

**Industry Update Newsletter – May 2026**  
**IMPORTANT DOT RULE CHANGE:**  
**Updated Guidance Regarding Direct Observation Collections and Oral Fluid Testing**

The U.S. Department of Transportation (DOT) has published a significant Final Rule affecting direct observation collections and oral fluid testing under 49 CFR Part 40. This Final Rule was published on May 11, 2026, and contains several important compliance changes that employers, collectors, TPAs, DERs, and service agents need to understand immediately.

The primary reason for these changes is straightforward: although oral fluid testing regulations were previously adopted, the Department of Health and Human Services (HHS) still has not certified any oral fluid laboratories for federal testing purposes. Because of this, the DOT has now delayed and modified several oral fluid testing requirements until the infrastructure is actually operational.

This is a very important development because there has been substantial confusion within the industry regarding how directly observed collections are supposed to be handled — particularly in situations involving transgender or nonbinary individuals, and in situations where a same-sex observer is not available.

**What Has Changed?**

Under the previous version of 49 CFR Part 40, DOT had created provisions requiring oral fluid collections in certain direct observation situations. However, because no HHS-certified oral fluid laboratories currently exist, the DOT has now essentially placed portions of those requirements on hold.

Effective June 10, 2026, directly observed collections under DOT rules will once again be handled **ONLY** through urine collections until further notice.

Specifically, the DOT has removed the prior requirement under 49 CFR section 40.67(g)(3) that an oral fluid collection be used as an alternative in certain situations involving transgender or nonbinary employees.

Additionally, DOT has suspended the requirement to automatically switch to oral fluid testing whenever a same-sex observer is unavailable.

**What This Means Operationally**

This means that beginning June 10, 2026:

- The only authorized DOT direct observation collections will be directly observed urine collections.
- Oral fluid collections will NOT currently replace direct observation urine collections.
- If a same-sex observer is unavailable, the collector must contact the Designated Employer Representative (DER).

The DER must either arrange for a same-sex observer, OR send the employee to another collection site acceptable to the employer where a directly observed urine collection can occur.

This is a major operational clarification and eliminates much of the uncertainty many collectors and employers have recently experienced.

**Future Oral Fluid Transition Still Planned**

It is extremely important to understand that the DOT has NOT abandoned oral fluid testing.

Instead, DOT is delaying portions of implementation until the infrastructure exists to support it properly.

According to the Final Rule, once HHS certifies a SECOND oral fluid laboratory, employers and service agents will then receive a grace period of up to 18 months to fully implement the newer oral fluid direct observation procedures.

The DOT specifically stated that this delay is intended to allow employers and service agents time to:

- establish relationships with oral fluid laboratories,
- gain access to approved oral fluid collection devices,
- locate and train qualified oral fluid collectors,
- and update operational procedures.

In other words, DOT appears to recognize that the industry is not yet realistically prepared for full oral fluid implementation.

### **New Requirements After Oral Fluid Laboratories Are Certified**

Once the second HHS-certified oral fluid laboratory is approved, additional procedures will eventually take effect. At that point, collectors will be required to determine whether the employer has a “standing order” regarding which specimen type should be collected during certain direct observation situations.

If no standing order exists, the collector will need to contact the DER for instructions regarding whether to proceed with a directly observed urine collection or an oral fluid collection. This means employers and TPAs should begin preparing NOW rather than waiting until the transition deadline arrives.

### **The Importance of Standing Orders**

One of the biggest practical takeaways from this Final Rule is the growing importance of standing orders.

Without standing orders in place, collectors may be forced to stop the collection process and attempt to contact DERs in real time for guidance. Anyone with real-world collection experience already knows how problematic this can become — especially after hours, on weekends, or during emergencies.

Certified Training Solutions strongly recommends that employers and TPAs begin developing internal standing-order procedures well in advance of future oral fluid implementation.

### **Short-Term Recommendations**

At a minimum, employers and TPAs should immediately ensure:

- current DER contact numbers are available,
- after-hours DER procedures are updated,
- collection sites understand the new requirements,
- and employers and collectors are aware that oral fluid collections are currently on hold.

### **Long-Term Recommendations**

Long-term preparation should include:

- developing written standing orders,
- evaluating future oral fluid collection capabilities,
- identifying qualified oral fluid collectors,

- reviewing relationships with laboratories,
- and updating internal policies and procedures.

### **Another Significant Change: “Gender” Replaced with “Sex”**

Another noteworthy revision within the Final Rule is the replacement of the term “gender” with “sex” throughout 49 CFR Part 40. The DOT states that “sex” will mean “male or female.”

The Department also indicated it may issue future guidance regarding how collectors and employers are expected to determine donor sex for purposes of directly observed collections. This portion of the rule will undoubtedly generate additional industry discussion and potential legal and operational questions moving forward.

### **Final Thoughts**

This Final Rule represents a substantial temporary reset regarding direct observation procedures and oral fluid implementation.

For now, DOT-regulated employers and collectors should understand the following clearly:

- Direct observation collections remain urine-based.
- Oral fluid testing requirements are effectively on hold.
- Same-sex observer requirements remain operational.
- DER communication procedures are now more important than ever.
- Standing orders will become critical in the future.

As always, employers, collectors, TPAs, and service agents should ensure they are following the most current version of 49 CFR Part 40 and should consult legal counsel when necessary regarding policy implementation and compliance obligations.

Certified Training Solutions LLC will continue monitoring developments closely and providing updated training and guidance as additional oral fluid testing infrastructure becomes operational.

You may contact Certified Training Solutions LLC for additional information regarding:

- [Urine specimen collector training](#),
- [Oral fluid specimen collector training](#),
- [Alcohol testing technician \(BAT and STT\) training](#),
- [Supervisor Reasonable Suspicion](#) (signs and symptoms of substance use) training,
- [Designated Employer Representative \(DER\) training](#),
- [Drug-Free Workplace Training](#), including [Ohio SUPR](#) and [Tennessee-specific](#) training,

We also offer post-accident determination training courses for [FRA](#), [FTA](#), and [FMCSA](#); as well as an online course on [how to start a drug and alcohol testing business](#).

Certified Training Solutions now offers [Lifeloc evidential breath testing devices and supplies](#), such as the Phoenix 6.0 and the EV30.

You may reach us by email at: [Admin@CertifiedTrainingSolutions.com](mailto:Admin@CertifiedTrainingSolutions.com)

Or by telephone at: 307-640-5859 or (888) 684-1658

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