.e.*, Basic Information, Qualification Training, Initial Proficiency Demonstration, Refresher Training, Error Correction Training, and Documentation).

While §§ 40.33 and 40.35 mirror each other to the extent possible, there are provisions in each section that are unique and tailored specifically to the particular specimen type (urine or oral fluid), recognizing the distinct differences between a urine collection and an oral fluid collection (*i.e.*, training on "shy bladder" collections for urine in § 40.33(b)(2), and training on "dry mouth" collections for oral fluid in § 40.35(b)(4); completion of a urine mock collection for a scenario in which the urine temperature is not within the acceptable range in § 40.33(c)(1), and

completion of an oral fluid mock collection for a scenario in which the employee has something in the employee's mouth that might interfere with the collection in § 40.35(c)(1)).

Beyond the training and qualification requirements for collectors in §§ 40.33 and 40.35, DOT established separate requirements for urine and oral fluid collections in Subpart D of Part 40, "Collection Sites, Forms, Equipment and Supplies Used in DOT Urine and Oral Fluid Collections" (see §§ 40.40–40.51), and in Subpart E of Part 40, "Specimen Collections" (see §§ 40.61–40.79).

Given the above, DOT clarifies that under the May 2023 final rule, a qualified urine collector (§ 40.33) is not a qualified oral fluid collector (§ 40.35), and vice-versa.

Section 40.35(c)(2) requires that a "qualified collector" monitor and evaluate an individual's performance in a series of mock oral fluid collections before that individual becomes a qualified oral fluid collector. And, per § 40.35(c)(2)(i), (ii), and (iii), the qualified collector that will serve as the monitor for the mock collections is additionally required to have demonstrated knowledge, skills, and abilities by (1) "regularly conducting DOT drug test collections for a period of at least one year"; (2) "conducting collector training under Part 40 for at least one year"; or (3) "successfully completing a 'train the trainer' course."

As currently written, § 40.35(c)(2) does not expressly state that the qualified collector needs to be a qualified *oral fluid* collector. Similarly, §§ 40.35(c)(2)(i), (ii), and (iii) do not expressly require the qualified collector that will serve as the monitor to have: (1) regularly conducted DOT *oral fluid* drug test collections for a period of at least one year; (2) conducted *oral fluid* collector training under Part 40 for at least one year; or (3) successfully completed an *oral fluid* "train the trainer" course.

However, and while § 40.35(c)(2) and § 40.35(c)(2)(i), (ii), and (iii) do not expressly state that the qualified collector for the oral fluid mock collections must be a qualified oral fluid collector and have specific experience in oral fluid collections or training, DOT believes that this is the only reasonable interpretation of the requirement as written based on (1) the manner in which § 40.35 is drafted and, more importantly, (2) the fact that a qualified urine collector is not a qualified oral fluid collector and, therefore, lacks the knowledge needed to monitor and attest in writing that the mock oral fluid collections are error-free. Qualified

urine collectors do not have the specific, detailed knowledge, skills, and abilities directly related to oral fluid devices and collections to serve as appropriate monitors for mock oral fluid collections. If DOT had intended to permit qualified urine collectors to serve as monitors for oral fluid mock collections, it would have affirmatively stated so in the regulatory text.

DOT acknowledged in its June 2024 DFR that it had inadvertently created a factual impossibility given the current language of § 40.35. There are no currently qualified oral fluid collectors per § 40.35(c)(2) who meet the additional qualifications at § 40.35(c)(2)(i), (ii) or (iii) to monitor and evaluate the trainee's mock collections; therefore, no one can be a qualified oral fluid collector at this time.

To best facilitate the timely training of oral fluid collectors, DOT continues to believe that it is appropriate to authorize individuals to monitor mock oral fluid collections without meeting the requirement of being a qualified oral fluid collector, specified in § 40.35 as proposed in the NPRM. As discussed above, qualified urine collectors are not qualified oral fluid collectors, and they are similarly not qualified to monitor and evaluate a trainee's performance in oral fluid mock collections merely because they are qualified in urine collections. As qualified urine collectors are not qualified to serve in this role, and because there are no qualified oral fluid collectors to serve in the same role, this rule permits individuals who are not qualified oral fluid collectors to serve as monitors for oral fluid mock collections provided that they meet certain requirements.

Specifically, to ensure the proficiency of collection monitors, this regulatory flexibility—consistent with what we proposed in the NPRM—will apply only to those individuals meeting the knowledge, skills, and abilities in § 40.35(c)(2)(ii) or (iii). With regard to 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, any certificate of successful completion provided to the

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 Part 40 oral fluid training would be eligible to observe oral fluid mock collections during the period of regulatory relief.³

As noted above, DOT specified in the preamble to the June 2024 DFR and NPRM that individuals conducting training *should* maintain good records to demonstrate that they conducted the training; however, DOT did not include regulatory text in the DFR, or propose regulatory text in the NPRM, regarding record retention requirements or expectations for oral fluid collector trainers. DOT also does not require in its Part 40 regulations that such records should or must be maintained—for trainers of urine collectors, breath alcohol technicians, or oral fluid collectors. Instead, the preamble language in the June 2024 DFR and NPRM stating that individuals conducting oral fluid collector training should keep certain records of these training sessions was based on our expectation that individuals conducting collector training would normally be retaining those records as a business

³ DOT also notes that § 40.209, "What procedural problems do not result in the cancellation of a test and do not require corrective action?," provides a list of matters that never result in the cancellation of a test. Included in that list at § 40.209(b)(3) is "The collection of a specimen by a collector who is required to have been trained (see § 40.33 or 40.35), but who has not met this requirement." As noted in the December 19, 2000 final rule (65 CFR 79462), this section is based on a "general principle" that "tests cannot be cancelled based on an error that does not have a significant adverse effect on the right of the employee to have a fair and accurate test. The point of this proposal was to prevent administrative or judicial decisions invalidating drug tests that were fair and accurate, but had certain de minimis irregularities." [65 FR 79503] DOT went further, and specifically with respect to the issue of collector training and qualifications, stated "One of the points we make in this section is that a urine collection or an alcohol test must not be cancelled solely because the collector, BAT, or STT has not met training requirements. Such a test would be cancelled only if there were a fatal flaw or other circumstances requiring cancellation." [Id.] [Emphasis added]. This means that if a collector properly conducts a urine test in accordance with the provisions of Part 40 (or an oral fluid test when laboratories have been approved) without having met the requirements of § 40.33, the test is not permitted to be cancelled. Simply stated, if an individual is not a qualified urine or oral fluid collector and that person collects a specimen by following Part 40 "to the letter," the collection is a good collection and is not to be cancelled. In a similar vein, DOT believes that in these beginning stages of oral fluid testing, it is appropriate for individuals who are conducting collector training, and who are well versed in the course content that they are teaching (*i.e.*, their instruction follows Part 40 procedures), to be qualified to serve as monitors for mock oral fluid collections.

best practice. NDASA and others objected to the same preamble language in the NPRM, contending that the preamble language imposed new standards and documentation retention requirements for monitors of mock collections.

The commenters are correct in stating that Part 40 requires urine and oral fluid collectors and breath alcohol technicians to maintain documentation showing that they meet all of the requirements to collect DOT specimens (see § 40.33(g), 40.35(g), and 40.213(g), respectively). In this final rule, DOT is not establishing any new regulatory requirement that monitors, trainers, and/or trainees retain specific records of the training materials used to qualify the trainees.

A4A recommended extending the sunset provision from 12 months, as proposed, to 18 months because it believes that 12 months is insufficient for the industry to establish the necessary number of qualified collectors to train all other collectors in the oral fluid collecting process. A4A contends that "This difficulty is exacerbated for airlines, which operate globally and in remote locations . . . that make it unreasonable to expect the establishment of the necessary cadre of qualified collectors exactly one year after publication that can train other collectors."

DOT does not believe that it is necessary to extend the sunset date beyond 12 months, as proposed. In its comments, NDASA stated that it alone has trained "several hundred" trainers through its train-the-trainer course since the issuance of DOT's oral fluid rule in May 2023. This—coupled with the regulatory flexibility established in this rule—will ensure that there are a sufficient number of qualified oral fluid collectors within the first year of laboratories being certified without the need for an extended sunset date.

As noted above, while §§ 40.35(c)(2) and 40.35(c)(2)(i), (ii), and (iii) do not expressly state that the qualified collector for the oral fluid mock collections must be a qualified *oral fluid* collector and have specific experience in *oral fluid* collections or training, DOT believes that this is the only reasonable interpretation of the requirement as written based on: (1) The manner in which § 40.35 is drafted, and more importantly, (2) the fact that a qualified urine collector is not a qualified oral fluid collector, and therefore, lacks the knowledge needed to monitor and attest in writing that the mock oral fluid collections are error-free. To clarify this, and consistent with our stated intent, we have amended the language in those

sections to specifically refer to “oral fluid” where necessary. For the same reasons, we have similarly amended the language in § 40.33(c)(2) and §§ 40.33(c)(2)(i), (ii), and (iii) regarding urine mock collections to refer specifically to “urine” where necessary.

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

DOT intended in the May 2023 final rule that the procedures for oral fluid testing parallel the alcohol testing procedures 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 from witnessing the testing process. Such a provision also affords privacy to the employee being tested.

In the NPRM, DOT proposed to correct the inadvertent omission of this provision from its oral fluid testing requirements. Specifically, we proposed to add 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 parallels the alcohol testing procedure found in § 40.223(b) and would afford the employee privacy during testing.

Comments

Two individuals opposed the proposed amendment, stating that restricting who may be present during the testing process to the collector, the employee, or a DOT agency representative is too restrictive and will hinder the ability of collection sites to train new staff and monitor for ongoing quality assurance. And, as noted earlier, A4A recommended that because the oral fluid testing process does not include immediate testing results or require exposure of private body parts, DOT “should empower the employee to orally waive the prohibition on others ‘actually witness[ing] the testing process.’” A4A believes that doing so may materially improve the efficiency of the collection process.

DOT Response

Part 40 outlines the steps that must be taken to protect the security of urine, oral fluid, and alcohol testing sites, including identifying who is considered to be an “authorized person” who is permitted to enter the testing site (see § 40.43(e)(1), § 40.48(d)(1), and § 40.223(a)(1), respectively). In each case, these authorized persons are limited to the individual being tested,

the collector/BAT/STT and other collection/testing site workers, DERs, employee and employer representatives authorized by the employer (*e.g.*, representatives authorized pursuant to an employer policy or collective bargaining agreement), and DOT agency representatives.

However, who may *enter the testing site* differs from who is permitted to *actually witness the collection/testing process*. Beyond identifying who is an “authorized person” that is permitted to enter a drug or alcohol testing site, Part 40 identifies who may actually witness the collection/testing process for drug and alcohol tests. Prior to the approval of oral fluid testing, this was limited to urine drug testing and alcohol testing. Because of the privacy concerns associated with urine testing, § 40.43(e)(2) expressly prohibits the collector from permitting anyone to enter the urination facility in which employees provide specimens (*i.e.*, actually witness the collection process) except for the observer in a directly observed collection or the monitor in a monitored collection. While alcohol tests are observed tests, § 40.223(b) has long prohibited BATs and STTs from permitting any person besides the BAT or STT, the employee, or a DOT agency representative to “actually witness the testing process.”

While Part 40 limits who is an “authorized person” that may be at the testing site, those authorized persons include other collection site workers. DOT understands the concerns articulated by the commenters, but we believe that limiting who may actually witness the oral fluid testing process, similar to what has been done for decades for alcohol testing, will not unduly restrict a collection site from conducting training or monitoring for ongoing quality assurance given that other collection site workers (including other collectors) may be present at the testing site. Oral fluid drug tests, like alcohol tests, are observed tests. As noted in the NPRM, it was our intention 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 BAT or STT to prohibit anyone other than the BAT or STT, the employee, or a DOT representative to witness the testing process.

We do not believe that there would be any material efficiency gains to be realized in the oral fluid testing process by permitting employees to orally waive the prohibition on others actually witnessing the testing process, as suggested by A4A. We believe that it is important to maintain consistency in

the DOT drug and alcohol testing program and process and will continue to limit who may witness the oral fluid testing process to the collector, the employee, and a DOT agency representative. As noted above and in the NPRM, limiting who may actually witness the oral fluid testing process also affords privacy to the employee being tested even though we recognize that the privacy interest for oral fluid is not as heightened as for urine testing. Given the above, we have retained the amendment to § 40.73(a)(1) as proposed in the NPRM.

C. 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 proposed to require the collector to also check the “Volume Indicator(s) Observed” box in Step 2 of the CCF. Specifically, we proposed to add 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.

Comments

NDASA provided the only comment on this issue and stated that the collector should not be relying on the volume indicator until after the specimen is collected. As such, NDASA recommended revising the proposed language to read as follows: “After the employee provides a sufficient specimen, check the “Volume [I]ndicator(s) Observed” box in Step 2 of the Federal CCF to document that you observed the volume indicator(s).”

DOT Response

DOT agrees with this editorial suggestion, and has incorporated the revised language as suggested.

D. Other Comments

While acknowledging that the language of the regulatory provisions of the DFR/NPRM does not prevent qualified trainers from beginning to train oral fluid collectors before HHS certifies a laboratory to conduct oral fluid testing, NDASA contends that the preamble to the DFR sets an “artificial barrier” to NDASA members and other qualified trainers from doing so, thereby “causing a detrimental financial burden to small businesses.” Specifically, NDASA stated “Delaying collector training until after laboratories are HHS-

certified will cause small businesses that have met the train the trainer requirements to suffer the loss of training revenue.” In addition, NDASA anticipates that if the process of training collectors and conducting those collectors’ proficiency demonstrations is delayed until after HHS certifies laboratories for oral fluid testing, that there will be a “rush on the market” to obtain approved oral fluid collection devices causing: (1) potential shortages of inventory, and (2) price increases because demand may exceed supply, and concluded that “small businesses will bear the brunt of these problems and costs.”

NDASA stated that “There is no need to wait for laboratories to be certified by the HHS National Laboratory Certification Program (NLCP) before the training of individuals to collect oral fluid specimens can begin.” In addition, NDASA stated that delaying collector training until after HHS certifies laboratories will “create a shortage of properly trained and qualified oral fluid collectors from being able to collect specimens for possibly months after the first laboratories are certified.” Finally, NDASA stated that delaying training and qualification of oral fluid collectors until after HHS certifies laboratories will further delay full implementation of the oral fluid rule provisions, including § 40.67(g)(3), which requires oral fluid collections to be conducted in specified scenarios.

DOT Response

The purpose of the amendment to § 40.35 is to facilitate the timely qualification of oral fluid collectors. However, 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, and until there is a device that meets DOT requirements per Appendix B of Part 40. As part of the laboratory application and certification process, a specific oral fluid collection device will be identified and approved for use by that laboratory by HHS and NLCP. To date, HHS has not yet certified any laboratories for oral fluid drug testing with a device that meets DOT standards. It follows that no oral fluid collection devices meeting DOT’s device standards have been approved as part of the HHS/NLCP lab certification.

At the same time, DOT acknowledges that oral fluid collection devices are currently available and are being used for non-DOT oral fluid drug testing purposes. Further, NDASA states that there is an oral fluid collection device

that has been approved for use by the Food and Drug Administration (FDA), and that several laboratories expect to use that same device when submitting applications to HHS/NLCP for certification at some point in the future.

DOT anticipated that oral fluid trainers and prospective oral fluid collectors would wait until a specific oral fluid collection device meeting DOT’s standards had been approved by HHS/NLCP as part of the official laboratory certification process before conducting and obtaining training on how to use that specific device. Otherwise, trainers and prospective collectors would be risking the expenditure of significant time and costs to become trained in the operation of an oral fluid collection device that may not ultimately be approved as part of a laboratory’s certification by HHS/NLCP.

DOT did not intend to prevent individuals from training on devices to collect oral fluid specimens before HHS certifies a laboratory and use of an associated oral fluid collection device. As noted above, training on an oral fluid collection device that has not been approved for use as part of an official HHS laboratory certification package comes with the risk that the device may not be ultimately included and approved for use by a laboratory by HHS.⁴ This risk is borne entirely by the trainer and prospective collector, as DOT does not have any role in determining which particular oral fluid collection device is submitted by a laboratory to HHS as part of the laboratory’s approval/certification.

Because there is no regulatory requirement to wait until the first laboratory is certified by HHS before beginning training on the use of oral fluid collection devices, there is no detrimental financial burden or loss of training revenue to those small businesses that have taken train-the-trainer courses. Additionally, while NDASA expressed concern that: (1) sufficient quantities of approved oral fluid collection devices may not be available if training is delayed until after laboratories have been certified, and (2) suppliers of those devices may increase the price of those devices because demand may exceed supply, DOT does not believe there will be any issues regarding market availability or cost of the devices for training purposes.

Importantly, and as discussed above, DOT makes it clear that while training

on the use of an oral fluid collection device can take place at any time—including prior to the certification by HHS of an oral fluid drug testing laboratory—mock collections (and therefore, qualification of oral fluid collectors) cannot take place unless/ until DOT provides regulatory flexibility with respect to the qualifications of the monitors for the required mock collections, which DOT accomplishes in this final rule. Therefore, because § 40.35(b)(2) requires oral fluid collectors to be trained to proficiency in the operation of the particular oral fluid collection device(s) that the collector will be using, an individual becoming a qualified oral fluid collector on a specific oral fluid device before a laboratory is certified by HHS to use that device risks having to (1) receive training to proficiency on another device, and (2) complete the mock collections on that other device if the laboratory is not ultimately certified by HHS to use the device that the collector was originally trained on and qualified to use.

IV. 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 action. DOT makes these statements on the basis that, as a series of 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 document that a sufficient volume of oral fluid was collected, this action will not impose any significant costs or have impacts beyond those analyzed in the May 2, 2023 final rule.

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

⁴ Section 40.35(b)(2) requires oral fluid collectors to be trained to proficiency “in the operation of the particular oral fluid collection device(s) you will be using.”

States. This rule does not constitute a major rule as defined in 5 U.S.C. 804(2).

In accordance with Compliance with Pay-As-You-Go Act of 2023 (Fiscal Responsibility Act of 2023, Pub. L. 118–5, D. B, Title III) and OMB Memorandum (M–23–21) dated September 1, 2023, the Department has determined that this final 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 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 as follows:

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

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

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

■ 2. In § 40.33, revise paragraph (c)(2) to read as follows:

§ 40.33 What training requirements must a collector meet for urine 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 the instructor and trainee, and attest in writing that the mock collections are “error-free.” This person must be a qualified urine collector who has demonstrated necessary knowledge, skills, and abilities by—

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

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

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

* * * * *

■ 3. 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 oral fluid collector who has demonstrated necessary knowledge, skills, and abilities by—

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

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

(iii) Successfully completing an oral fluid “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 paragraph (c)(2)(ii) is not applicable until otherwise specified (one year after the HHS notification).

* * * * *

■ 4. 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. After the employee provides a sufficient specimen, 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.

[FR Doc. 2024–25403 Filed 11–4–24; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 240304–0068; RTID 0648–XE445]

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amount of Pacific cod from trawl catcher vessels and from catcher vessels greater than or equal to 60 feet (18.3 meters (m)) length overall (LOA) using pot gear to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear, Amendment 80 vessels, and catcher/processors using hook-and-line gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to allow the 2024 total allowable catch (TAC) of Pacific cod to be harvested.

DATES: Effective October 31, 2024, through 2400 hours, Alaska local time (A.l.t.), December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Andrew Olson, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR parts 600 and 679.

The 2024 Pacific cod TAC specified for trawl catcher vessels in the BSAI is 28,754 mt as established by the final 2024 and 2025 harvest specifications for groundfish in the BSAI (89 FR 17287, March 11, 2024) and reallocations (89 FR 67327, August 20, 2024 and 89 FR 79454, September 30, 2024).