

No Drugs, Inc is a Third-Party Administrator with six company owned collection sites in Northern California. We employ about 20 full time drug and alcohol collectors that combined collect more than 45,000 samples a year. We have been performing drug and alcohol testing since 1993. As the trainer for our company, I train and educate collectors in the federal drug and alcohol testing regulations and procedures. Our sites regularly experience donors leaving the site once they have been told the sample type. This occurs with both oral fluid and urine, indicating that donors can and do know the advantages and disadvantages of specimen types to manipulate the testing process. As I understand it oral fluid is to be the alternative specimen type and urine will remain the primary specimen used in DOT drug testing.

Proposed Rules

40.31 As proposed will require similar training as urine specimen collectors. **I Agree.** Requirements for an Oral Fluid collector under 40.35 should require: *Oral Fluid collectors to join ODAPC list serve, Complete manufactures training on each oral fluid testing device, All steps of the CCF, Problem Collections, Fatal Flaws, Collection site integrity, 5 Mock collections, 5-year certification with renewals.*

40.33 Training Requirements Urine, the proposal will clarify that damage to a specimen does not require collector retraining. **I Agree.**

40.35 Training requirements Oral Fluid. The specimen type in the collection is not that difficult to cross over. If the Monitor has **been performing DOT urine specimen collections for at least 1 year** and has attend the manufactures training on the device along with the other requirements currently in place for urine specimen collectors, they should be able to act as a monitor for initial proficiency requirements. Non-DOT oral fluid collections should have no bearing on DOT collection experience.

40.43(d)(1) With urine and oral you are limited to conducting a collection for only one employee at a time except when waiting during a shy bladder or dry mouth collection. **I Agree,** allowing simultaneous collections will cause mix ups and negatively affect the entire drug testing program.

40.49 Collection Device, devices should be at least **semi-transparent** to assist in detecting adulteration and have a minimum volume indicator built into the device or vials and be split-able for **split sample** collections.

40.61(5)(i) Whenever a directly observed collection is required, they propose adding “or oral fluid specimen collection”. **This needs to be dependent upon the situation.** The collector should have clear instructions on when the type of sample can be switched. Ideally the collector would get instruction from the DER, however the DER is rarely available when a problem collection arises.

40.65 What does the collector check for? **This needs to be dependent upon the situation.** The collector should have clear instructions on when the type of sample can be switched. Oral Fluid testing is the alternative sample and as such it should be used when an alternative sample is needed.

40.67 Directly Observed Remarks, **I Agree** there is no reason to remark on a test that must be completed directly observed. The remarks should be reserved for situations where the collector initiates the directly observed collection. This has been needed for a long time.

40.191 Refusal, **I Agree** making collection site refusal decisions is a “non-delegable” duty of the actual employer.

40.193 On a NSQ after the 3-hour waiting period you can, if qualified as an oral fluid collector, use oral fluid to collect a sample. **I Agree.** This is a place where the rule could instruct the collector to switch the

specimen without the DER's input. Another would be on a shy bladder and the site is closing before the 3-hour wait period will expire. Another would be when an observed collection is required but same sex collector is unavailable. In each of these situations the collector should try to reach the DER for guidance, when the DER is not reachable the collector would switch the sample if available to facilitate the collection of the sample.

40.207 Cancelled Drug Test, **I Agree** the MRO should be allowed to un-cancel a drug test.

40.210 What kind of tests? **In my opinion** the urine drug screen is the primary specimen used for DOT testing and should be the primary type collected. Oral fluid could be used as an alternative testing type when circumstances permit and to complete a required DOT test that would not have occurred otherwise.

I believe that 49 CFR Part 382 and each administrations procedures needs to be updated to clearly state which sample is the primary specimen collection type for each reason for testing and when an alternative testing type may be used.

The request for public comment opens a discussion about employers collecting Oral Fluid samples instead of using profession trained collectors. The current Urine Specimen Guidelines allows for employers to collect DOT urine samples, **this is a bad idea**. Large employers with paid medical staff onsite could absolutely collect samples from other employees however, in most situations, small, medium, and large employers do not have staffed onsite medical facilities. Having employees collect samples from employees increases the risk of collusion.

1. Management is short staffed and needs drivers therefore they may be willing to assist a donor in providing another's clean sample to fill a vacancy.
2. An employer may be willing to falsify a post-accident test when a fatality is involved to protect their own liability.
3. Professional drug screen collectors are currently offered bribes and favors from donors and employers to manipulate testing, as a professional collector they are less likely to accept and less likely to be approached then a co-worker, supervisor or union representative that would be chosen to collect samples for an employer.
4. Employers could use the DOT drug testing collection as a form of retribution and or discrimination.
5. The Drug and Alcohol Testing Industry Association, The National Drug and Alcohol Screening Association and The Substance Abuse Program Administrators Association are evidence of a professional, full-time, trained, and experienced industry of collectors available to employers on a national level.

Oral Fluid **Should** be used as an alternative testing method for all reasons of testing for an individual donor when an MRO has determined that donor has a shy bladder situation caused by an on-going medical condition and has notified the DER of the requirement that that donor use the alternative method of testing while employed for that employer. It would be beneficial for that notice to be passed on through the clearinghouse for the donors' future or other employers as well.

Oral fluid **Should** be used at the direction of the DER when the collector notifies the employer after the arrival of the donor at the collection site and directly observed collection is required but the same gender collector is unavailable. This decision should not involve the donor and no notice should be given to the donor ahead of time.

Oral fluid testing **Should** be used as an alternative testing method for Post-Accident and Reasonable-Suspicion testing where there is not ready access to a bathroom. This decision should be made by the DER after conferring with the collector to determine that a bathroom is not readily available, and no notice should be given to the donor ahead of time.

Oral fluid **Could** be the primary testing type for Post-Accident and Reasonable-Suspicion testing. These testing reasons are used to determine the donors current state of influence. Oral Fluid detection times better align with the intent of the reason for test. Urine samples **Could** be used as an alternative testing method for Post-Accident and Reasonable-Suspicion testing when a valid Oral Fluid sample cannot be collected i.e., supply shortages, trained collector not available, dry mouth. Using the combination of sample choices would ensure a higher success of the tests being collected under difficult situations. However, the determination of using an alternative sample should be made by the DER with the collectors input once the donor has arrived at the collection site.

The primary testing method for each reason for test **needs to be specified** by the rule with the DER having the ability to use an alternative method of testing based upon information provided to the DER by the MRO, Collector and or situational circumstances that must be noted in the remarks line of the CCF.

An alternative method of testing **should not** be used when the donor creates the situation necessitating the change. Such as NSQ urine, temp out of range or dry mouth. The donor creating the change of specimen type infers that the donor has intended to use the testing methods inadequacies to beat the test.

Oral fluid testing **does not save time**. Oral fluid collections take about twice as long as the average urine collection. The 10-minute required absorption period for the oral fluid testing is longer than the average person takes to provide a urine sample. Trained collectors following CFR part 40 can process 90-100 urine samples in an 8-hour day per collector per restroom (5-6 minutes on average). Oral Fluid collections run about 45-50 per day for that same collector (12 minutes on average). During a urine non-sufficient quantity collection, the oral fluid would save time on that donor but if the collector has additional specimens to collect while the NSQ donor was waiting the employer sees no extra charges. A dry mouth oral Fluid Collection can take 1-hour vs urine 3-hour wait time. The real change in costs will occur in drug screening clinics performing 50-250 samples a day this will require additional collectors to perform at the same rate.

Oral fluid testing **does not save money!** Oral fluid collection kits cost money to purchase currently about \$4.00 and oral fluid collection devices have an expiration date requiring an inventory system, loss due to expiration and theft as they must be purchased. Urine collection kits do not expire and are sent no charge to the collection sites. As a TPA each of the laboratories I currently use are charging more for oral fluid testing then urine analysis. In addition, oral fluid collections take longer and as such will demand an increase in fees charged per collection.

Detection times for Oral fluid vs Urine needs to be researched. Oral Fluid detects Marijuana for 24 hours or less vs Urine that detects use for 7-30 days. Using Oral Fluid testing for Pre-Employment, Random or Follow-Up testing will greatly reduce the removal of employees that consume marijuana from safety sensitive functions contradicting the intent of the rule which is public safety. I believe the agency needs to **research** how many days an individual is negatively affected after ingesting marijuana, reaction times, depth perception and decision making before deciding on which testing type is to be used in a particular situation.

The Urine Specimen Collection Procedures and **creating** The Oral Fluid Specimen Collection Procedures is essential in ensuring that DOT specimen collection is consistent and complies with the rule. The two specimen type collection procedures need to be created separately but referenced to each other when changing the specimen type ensuring more required DOT tests are completed in problem situations.