

What Will DOT Oral Fluid Testing Mean for Members of the American Short Line and Regional Railroad Association?

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The Disclaimer

I am an employee of the United States Department of Transportation (DOT) on detail to the National Drug and Alcohol Screening Association (NDASA) as the Senior Policy Executive Advisor. The views reflected here are expressed in my personal capacity.

My views have not been subjected to review, clearance, or approval by DOT, and they do not necessarily represent the views of DOT.

The National Drug and Alcohol Screening Association – NDASA – www.ndasa.com

- “Our mission is to advocate for safe and drug-free workplaces and communities through legislative advocacy, education, training and excellence in drug and alcohol screening services.”
- Largest trade association in the drug and alcohol testing industry (the Drug and Alcohol Testing Industry Association – “DATIA” – merged into NDASA on June 1, 2023)
- Members include: employers and service agents (Consortia/ Third Party Administrators, Medical Review Officers, Collectors for DOT-regulated and non-DOT collections [urine, oral fluid, hair, sweat, etc.], Alcohol Collectors, Substance Abuse Professionals, etc.)
- Member Owned and Member Driven
- NDASA’s Executive Director: Jo McGuire – jmcguire@ndasa.com
- Please join us for “Town Hall” webinar meetings Wednesdays at 2:00 Eastern Time

Presentation Overview

- ✓ Approval of Oral Fluid and Timing for Implementation
- ✓ Is Oral Fluid Testing as Reliable as Urine Testing?
- ✓ Is Oral Fluid Testing Authorized for All DOT Agencies?
- ✓ Refresher on Employer-Determined Refusals
- ✓ What Do Employers Need to Know for Their Own Programs?
- ✓ Business Choices for Employers
- ✓ Standing Orders/ Employer Protocols
- ✓ Questions and Answers

Oral fluid is approved. What next?

- Oral fluid testing has been approved by the Department of Health and Human Services (HHS).
- The US Department of Transportation (DOT) published the oral fluid final rule on May 2, and it became effective June 1, 2023.
- DOT must use HHS-certified laboratories to conduct DOT-regulated testing.
- There must be one HHS-certified primary lab and one secondary HHS-certified lab (for the split specimen).
- No labs have applied for HHS certification.
- HHS Certification usually takes around 3 to 6 months from the point an application is received.

Oral Fluid Testing Will be Allowable for DOT–regulated tests under 49 CFR Part 40, BUT NOT YET!

- DOT must wait for HHS to certify a primary laboratory and a secondary/ split specimen laboratory
- How will you know when this has happened?
 - Expect notification from ODAPC and/or the HHS National Laboratory Certification Program
 - Check here for the listing of HHS certified laboratories
<https://www.transportation.gov/odapc/labs>

Is Oral Fluid Testing as Reliable as Urine Testing?

Yes! In its 2019 final rule, HHS stated:

- ✓ “[t]he scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established and the advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in Federal programs **with the same level of confidence that has been applied to the use of urine.**” (84 FR 57554; Oct. 25, 2019).
- ✓ “[the HHS testing scientific and technical guidelines] provide **the same scientific and forensic supportability of drug test results as** the Mandatory Guidelines for Federal Workplace Drug Testing Programs using **Urine.** . . .” Id.

Is Oral Fluid Testing as Reliable as Urine Testing?

- ✓ In evaluating the progress of science of oral fluid testing and its scientific viability, HHS also looked at its **forensic defensibility in workplace testing**.
- ✓ HHS addressed concerns about **passive exposure** as the result of someone else's drug use (e.g., from second-hand smoke) in the context of cutoffs or metabolites used in oral fluid testing, particularly with regard to marijuana. (84 FR 57557, 57558; Oct. 25, 2019).
 - HHS concluded that a **4 ng/mL screening test cutoff for THC would detect marijuana use while eliminating possibilities of positive tests resulting from passive exposure**. (See 84 FR at 57558; Oct. 25, 2019).

Is Oral Fluid Testing as Reliable as Urine Testing?

DOT has stated that oral fluid testing is as effective as directly observed urine testing. 88 Fed. Reg. 27597 (May 2, 2023)

- ✓ “We recognize directly observed urine specimen collections have long been the most effective method for preventing individuals from cheating on their drug tests by substituting or adulterating their specimens, but directly observed urine collection may only be done in certain circumstances due to employee privacy concerns (see 49 CFR 40.67).”
- ✓ “All oral fluid collections are directly observed because they are always collected in front of the collector. “
- ✓ “Unlike a directly observed urine collection, an oral fluid collection is much less intrusive on the tested employee’s privacy.”
- ✓ “Therefore, adding oral fluid testing as an option is consistent with the careful balancing of an individual’s right to privacy with the Department’s strong interest in preserving transportation safety by deterring illicit drug use.”

Is Oral Fluid Testing Authorized for All DOT Agencies?

- Yes!!!
- The final rule includes changes made by FAA, FMCSA, FTA, and FRA to permit their respective regulated employers to use the oral fluid final rule.
 - These changes also became effective June 1, 2023.
 - **Oral fluid testing does not apply to the FRA's post-accident testing program, which is not conducted under Part 40.**

There is time for you to prepare!

- There is work to be done on the employer's side.
- Policies may need to be updated.
- Collective bargaining agreements may need to be updated.
- You may have about 6 months to get ready.

Oral Fluid Final Rule Overview

Changes Directly Impacting EMPLOYERS:

- ✓ You, not the employee, choose the collection methodology for the test reason (e.g., randoms will start with urine; follow-ups will use oral fluid).
- ✓ You, not the employee, choose the collection methodology for the subsequent collection following a shy bladder, dry mouth, or other test that requires a directly observed collection.

Oral Fluid Final Rule Overview

Changes Directly Impacting EMPLOYERS:

- ✓ Ensure you have business relationships with the oral fluid collectors and labs, whether directly or through your service agents.
- ✓ You need to be available to the collector to discuss if there are problem collections.
- ✓ It is a best business practice to have a standing order in place with your instructions for each of your collection sites to direct what kind of collection you want performed (i.e., urine or oral fluid) and when.
 - Otherwise, you will need to talk with the collector before every single test.

Oral Fluid Final Rule Overview

Changes Directly Impacting EMPLOYERS:

- ✓ Direct observation urine collections must NOT be performed for transgender and nonbinary individuals, once oral fluid testing is available.
 - Your collectors will no longer try to determine who will be the “same gender” for transgender and nonbinary collections – those collections will go to oral fluid for the direct observation and gender becomes irrelevant.
- ✓ Oral fluid testing must be performed for ALL direct observation collections for transgender and nonbinary individuals.
 - The desired outcome is achieved because EVERY oral fluid collection is a direct observation collection!

Oral Fluid Final Rule Overview

Changes Directly Impacting EMPLOYERS:

There will STILL be urine directly observed collections!

- ✓ It will be the employer's choice about whether they will continue with urine testing in a shy bladder scenario. *But why would any employer choose that?*
 - ***Because you can does not mean you should.***
 - ***It may be time to revisit your CBA on the issue of directly observed collections!***
- ✓ It will be the employer's option as to when oral fluid testing or urine testing is to be used and that choice needs to be expressed to the collection site.
- ✓ For the extraordinarily rare circumstance of a directly observed collection being needed for a transgender or nonbinary individual, an oral fluid collection is mandated for the directly observed collection.

Oral Fluid Final Rule Overview

Changes Directly Impacting EMPLOYERS – Employer Policies:

- ✓ Changes will need to be made if an employer's DOT policy lists the following optional information:
 - If the policy specifically states that “urine” is the only specimen authorized for drug testing, then that text will need to be updated to read “urine and/or oral fluid” and state the testing events (e.g., random, pre-employment, follow up) for which an oral fluid collection will occur.

Oral Fluid Final Rule Overview

Changes Directly Impacting EMPLOYERS – Employer Policies (continued):

- ✓ It would be a good idea for the employer's policy to state:
 - Whether oral fluid collections will be authorized for shy bladder situations and direct observation collections.
 - Employees do not have the option to choose what testing methodology will be used.
- ✓ When it comes to the employer's DOT policy, make sure you are following the requirements of Part 219!
- ✓ When in doubt, contact the Federal Railroad Administration (FRA) directly!

Oral Fluid Final Rule Overview

Changes Impacting the Employer's Current Urine Collectors and Future Oral Fluid Collectors:

- ✓ The collector must ensure that the collector's phone number provided on the Federal Drug Testing Custody Control Form (CCF) in Step 1.G. connects directly to the collector and/or the collector's supervisor, and not a general call center.
 - That way, the employer can reach the actual collector with any questions about the test and/or about a reported refusal.
 - The employer will have a direct way to reach collectors they may need as witnesses.

Oral Fluid Final Rule Overview

Reminders in the Preamble for EMPLOYERS:

- ✓ It is the employer's duty to determine whether a refusal has occurred at the collection site.
 - Employers have never been able to delegate this duty.
 - A collector can tell you something appears to be a refusal, but the final determination is yours.

Oral Fluid Final Rule Overview

Reminders in the Preamble for EMPLOYERS:

- ✓ Pre-employment drug tests are different
 - If an applicant/employee does not appear for a pre-employment drug test or leaves the collection site before receiving a cup (for a urine collection) or unwrapping the device (for an oral fluid collection) it is NOT a refusal.
 - Why not? Because an applicant may have another offer, may not want the job, may not want to be in an industry that drug tests. Whatever the applicant's reason, it's not a refusal until the process of the pre-employment test begins.

Refresher on Employer-Determined Refusals

Aka: What is a Refusal and Who Determines It?

For refusals that occur at the collection site, the employer must make the determination about whether a refusal has occurred.

- ✓ This is not new. It has always been the non-delegable duty of the actual employer.
- ✓ A collector can tell the employer that something appears to be a refusal, but the final determination is for the employer to make.
- ✓ In a pre-employment drug test, if the applicant does not show up or leaves the collection site before receiving a cup (for a urine collection) or unwrapping the device (for an oral fluid collection) it is not a refusal.

Refresher on Employer-Determined Refusals

Aka: What is a Refusal and Who Determines It?

Service agents can provide advice and information to employers regarding refusal-to-test issues.

- However, a service agent's advice does not replace the **judgment of the employer**.
- The EMPLOYER is the one determining whether a refusal under the DOT's regulation, 49 CFR Part 40, has occurred. It's your **non-delegable duty!**

❖ **Practice tip:** Be familiar with the DOT's Employer Handbook, "What Employers Need to Know About DOT Drug and Alcohol Testing," pp. 25 – 28. [https://www.transportation.gov/sites/dot.gov/files/docs/ODAPC_Employer_Guidelines %20June 1 2015 A.pdf](https://www.transportation.gov/sites/dot.gov/files/docs/ODAPC_Employer_Guidelines_%20June_1_2015_A.pdf)

Refresher on Employer-Determined Refusals

Aka: What is a Refusal and Who Determines It?

Here are some examples of employer-determined refusals from page 25 of the Employer Handbook:

Event	Decision Maker	DOT Instructions
Fail to appear at a urine collection site when directed to report	Employer / DER * [after review of the collector documentation]	If the employee did not get to the site or spent too much time getting there, it is a refusal.
Fail to remain at the urine collection site	Employer / DER * [after review of the collector documentation]	If the collector reports that the employee left the collection site before the testing process was complete, it is a refusal.
Fail to provide a urine specimen	Employer / DER * [after review of the collector documentation]	If the collector reports that the employee left the collection site before providing a required specimen, it is a refusal.
Fail to permit a monitored or observed urine collection	Employer / DER * [after review of the collector documentation]	If the employer ordered an observed collection or if the collector required the collection to be monitored or observed, it is a refusal if the employee does not permit it to occur.

Refresher on employer-determined refusals

Aka: What is a Refusal and Who Determines It?

Here are some examples of employer-determined refusals from page 26 of the Employer Handbook:

Event	Decision Maker	DOT Instructions
Fail to undergo a medical examination or evaluation the MRO or employer has directed	MRO	If the employee does not go in for a medical evaluation or does not permit it to occur, it is a refusal.
Fail to cooperate with any part of the urine collection process	Employer / DER * [after review of the collector documentation]	Some examples of failure to cooperate are when the employee: <ol style="list-style-type: none"> 1. Refuses to empty pockets when directed; 2. Behaves in a confrontational manner that disrupts the collection process; 3. Refuses to remove hat, coat, gloves, coveralls when directed; or 4. Fails to wash hands when directed.
For an observed collection, fail to follow the instructions to raise and lower clothing and turn around	Employer / DER * [after review of the collector documentation]	If the employee does not follow these instructions so that the observer can check for prosthetic or other devices that could be used to interfere with the collection process, it is a refusal.
Possess or wear a prosthetic or other device that could be used to interfere with the collection process	Employer / DER * [after review of the collector documentation]	If the employee is found to have or wear a prosthetic or other device designed to carry clean urine or a urine substitute, it is a refusal.

What Do Employers Need to Know for Their Own Programs?

Reminders:

- ✓ Review your laboratory's semi-annual reports and question data (with your MRO or C/TPA).
 - This will help to ensure the accuracy of data reported to DOT by laboratories.
 - These reports are a good pulse on what's going on in your own program (e.g., cancelled tests, rejected etc.)

- ✓ Document your good faith efforts to obtain the drug and alcohol testing records from an applicant's previous employer, as required by 49 CFR section 40.25.

- ✓ Provide a list of qualified SAPs to BOTH employees and to applicants who failed/refused a DOT-regulated pre-employment test.

- ✓ For all tests other than Pre-employment, it is a best business practice to escort the employee to collection site once you have notified the employee.
 - Once oral fluid testing laboratories are HHS-certified, this will be less necessary.

Business Choices for Employers

Do you want to use external collectors to perform oral fluid collections, or do you want to train your staff to perform oral fluid collections?

- ✓ Does your railroad perform urine collections and breath alcohol testing in-house now?
 - If so, you know the upsides and downsides of internal collections and you probably are using staff who have no working relationship with donors and who would not be involved in taking disciplinary actions.
 - Let's explore this...

Business Choices for Employers

Using external professional collectors versus your own staff to perform oral fluid collections – considerations for employers:

- ✓ Do you have staff who have no working relationship with donors and who will not be involved in disciplinary actions who can perform the oral fluid collections?
 - **If not, and you want to start internal collections, consult counsel about the liability issues.**
- ✓ Is it worth your time and money to train your own personnel to become qualified under the DOT regulations simply to collect specimens occasionally?
- ✓ Are you willing to keep on hand, at your place of employment, oral fluid collection devices that you must pay for and that have expiration dates?
- ✓ What if an employee is called for a drug test and an alcohol test (for example, random or post-accident)? – Will you conduct one test in-house and send the employee to an outside location for the other?

Business Choices for Employers

Using external professional collectors versus your own staff to perform oral fluid collections – Considerations for employers:

- ✓ Anyone conducting oral fluid testing will need to have:
 - Oral fluid collectors trained and qualified under DOT's regulation, "Part 40".
 - A contract with an oral fluid laboratory (and arrangements for paying for a split specimen).
 - A supply of oral fluid collection devices that are NOT EXPIRED.

- ✓ In the public comments, many employers said they would NOT bring collections in-house because:
 - Some noted the costs of training employees to collect and keeping them current on collections.
 - Some said they did not want the liability of having the Human Resources person who collected the specimen also be the person involved in the disciplinary action or termination of the employee who has a non-negative result.

Standing Orders – Employer Protocols

Every employer NEEDS a standing order, sometimes called “employer protocols” with its TPA and/or the collection sites servicing the employer.

- ✓ Is this a regulatory requirement? – No.
- ✓ Can you run a testing program without one? – No.
- ✓ A Standing Order will ensure the collector knows what kind of collection the employer wants performed (i.e., urine or oral fluid) and when (for example: by test type).
- ✓ The standing order also needs to cover what happens when a directly observed collection is needed.
- ✓ AND what test does the employer want if it is a shy bladder or dry mouth.

Standing Orders - Employer Protocols

Have you started thinking about your “standing order” (aka “Employer Protocols” or “instructions”) for your collectors?

- ✓ You will need to instruct your collection sites directly or through a C/TPA as to what type of testing you want used in what kind of situation.
- ✓ Even if you only want one methodology used, you will want to be clear about it.
- ✓ You can use NDASA’s Model Standing Order format, develop your own format, or sign one developed by your C/TPA.

Questions?