DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 120

Office of the Secretary

49 CFR Part 40

Federal Railroad Administration

49 CFR Parts 219, 240, and 242

Federal Motor Carrier Safety Administration

49 CFR Part 382

Federal Transit Administration

49 CFR Part 655

[Docket DOT–OST–2021–0093]

RIN 2105–AE94

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Oral Fluid Specimen Testing for Drugs

AGENCY: Office of the Secretary of Transportation (OST), Federal Aviation Administration (FAA), Federal Motor Carrier Safety Administration (FMCSA), Federal Railroad Administration (FRA), and Federal Transit Administration (FTA); U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Department of Transportation's regulated industry drug testing program to include oral fluid testing. This additional methodology for drug testing will give employers a choice that will help combat employee cheating on urine drug tests and provide a less intrusive means of achieving the safety goals of the program. In order for an employer to implement oral fluid testing under the Department's regulation, the U.S. Department of Health and Human Services will need to certify at least two laboratories for oral fluid testing, which has not yet been done. The final rule includes other provisions to update the Department's regulation and to harmonize, as needed, with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid established by the U.S. Department of Health and Human Services. In addition, this rule amends the FAA, FMCSA, FRA and FTA regulations to ensure consistency within the Department of Transportation and by removing or adjusting references to the word ''urine'' and/or add references to oral fluid, as well as removing or amending some definitions for conformity and to make other miscellaneous technical changes or corrections.

DATES: This final rule is effective on June 1, 2023.

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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This rulemaking is promulgated under the authority originally enacted in the Omnibus Transportation Employee Testing Act (OTETA) of 1991, codified at 49 U.S.C. 45102 and 45104 (aviation industry testing), 49 U.S.C. 20140 (rail),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),[1] motor carrier, and transit testing. Additional authority at 5 U.S.C. 7301 note and Executive Order 12564, establish 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

On November 21, 1988, the Department first published its drug testing program regulation, ''Procedures for Transportation Workplace Drug and Alcohol Testing Programs'', part 40 of Title 49 of the Code of Federal Regulations (part 40), as an interim final rule (53 FR 47002). The Department based the scientific requirements in that rule on the 1988 HHS Mandatory Guidelines for Federal Agency Employee Drug Testing Programs (53 FR 11970, Apr. 11, 1988), which set forth the scientific procedures for laboratories to analyze urine specimens for the presence of specified drugs at the HHS-required cutoff levels for the initial and confirmation tests for each specific drug in urine testing. These cutoff levels for urine were established at levels to show use of the specified prohibited drugs.

When the Department adopted its first drug testing final rule, we established a procedure for urine collections generally to take place with visual and aural privacy afforded to each employee, unless suspicious activity under 49 CFR 40.25(f)(14), (16) and (23) called for a direct observed collection (*i.e.,* body-to-bottle observation). (53 FR 47002, Nov. 21, 1988). In December 2000, the Department comprehensively rewrote part 40 into plain language. The direct observation provisions for urine were placed in 49 CFR 40.67, with the body-to-bottle observation requirement remaining unchanged. (65 FR 79462, Dec. 19, 2000).

Urine collections of private citizens are potentially invasive searches and seizures subject to scrutiny under the Fourth Amendment of the United States Constitution. Consequently, the Department has always approached the collection of urine from transportation safety-sensitive employees with a

[1] As will be discussed further below, post-accident toxicological testing conducted under FRA authority is not subject to the OTETA mandate and therefore does not follow Part 40 procedures. See 49 U.S.C. 20140(f), 40.1(c), 219.205(a), and 219.701(a)–(b).

concern for employee privacy, which must be balanced carefully against the Department's need to protect transportation safety. The Department protects individual rights by ensuring privacy for employees undergoing urine testing. Allowing directly observed urine collections only for ''cause'' (*e.g.,* suspicious activity at the collection site, previous violations, or irregularities determined by the laboratory testing of a specimen), but not for all urine collections under part 40, is another protection for employees undergoing testing.

In June 2008, the Department strengthened direct observation collection requirements to include more effective observation procedures and expanded the circumstances that would warrant a direct observation procedure to address cheating on drug tests. (73 FR 35961, Jun. 25, 2008). Although the 2008 final rule was challenged in court and initially stayed, the stay was lifted, and the final rule was reinstated. (74 FR 37949, Jul. 30, 2019). The United States Court of Appeals for the District of Columbia Circuit unanimously affirmed the Department's enhanced direct observation procedures to prevent the use of prosthetic devices used for cheating and to expand direct observation to tests of people who had already violated the rules (*e.g.,* return-to-duty and follow-up tests for persons who had tested positive or refused to test). See *BNSF Railway Company* v. *Department of Transportation,* 566 F.3d 200 (D.C. Cir. 2009).

Before the Department's move to expand the direct observation procedures, HHS was aware of the potential for cheating on urine tests and had begun its own rulemaking to explore alternative testing methods. In 2004, HHS solicited public comment on the following alternative testing methods, all of which would be directly observed: oral fluid, hair, and sweat testing. (69 FR 19673, Apr. 13, 2004). HHS stated: ''Addition of these specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the threat from industries devoted to subverting drug testing through adulteration, substitution, and dilution.'' (*Id.* at 19675). HHS noted that there were problems with all three of the proposed alternative matrices but asked for additional scientific information and sought information on appropriate levels for proficiency testing for these alternatives.

While the science supporting oral fluid testing did not meet the standards of HHS in 2004, science and research studies have now reached the point where HHS has been able to determine that oral fluid testing is an appropriate alternate testing method for identifying illicit drug use in the Federal workplace. The scientific viability of oral fluid testing has greatly advanced since 2004 to the point where HHS determined, in 2019, that the methodology is accurate and appropriate for Federal employee testing.

In its 2019 final rule, HHS stated that ''[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). Importantly, HHS stated that its ''OFMG provide the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine. . . .'' *Id.*

In evaluating the progress of science of oral fluid testing and its scientific viability, HHS also looked at its forensic defensibility in workplace testing. Specifically, in its preamble to the OFMG, 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, as directed by the SUPPORT for Patients and Communities Act, Public Law 115–271, § 8107(b). (See 84 FR at 57558; Oct. 25, 2019).

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.

OTETA specifically requires the Department to follow the HHS Mandatory Guidelines, which are the scientific and technical guidelines that establish comprehensive standards for all aspects of laboratory-controlled substances testing to ensure full reliability and accuracy in testing. Consequently, the Department published a notice of proposed rulemaking (NPRM) that proposed to revise part 40 to add the oral fluid testing procedures to its existing urine drug testing procedures for safety-sensitive transportation employees subject to drug testing under part 40 (hereinafter referred to as ''employees''). (87 FR 11156; Feb. 28, 2022). In response to public comments requesting an extension of the comment period, we provided additional time through April 29, 2022. (87 FR 16160; Mar. 22, 2022).

Like HHS in its OFMG, we proposed, and are now including in this final rule, the option for employers to use either urine or oral fluid testing (except for FRA post-accident toxicological testing).[2] By providing the option for an employer to choose collecting an oral fluid specimen or a urine specimen, DOT is broadening options for the testing of safety-sensitive employees in the transportation industries.

Importantly, in order for an employer to implement oral fluid testing there must be at least two HHS-certified laboratories for oral fluid testing. There must be one HHS-certified laboratory to conduct the screening and confirmation drug testing on the primary specimen. There must be a different HHS-certified laboratory to conduct the split specimen drug testing on the secondary specimen, if the employee requests split specimen testing for a non-negative result. As of the date of the publication of this final rule, HHS has not yet certified any laboratories to conduct oral fluid testing. The following is a link to HHS-certified laboratories: *https://www.samhsa.gov/workplace/drug-testing-resources/certified-lab-list* As a reminder, if the employee requests the testing of their split specimen and there is not a second HHS-certified laboratory to test it, then the positive/adulterated/substituted test result would be cancelled per § 40.187(e) because there

[2] Because FRA post-accident toxicological testing requirements in part 219, subpart C are not subject to the OTETA mandate and do not follow Part 40 procedures, this rule does not allow oral fluid testing for FRA post-accident toxicological testing, which still requires urine and blood specimens, as well as body fluid and tissue specimens for post-mortem tests. See §§ 40.1(c), 219.203(a)(1), 219.205(a), and 219.207(a).

would not be a way for the employee to have their split specimen tested and this would undermine the fairness and accuracy of the underlying test. Thus, for the reasons set forth above, oral fluid testing under part 40 cannot be fully implemented until HHS certifies at least two laboratories.

The Department has amended some provisions of part 40 to harmonize with pertinent sections of the urine and oral fluid HHS Mandatory Guidelines. We have clarified certain existing part 40 provisions that cover the handling of urine specimens, removed provisions that are no longer necessary (such as erroneous compliance dates), added clarifying language to other provisions (such as updated definitions and web links where necessary), and modified a few substantive provisions to address issues that have arisen in practice (such as whether a test cancelled by a medical review officer (MRO) can ever be uncancelled, and whether a Substance Abuse Professional (SAP) can conduct evaluations virtually and across State lines). We have also modified some proposed revisions and added some new provisions to part 40, in response to public comments. This final rule also makes changes to the regulations of some DOT agencies, to ensure harmonization within the Department with the part 40 regulation.

There were 417 commenters, most of whom provided multiple substantive and valuable points within each comment. The Department appreciates the time and effort the commenters expended in providing literally thousands of meaningful points. As we explained in our final rule in December of 2000, what matters the most is not a count of how many commenters favored or opposed a particular proposal. Instead, the Department's ''central concern is with the substance of the comments. In discussing comments on this rule and our response to them, we will focus on the substance of positions that commenters expressed, and on why we did or did not make changes in response to various comments.'' (65 FR 79462, Dec. 19, 2000). Similarly, in this preamble, with thousands of substantive comments, we have not ''counted the number of comments supporting a given position except in the most general way, believing that doing so would distract from the discussion of substantive issues.'' *Id.* However, we have attempted to meaningfully address all comments, including the questions and concerns expressed therein.

As the final part of this Background section, we are providing readers with a Redesignation Table to provide what sections in the existing part 40 are changing and what their new redesignations are.

Redesignation Table

Beginning with subpart D (see below), the Department is redesignating (*i.e.,* renumbering and reordering) numerous sections of part 40 to provide a more easily followed flow for users of the regulation provisions specific to oral fluid drug testing.

REDESIGNATIONS OF SECTIONS IN PART 40

Old section	New section
40.35	40.36.
40.41	40.42.
40.45	40.40.
40.47	40.41.
40.49	40.44.
40.51	40.45.
40.73	40.79.
40.85	40.82.
40.87	40.85.
40.89	40.86.
40.91	40.87.
40.93	40.88.
40.95	40.89.
40.96	40.90.
40.99	40.84.
Appendix B	Appendix D.
Appendix C	Appendix E.
Appendix D	Appendix F.
Appendix E	Appendix G.
Appendix F	Appendix H.
Appendix G	Appendix I.
Appendix H	Appendix J.

III. Principal Policy Considerations

Oral Fluid as an Alternate Drug Testing Method for Workplace Testing

When the HHS finalized its OFMG in 2019, it opened oral fluid testing to Federal agencies as an alternate methodology to choose and not as a replacement for urine drug testing. Similarly, the Department has determined that oral fluid testing will be an option for regulated employers and not a replacement for urine testing.

The commenters expressed many different opinions on whether oral fluid testing should be mandated in some or all circumstances; whether it should be purely the employer's choice; whether it should be the employee's choice; and whether it should be the collector's choice. There were suggestions to allow only oral fluid testing for reasonable suspicion and post-accident testing. Some commenters wanted to see oral fluid testing prohibited for pre-employment and random testing because they preferred the potentially longer windows of detection of urine versus oral fluid testing. Individuals who were concerned with paruresis wanted the employee to be able to choose oral fluid for every test and some of those commenters wanted urine testing banned. Some commenters were concerned that, if we mandated oral fluid testing in any circumstances, then every collector would need to be trained in oral fluid collections and every collection site would need to purchase oral fluid testing kits at an additional expense to such small businesses. The commenters who opposed oral fluid testing generally said they were concerned that oral fluid specimens would be used for DNA testing, or the commenters wanted drug testing of safety sensitive employees to stop.

As discussed earlier, HHS has determined oral fluid drug testing, like urine drug testing, is accurate and defensible. With both drug testing methodologies being scientifically accurate and forensically defensible, there is no reason to eliminate either methodology. Similarly, we see no reason to mandate either methodology. However, we will discuss below, in reference to problem collection scenarios covered by § 40.67 (direct observation collections) and § 40.193 (insufficient specimen ''shy bladder'' cases), that we strongly suggest employers consider moving to an oral fluid testing methodology. Employers should communicate to their consortium/third party administrator (C/TPA) and to their collection sites whether they want to utilize urine testing, oral fluid testing, or some combination of both. Employers should also provide their service agents with the specific instances that would trigger a different methodology (*e.g.,* an insufficient oral fluid collection should immediately become a urine collection or vice-versa).

If we were to mandate an alternate methodology be used, but the collection kit was not available at the collection site, the test would likely not occur at that site. If no test occurs, that would not be in the best interest of safety.

Those who commented that not every collection site will offer oral fluid testing have a valid point. It is possible a collection site will make a business decision not to offer oral fluid testing because of costs or training issues. Although it is the ultimate duty of the employer to ensure their collection sites are able and available to perform testing in accordance with part 40, it would be helpful for collections sites to notify their DOT-regulated clients that they will not offer oral fluid collections.

It is also important to remember that under § 40.209(b)(3), if an unqualified collector were to conduct a collection, it would not cancel the test. As we said in our 2000 preamble to § 40.209, ''a test is

not invalidated because a collector has not fulfilled a training requirement. For example, suppose someone collects a specimen correctly but has not completed required training or retraining. The test would not be cancelled because the training requirement was not met.'' 65 FR 79472. To reflect this point, we have updated § 40.209(b)(3) to add a reference to § 40.35 for oral fluid collector training, in addition to the existing reference to § 40.33 for urine collector training. Although it would not cancel the test result if the collector has not been trained in accordance with part 40, the collector, other service agents, and employer involved might be found in noncompliance as the result of the failure to meet training requirements.

Since the inception of DOT-regulated alcohol testing in 1994, we have allowed screening testing to be conducted using saliva testing devices, and we have required all confirmation testing to be conducted on an evidential breath testing (EBT) device. See 49 CFR 40.231. A facility that conducts alcohol saliva screening but that does not have an EBT must work expeditiously with the employer to ensure that the confirmation test takes place on an EBT.

Similarly, if a collection site only offers urine collections and an insufficient specimen is presented or if a direct observation collection is triggered, that collection site is expected to work expeditiously with the employer to ensure that the oral fluid collection occurs if the employer wants an oral fluid collection performed for an employee. Collection sites need to make business decisions about whether they will offer urine collections, oral fluid collections or both. Thus, not every collector needs to be trained on both urine and oral fluid collections unless they offer both.

The Owner-Operator Independent Drivers Association (OOIDA) asked that we ''continue educating industry stakeholders about the scientific and forensic supportability of oral fluid testing . . . (and) about how oral fluid testing would be implemented and administered.'' OOIDA reminded us that State and local law enforcement execute roadside testing, and OOIDA wanted us to differentiate and address concerns in the trucking industry about the differences between roadside oral fluid drug tests and DOT's regulated laboratory tests.

The Department will continue educating industry stakeholders, as we have always done, for urine testing and for part 40 compliance. Traditionally, State and local law enforcement have implemented their own testing entirely outside DOT-regulated drug testing and will continue to do so. Often, law enforcement entities have chosen point-of-collection testing (POCT) devices that provide initial screening test results, instead of laboratory-based screening testing. The POCT testing can cover the same drugs for which we test and more (or fewer) substances. The cutoff levels of the drugs being tested for in POCT devices differ widely among POCT devices. Thus, the differences are varying and may be significant. We will educate our regulated industries about DOT's regulated oral fluid testing alone. However, we welcome our industry partners to continue to educate their memberships about the differences they are encountering beyond DOT-regulated testing.

In buffered collections, the employee's oral fluid is collected on a device and then the device is subdivided into Bottles A and B, which contain a buffering solution. The buffering solution draws the oral fluid from the device, so that the liquid can be analyzed by the laboratory for the drugs for which we test. OOIDA raised concerns about whether drugs sufficiently enter the buffering solution. In its oversight of laboratory testing under the OFMG, HHS sets the standards for the devices and recovery of drug from the same. These are assessed two times: first, by the manufacturer and second, during laboratory validation of the collection device. While HHS does not certify or validate the collection devices or the buffer, the NLCP laboratory inspection process does ensure accuracy of the results obtained by the laboratories as evidenced by each laboratory's method of validation documentation which must specify the collection device(s) used. HHS will approve each specific HHS-certified oral fluid laboratory to use only one or more specific devices for which the laboratory can ensure the accuracy of the results. For further discussion of this subject, see the HHS final rule on oral fluid testing at 84 FR 57559, 57584 (Oct. 25, 2019).

Also, OOIDA stated they do not want hair testing in the DOT regulated program. It is important to note hair testing is outside the scope of this rulemaking, as we will discuss further in this preamble.

Finally, in response to the commenters who opposed the proposal to allow oral fluid testing due to concerns about DNA information or who oppose the principle of drug testing of safety-sensitive employees, we disagree on both points. As for DNA testing, part 40 already prohibits the DNA testing of any specimen collected for a DOT-regulated test. In fact, this rulemaking proposed to update the prohibitions on DNA testing contained in §§ 40.13(c) and (e) (now §§ 40.13(c) and (f)) to ensure that they extend to oral fluid testing.

As for the commenters who generally opposed drug testing, they offered no data to support why eliminating drug testing would be in the best interest of transportation safety. Instead, they merely said that transportation safety-sensitive employees should be permitted to use marijuana. However, it is important to remember that the beginning of DOT-regulated testing in 1988 was prompted by marijuana-related accidents that occurred in 1985 (two New York City subway accidents) and 1987 (one railroad accident in Chase, Maryland).

Whether Using Oral Fluid Testing as an Alternate Method Can Reduce Costs

In the proposal for this rulemaking, we stated that oral fluid testing is generally less expensive than urine testing. We said an oral fluid test can cost between $10 to $20 less than a urine test (*e.g.,* about $50 for a typical urine testing process, vs. about $35 for an oral fluid testing process, with the largest part of the difference being attributable to the collection process). We asked for public comment on the costs of oral fluid testing as compared to urine testing to affirm or adjust this cost assumption.

The majority of commenters on this point said the cost of an oral fluid test would be more expensive than a urine test, but that there were other, mostly unquantifiable benefits that oral fluid testing would bring. Specifically, those benefits included: eliminating the costs of shy bladder evaluations; alleviating the burden on individuals who cannot produce a sufficient urine specimen due to a psychological and/or physical medical condition; opening transportation safety-sensitive employment possibilities to many who have disabilities rendering them unable to produce an adequate urine specimen; and the thwarting of cheating. Many commenters said these benefits would outweigh the additional costs of conducting an oral fluid specimen collection.

Several commenters who conduct non-DOT collections said laboratories currently conducting oral fluid testing charge about $4.00 per buffered collection device, versus urine collection devices that are provided at no charge. A number of commenters in the laboratory and manufacturing businesses explained the need to charge because the buffering solutions included

in the oral fluid collection tubes are an added expense. Urine specimen collection devices are empty plastic containers, with no solutions involved, and are thus less expensive to provide and need no Food and Drug Administration (FDA) approval. In addition, the oral fluid collection kits expire, often as soon as twelve months after manufacturing because of the limited shelf life of the buffering solution and sometimes the collection pads themselves, which are included in the collection kits. Collection sites noted that they not only pay the $4.00 per oral fluid collection kit, but then they must discard each kit that expires before it is used. Of course, urine collection kits do not expire.

We proposed the use of a single oral fluid collection device that would be subdivided in the presence of the donor, as required by OTETA. Some commenters expressed appreciation that DOT would use a single device versus two separate devices. Those commenters noted that even if the single device were to be subdivided, it might cost more than $4.00, but was not likely to be the same expense as two separate kits at $4.00 each, which could have different expiration dates. Some commenters suggested the new devices would cost no more than $4.00 each, giving the new devices appeal in the non-DOT oral fluid market, also. They said the oral fluid device manufacturers and the laboratories would want to keep up with the DOT's requirements for DOT-regulated testing and they would not want to price themselves out of the market for non-DOT testing, since many in the non-DOT market would follow DOT's requirements, as they now do.

We had a tremendous number of comments from individuals who have an inability to provide a sufficient quantity of urine due to a psychological condition known as paruresis. Individuals in this group told stories of losing their careers due to an inability to provide a sufficient quantity of urine. Others said they chose not to pursue transportation safety-sensitive careers because of the requirements of urine testing. Some commenters told of aspirations of becoming commercial truck drivers or airline pilots, once the perceived barrier of urine testing is removed. With the option of oral fluid testing methodology, these individuals emphasized their marketability in the transportation workplace would increase.

While part 40 has a process for a medical evaluation to be conducted to determine if one's inability to provide urine is legitimate under § 40.193, the commenters noted the process was arduous for them and expensive. In addition, such individuals often do not have a diagnosis of a pre-existing psychological condition that would substantiate their inability to provide a sufficient quantity of urine. We received comments from the International Paruresis Association (IPA), who thoroughly explained the condition of paruresis. The IPA and the individual commenters applauded DOT for proposing to allow oral fluid testing. Many asked for the Department to end urine testing or to allow employees to choose the methodology that would be used for their testing. By allowing the employee to choose the methodology, they believed those with paruresis could receive a reasonable accommodation without needing to disclose their disability to their respective employer or prospective employer.

We asked for public comment about the number of shy bladder evaluations that are occurring and how much they cost. We did not receive any public comment to add clarity to those points.

Overall, the commenters did not provide specific data on the numbers we sought clarification on through the public notice and comment process, but they did provide many comments about the qualitative improvements to DOT drug testing that would be added through the adoption of oral fluid testing. Consequently, we adjusted our approach to the economic analysis for this rule. Instead of the quantitative economic analysis we began in the NPRM, we have conducted a qualitative analysis for this final rule.

As discussed above under *Oral Fluid as an Alternate Methodology* section, we have decided to make oral fluid testing available to employers as an alternate methodology to urine testing. We are not eliminating urine testing. We are including oral fluid testing as an option available to employers. Whether an oral fluid or urine test is administered is the employer's choice and not the choice of the employee, for the reasons explained in this preamble.

Who will perform the oral fluid collection?

Recognizing that employers often utilize the services of external qualified collectors for urine testing, we asked for comment as to whether this would continue for oral fluid testing, or if employers would train their own company personnel to become qualified collectors for oral fluid testing purposes. We also specifically asked if companies thought they would train internal personnel instead of contracting with external providers, whether this would this be due to costs, convenience or other reasons, and what would be the cost implications of the two approaches.

The majority of commenters disagreed with the concept of employers conducting their own collections. The commenters cited concerns such as invasion of privacy by supervisors and a lack of professionalism if an employer's own staff conducted oral fluid collections. Other commenters said allowing a co-worker to conduct oral fluid collections would lead to fraud because an employee with a substance use disorder might influence the objectivity of a colleague who is collecting. Some employers said that they would not want to incur the training costs or liability for their corporate employees to conduct collections. Some commenters wondered if internal collectors would thwart the testing process so that their fellow employees would not test positive. A few external collectors worried that in-house collections would lead to less demand for external collectors, thereby driving up costs for those who still want to use external collectors. One collection company polled its clients and found that 90 percent of their clients would continue to use external collectors.

Even those who favored internal collections agreed that there should be limitations on internal collectors within an employer's organization. They supported the proposal to make it clear that employees, relatives, and close friends of the employees cannot conduct collections, consistent with existing guidance in the Department's Urine Specimen Collection Guidelines, which can be found at: *https://www.transportation.gov/odapc/urine-specimen-collection-guidelines.*

Interestingly, many of those commenters appeared not to realize that employers have been allowed to collect urine specimens in-house for more than 30 years. For example, some of the large employers in the transportation industries have on-site clinics and regularly conduct many urine collections, including those requiring direct observation collections. Thus, we were asking more about whether oral fluid collections would occur externally or in-house, and were separately proposing the existing constraints regarding employees, relatives, and close friends of the employees as we have in urine testing.

We have amended § 40.31 to separately specify the requirements for collectors of urine and oral fluid specimens, respectively. We have adopted wording to require oral fluid collectors to be qualified. The final rule clarifies that employees, relatives, and

close friends of the employees cannot conduct collections, consistent with existing guidance in the Department's Urine Specimen Collection Guidelines.

Allowing Alternate Specimens Provides Flexibility to Employers

The Department proposed to offer employers flexibility in the type of specimen they collect. This final rule provides flexibility to employers in most situations, although we strongly encourage employers to consider having an alternate methodology ready and available to plan for contingencies (*e.g.,* an employee's inability to produce a sufficient specimen as a permanent, long-term, or short-term condition; direct observation urine collections that could be handled easily by switching to oral fluid testing; reasonable accommodation requests; etc.).

In addition, when an employer offers both oral fluid and urine testing, this can afford flexibility and other benefits. For example, when an employer determines that a DOT post-accident or a reasonable cause/suspicion test is needed, an oral fluid collection could be done at the scene of the accident or the workplace without the need to provide access to a bathroom. Oral fluid testing allows the collection to be done by any oral fluid collector qualified under part 40—either an external contractor or an employee the DOT-regulated employer dispatches to the scene of the accident or incident. In addition, offering both urine and oral fluid testing would permit an employer and its service agent to efficiently deal with situations when an employee cannot provide a sufficient specimen. Finally, having the flexibility of both options allows an employer and its service agent the ability to perform a directly observed collection as an oral fluid test, without concerns about the gender of the observer.

Understanding Windows of Detection

As discussed earlier, like urine testing, oral fluid testing is scientifically accurate and forensically defensible. As our scientific authority for drug testing under OTETA, HHS has determined that oral fluid testing, set at the cutoffs established by HHS, meets the requirements for accurate Federal drug testing.

Urine and oral fluid specimen testing each offer different benefits and limitations in assisting employers in detecting and deterring illegal drug use, and no single specimen type is perfect for every situation. In an effort to assist employers in understanding some benefits and limitations to each methodology, we reviewed and referenced various scientific sources in compiling a table of the windows of detection. This table provided information regarding the specific timeframe in which an oral fluid or a urine drug test could identify the presence of the drugs for which we test. We asked for public comment on the accuracy and completeness of the information in the windows of detection table we provided.

We received a few public comments on the actual information in the table. A couple of commenters believed that the windows of detection we had listed for oral fluid testing were too long. Several commenters suggested that we remove the table from the final rule, saying that it caused confusion. Another commenter cautioned that windows of detection should be interpreted carefully because the results depend on study design and context. They noted that the window of detection ''for a single dose may differ from those observed in individuals who are regular users. In addition, route of administration has significant impact on concentrations and detection of drugs in oral fluid over time.'' That commenter, a laboratory, also noted, ''in general, detection windows in oral fluid are shorter than those in urine, but it should not be inferred that the cutoffs are equivalent''. Another laboratory cautioned against including a windows of detection table in the final rule because ''the **Federal Register** is not updated each time a new scientific reference becomes available that may or may not support the duration and literature referenced was very limited and not very recently published.'' Quest Diagnostics discussed the complexity in understanding windows of detection due to ''numerous variables in play including: drug dose, drug purity, route of administration, time since dosing, individual metabolic rate variability and hydration state (for urine).'' As the study of oral fluid continues, Quest Diagnostics noted ''more data will be forthcoming as oral fluid testing is instituted across the United States that will provide more detailed information about oral fluid detection windows which will make these stated detection windows obsolete and likely misleading.''

Many commenters relied on the shorter windows of detection for oral fluid testing listed in the table from the preamble to the NPRM to reach the assumption that oral fluid test results are more akin to impairment tests. That is not a correct assumption. While oral fluid testing may provide a better indicator of an employee's recent use of the drug, it also detects frequent users. Furthermore, there is no definitive drug impairment test. Importantly, the DOT testing program is a deterrence-based program to prevent illegal drug use, not an impairment testing program.

We agree with the commenters who cautioned against including a windows of detection table in the final rule. Any information that is accurate today in a table of windows of detection may not be accurate shortly thereafter, as oral fluid testing is deployed by DOT-regulated employers and related research on the windows of detection continues. For the reasons stated above, we have removed the windows of detection table and we note that oral fluid windows of detection will likely be shorter than for urine. Employers, working in conjunction with their service agents, should determine whether urine or oral fluid collection is best for their program and in what contexts.

Substance Abuse Professional Issues

For more than twenty years, part 40 has been clear that all evaluations with a Substance Abuse Professional (SAP) must be face-to-face and in-person. During the COVID–19 public health emergency, we realized conducting face-to-face in-person evaluations may not be possible or advisable for certain individuals. As a result, the Department issued a notice of enforcement discretion on April 4, 2020, to allow SAPs to conduct, for a specified period of time, what we called ''face-to-face remote evaluations''. We extended that notice several times from 2020–2022, and on December 20, 2022, we extended the notice to remain in effect until the effective date of this final rule. (*https://www.transportation.gov/odapc/Statement_of_Enforcement_Discretion_SAPs*)

To make a remote evaluation as effective as possible, within the notice of enforcement discretion we provided, we said the technology the SAP uses should permit a real-time two-way audio and visual communication and interaction between the SAP and the employee. We said the SAP should determine if the quality of the technology (*e.g.,* speed of the internet connection, clarity of the display, application being used, etc.) is sufficient for the SAP to gather all the visual (*e.g.,* non-verbal physical cues) and audible information you would normally observe in an in-person face-to-face interaction. In other words, the SAP must be able to objectively evaluate verbal, non-verbal and physical characteristics to a sufficient extent through the chosen technology. We added that SAPs should document the format of the assessment in the final

SAP report. We also stated we would not consider a remote evaluation to be an act of serious noncompliance meriting resort to the Public Interest Exclusion (PIE) process.

We proposed amendments to several sections of subpart O of part 40 to make the notice of enforcement discretion permanent. We proposed and are adopting modifications to § 40.291(a)(1) to allow the SAP to conduct the evaluations either in-person or remotely, with criteria based on those from the COVID–19 notice as conditions for remote evaluations. First, the revisions require the technology used to permit real-time two-way audio and visual interaction between the SAP and the employee (*i.e.,* a conversation without video would not meet this criterion). Second, the quality of the technology (*e.g.,* speed of the internet connection, clarity of the display) must be sufficient to allow the SAP to gather all the visual and audible information the SAP would normally observe in a face-to-face in-person interaction. In addition, the technology must incorporate sufficiently robust security to protect the confidentiality of the conversation. Third, a SAP can only use the technology in question if the SAP's State-issued license authorizes the SAP to do so (*e.g.,* a State license may permit a practitioner to work only with clients in the State of licensure).

On a second but related topic, we asked for public comment about whether a SAP's respective ''qualifying credential'' (*i.e.,* State license or other credential under § 40.281) would allow them to evaluate individuals who live in a different State from where the SAP is licensed. We asked if this was already allowed, especially since virtual video evaluations are often done outside of the DOT-regulated context. We also asked for public comment about what steps a SAP, who is remotely evaluating an individual outside of the SAP's locality, could take to ensure a working knowledge of quality programs and qualified counselors available to the employee when recommending a course of treatment and/or education.

The comments we received on SAP remote evaluations and crossing ''State lines'' were thought-provoking and abundant. There were many supporting, opposing, qualifying and suggesting improvements to the proposals. We will discuss them in-depth.

Regarding remote SAP evaluations, the majority of commenters enthusiastically supported the proposal. Many commenters who identified themselves as qualified SAPs who have practiced for years said remote evaluations offered unforeseen benefits. Several said they had learned to use technology to better study the employee's mannerisms, facial expressions, and nonverbal cues as effectively as they could for their in-person consultations. One SAP admitted to not being receptive to remote evaluations before the COVID–19 public health emergency, but acknowledged that ''everything has changed, including people's receptivity to virtual interactions . . . even extensive treatment is often virtual.'' That same SAP acknowledged reading comments from other SAPs who do not support virtual evaluations, but strongly disagreed with those fellow commenters because of the advances in telehealth and the skills SAPs are developing for evaluating clients virtually as effectively as in-person. Specifically, this SAP and many others recognized that they had built skill in assessing eye movement, involuntary body twitches, and other aspects of nonverbal indicators that are key to accurate and complete evaluations. One SAP pointed out there would be no difference between a virtual and an in-person evaluation if the technology is ''sufficient to allow the SAP to gather all visual and audible information that would be apparent in a face-to-face interaction.'' One commenter wanted DOT to gather more information on the effectiveness of remote evaluations, believing the SAP will miss too many details if the evaluation is not conducted in-person. However, with the advances in telehealth and the robust comments by the many SAPs who took the time to comment, we believe that we have reliable information from practicing SAPs who are confident that face-to-face remote evaluations are as effective as in-person face-to-face evaluations.

In addition, several practicing SAPs said they learn more about the employee and circumstances in virtual assessments in the home of the employee, because the SAP can ''speak to family members and obtain other collateral information that is not always readily available in the office setting.'' Some said that the employees seem to be more relaxed and communicative when they can participate from the comfort of their home. Several SAPs believed it is less stressful for employees in remote areas to be able to see a SAP without having to travel to the SAP's office. Many SAPs expressed gratitude about the reduction in cost to the employees, who often needed to travel significant distances to see the SAP in-person. Several SAPs said that this innovation that arose temporarily during 2020–2022 should be finalized because it created access to evaluation for many employees who were at a loss for where to go to seek help, especially for those who live in remote rural areas.

Some SAPs mentioned multiple ''safety'' factors as a reason to allow remote evaluations. One said, ''If someone has been removed from safety-sensitive duties . . . meeting remotely keeps them off the road further lessening the potential for harm to the public.'' Another SAP pointed out that, after an employee was ''drinking and driving, does it really make sense to say 'hey I know you were under the influence while driving, but can you get in your car and come see me?' '' Some of the SAPs said that there are occasional personal safety issues with employees who are angry because of their non-negative results or refusals. One commenter who has been involved with SAP evaluations and training for more than 30 years said, ''virtual assessments have increased personal safety for SAPs dealing with belligerent employees.'' Multiple SAP commenters noted the personal safety issues are significantly lessened when the contact between the employee and the SAP can be conducted virtually.

A number of SAPs noted a reduction in cost for themselves. Although there was an initial cost of setting up the details for conducting remote evaluations generally (*e.g.,* subscribing to HIPAA-compliant software platforms, obtaining the right equipment for audio and visual interactions), the costs of not needing to conduct evaluations in a formal office setting was a significant cost savings. One SAP asked if we could allow post office boxes for the SAP's address because many SAPs no longer maintain a professional office space outside their home.

Regarding the use of a post office box instead of a physical address, we will not consider that change at this time. While many SAPs conduct a significant number of evaluations virtually, we are still maintaining the option for in-person evaluations. In some situations, in-person evaluations may be the best choice and we want to ensure that SAPs consider that. Also, having a physical location where DOT can inspect, audit, or investigate a SAP and their records is important, and we require this of service agents in part 40. If the SAP chooses to run their operations from their home, they must furnish the address from that place of business on their letterhead. If using one's home address is not acceptable to an individual SAP, they must continue to provide a physical commercial location address for part 40 purposes.

In not allowing SAPs to use post office boxes, we are being consistent with our Question and Answer from September of 2001, which reads, in pertinent part, as follows: ''May the MRO's address entered on the CCF be a post-office box number only? . . . No. The address must contain at least a number and street address. . . . The post-office box can be included, but not in lieu of the number and street address.'' *https://www.transportation.gov/odapc/part40QA/40-311* We are also adding this reminder to § 40.40(c)(2), to note MRO addresses must not be simply a post office box.

The SAP commenters who favored allowing remote evaluations agreed the technology must provide real-time audio and visual interaction between the SAP and the employee. We agree that an audio call, alone, will not satisfy the requirements of part 40 or the expectations of these professionals.

Technology security concerns were on the mind of some commenters, also. Many SAPs suggested that we require a HIPAA-compliant software or platform for these audio-visual interactions. Commenters also recommended using high-level platforms to ensure confidentiality, and not merely commercial platforms that are available for video calls.

It is important to note that HIPAA does not apply to the DOT testing, which involves searches and seizures under the Fourth Amendment of the United States Constitution. However, we recognize SAPs may be required by the State that licenses the SAP to follow HIPAA as part of their clinical evaluations. While we will not require specific software and we will not reference HIPAA compliance as a criteria, we have specified in § 40.291(a)(1)(ii) of the final rule the performance standard that the technology must provide ''security to protect the confidentiality of the communication.'' We also added language to § 40.291 to explain that the technology needs to be at the expected level of confidentiality and security as is required for substance abuse evaluations. It is important to note that this is a performance standard. We did not prescribe exact measures, which may currently be appropriate, because those standards will change, and we want to ensure the most effective standards continue to be applied.

Often, the individual State's licensing and/or private credentialing authority set ethical and confidentiality criteria for licensed professionals who are performing their duties via virtual platforms. Some of the SAP commenters have noted that there are additional ethical guidelines and standards that they follow in order to provide remote evaluation services. Sometimes these additional requirements are set by the qualifying credential authorities, other times these are guidelines the SAPs follow because they are recommended by the professional organizations with which they affiliate. We urge SAPs to continue to follow their respective codes of ethics and confidentiality. The ethics of using video technology is an evolving field, and we expect SAPs to keep up with their ethical requirements as this aspect of their profession continues to improve and evolve.

One SAP suggested that we make telehealth education part of SAP training. We will not require that because not all SAPs will offer remote evaluations. Also, SAP training should continue to focus upon part 40 requirements and not about generally how to practice more effectively.

SAPs who opposed the proposal varied in wanting to see remote evaluations prohibited versus allowed in special circumstances. Some commenters only wanted to see remote evaluations when there is a pandemic, while others would support remote evaluations in a national crisis or in situations where the employee was located hundreds of miles from the nearest SAP. Other SAPs disliked remote evaluations because ''paperwork and payment'' are better collected in person. Some SAP commenters were concerned about employees ''shopping for less expensive SAPs'' outside their own high-cost zip code. Conversely, one commenter who favored the remote evaluation option said that this reduction in cost for the out-of-work employee was exactly why the Department should allow an employee to seek a SAP outside their home area. Also, SAPs who opposed remote evaluations said it would be difficult to find qualified and appropriate treatment resources outside the SAP's local area, while other SAPs said this would not be a problem because of the ability to search for treatment resources on the internet. Those SAPs who suggested using the internet also said the SAP would then call the treatment facility to establish communication and determine if the treatment resource was appropriate for the employee's needs.

One employer's association provided a reply to other commenters who wanted the SAP to justify why a remote evaluation is being held instead of an in-person evaluation. The employer's association recommended allowing the SAP to choose remote or in-person without the need to justify one over the other ''because 'DOT cannot predict and codify the wide range of circumstances that could reasonably justify remote SAP evaluation, nor could employers effectively determine whether a particular circumstance is appropriate if the DOT applies an ambiguous standard, like 'extraordinary circumstances'.'' Reply comments such as this are very helpful to us as regulators, and we thank this commenter and others who took the time to read and respond to the comments of others.

Commenters who favored and those who opposed the proposal were almost unanimous in wanting in-person evaluations to continue as an option. That option should be decided by the SAP, many of the commenters said.

We had proposed and agree with allowing SAPs the option of choosing to conduct face-to-face evaluations remotely in lieu of in-person meetings, and never proposed for the in-person evaluations to be eliminated. We have decided to adopt the proposed provision with minor modifications. We agree with the commenters and will permit both evaluations in-person or via virtual technology meeting the requirements of part 40. The choice of which option to use will be the decision of the SAP, without any need to justify the use of one or the other.

With SAPs being permitted to conduct remote evaluations, we anticipated the issue of SAPs providing evaluations across State lines would be something we needed to address. On this subject, we received a few favorable comments, but most commenters disagreed with the Department taking action in this area.

Some commenters had no objections to a SAP providing part 40 services outside the State in which the SAP is licensed. One of these commenters noted the MROs are licensed in one State but are permitted to provide MRO services under part 40 in all 50 States, the U.S. Territories, Canada and Mexico. Other commenters said they had no objections to allowing SAPs to practice across State lines, as long as part 40 clarified that the SAP could specifically do so as a qualified SAP under part 40. Some told us their certifications as ''national'' or ''international'' drug and alcohol counselors, which they received through larger organizations that administer the SAP examinations, already allow them to practice throughout the United States. Also, several commenters, who are practicing SAPs, told us their licensing States already allowed them to practice across State lines. Consequently, within the parameters of their own State's licensure, they have been conducting

SAP evaluations of DOT-regulated employees for approximately two years. Another SAP told us the licensure from their State ''does not permit me to conduct assessments across state lines, however, I have an additional certification for telemental health (BC–TMH). Together, my credentials permit me to practice both counseling and my SAP assessments remotely.'' One commenter asserted that ''SAP is a federal qualification and I believe we should be permitted by federal designation to see a DOT-governed employee from anywhere.'' Another commenter stated, ''As a federal program, drug testing requirements for transportation workers already span jurisdictions; it follows that an SAP should likewise be able to conduct evaluations across jurisdictions . . .'' An MRO association characterized the SAP as ''not a treatment provider, just as the MRO is not a treatment provider for donors. . . . Thus, performing a substance abuse assessment and recommending treatment and a plan, the SAP would unlikely be in violation of any state practice act.''

The commenters who opposed allowing practice across State lines said there was value in State licensing and overseeing counselors who provide services to individuals within the State. Others who disfavored the proposal raised the argument addressed above about a distant SAP not knowing the treatment facilities that offer the appropriate treatment for an individual employee.

The commenters have made it clear that there is much confusion about whether a SAP can practice across State lines. It is also clear that this is an evolving topic, having nothing to do with part 40. The States, individually, are addressing needs that have arisen during the past two years and the resulting evolution of telehealth options. The SAP certification organizations (*see* § 40.283) should make their own determinations about whether those individuals who hold their respective qualifying credential can practice throughout the United States. SAPs should continue to keep informed about the permissions and jurisdictional limitations of their qualifying credentials. If a State licensing authority or DOT-recognized credentialing organization decides that it is appropriate for one or more of their authorized practitioner categories that qualifies a person to be a SAP to practice across State lines, DOT will defer to that granting authority.

With that said, in the short-term, the current inconsistency as to where a SAP can practice remotely is creating problems for some DOT-regulated employees who are seeking SAP services. With an in-person SAP evaluation, the employee sits in the SAP's own office, and there is no question that the SAP is licensed to practice in their own office. Unique to a remote SAP evaluation, an employee may not be located in the same geographic jurisdiction where the SAP is authorized to practice, thereby making the SAP's underlying qualifying credential not valid for that particular evaluation. Under the DOT COVID–19 notice allowing remote evaluations, we stated: ''You may only utilize the technology if your State-issued license authorizes you to do so and within the parameters of that authority.'' Consequently, any SAP who evaluates an employee outside the parameters of the SAP's State-issued license or other credential is acting without authority and violating part 40. To address this, we have added a new § 40.281(f) to create a limitation on an otherwise qualified SAP under this part who conducts evaluations outside the geographic limitations applicable to their credential.

Some otherwise qualified SAPs have acted outside their authority and created problems for employees who received evaluations under the DOT COVID–19 notice. When we have learned that a qualified SAP evaluated an employee outside the SAP's authorized geographic jurisdiction, we have asked the employee to seek the services of a different SAP who is qualified and can conduct the evaluation as permitted by their credential. There has been no other option under part 40 until this final rule.

However, we acknowledge the costs of having an out-of-work employee seek and pay for a second SAP evaluation is an unfair and unintended consequence of allowing remote evaluations. Therefore, we are adding a new § 40.297(c) to notify the otherwise qualified SAP (*see* § 40.281(a) through (d)) that they must not perform evaluations outside the geographic jurisdiction of their credential(s). If the SAP who made the evaluation exceeds their geographic jurisdiction, the employee will not be required to seek the evaluation of a second SAP. The evaluation and assessment of the SAP is still valid for the employee, even if the SAP has failed to follow § 40.297(c) by exceeding their geographic jurisdiction. The employer must carry out the follow-up testing plan of the SAP, even though the SAP was acting outside their geographic jurisdiction. We have added a new § 40.303(d) to let employers know they can utilize such evaluations and follow-up plans, if they choose to return the employee to work. We believe that these new sections, along with new § 40.281(f), address the unintended consequences of costs and stress to employees.

The new §§ 40.281(f) and 40.297(c) also require that a qualified SAP must not evaluate any employee outside the jurisdiction in which the SAP can practice. In other words, the intention is to prohibit the SAP from crossing geographic lines without authority and to relieve the employee from the need to pay the cost of seeking a new SAP evaluation. If the SAP engages in evaluations outside the limits of their credential, then this activity could constitute serious noncompliance and the SAP could be subject to a PIE.

Finally, as a compliance reminder: Every SAP is expected to be aware of the specific requirements of their State or credentialing authority and may not be authorized to practice across State lines. Some of the SAPs who commented that they have national and international credentials through certain organizations may not be correct and should check with those organizations who, previously, have told us their credentials are not nationwide. It will benefit both the SAP and every DOT-regulated employee they evaluate to know what their geographic jurisdiction is.

Using Identification Numbers Other Than a Social Security Number or Employee Identification Number

Since the inception of the DOT's drug testing program, the Federal Drug Testing Custody and Control Form (CCF) has included a space for the Social Security Number or Employee Identification Number (SSN or Employee ID No.). We proposed to add a new definition for ''SSN or Employee ID No.'', and some minor changes to rule language that mentioned ''SSN'' in §§ 40.14, 40.45, 40.97, 40.163, and 40.311. The rationale for the change includes privacy concerns and identity theft considerations that arose over the years since the 1988 inception of part 40. Also prompting these amendments was a final rule in 2016, in which the Federal Motor Carrier Safety Administration (FMCSA) changed the information Commercial Driver's License (CDL) holders and Commercial Learner's Permit (CLP) holders must provide on the CCF and Alcohol Testing Form (ATF). Specifically, in 2016, FMCSA amended 49 CFR 382.123(a) and (b) to require FMCSA-regulated drivers undergoing DOT-regulated testing and their employers to use the CDL number and State of issuance,

instead of the SSN or other employee ID number, on the CCF and ATF for all drug and alcohol tests conducted under 49 CFR part 382 (part 382). See FMCSA's Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse) final rule (81 FR 87686; Dec. 5, 2016). The Clearinghouse final rule did not affect or otherwise allow use of the CDL number for a CDL driver operating under another DOT agency's regulation and subject to a test not under part 382 (*e.g.,* employers of CDL drivers under the Pipeline and Hazardous Materials Safety Administration (PHMSA) or FTA).

To address the concerns about using SSNs and to conform to the existing requirement for CDL numbers to be used for employees regulated by FMCSA, we proposed changing the provisions of part 40 requiring the use of the employee's SSN or an employee ID number. We proposed a definition of the term ''SSN or Employee ID No.'' in § 40.3, as well as amendments to sections pertaining to the CCF and/or the Alcohol Testing Form (ATF), and in SAP reports. We proposed to require CDL numbers for FMCSA-regulated employees, for consistency with part 382. We proposed to add that identification numbers issued by States or the Federal government would also be allowed for employees not regulated by the FMCSA.

We received several public comments on this issue. The majority of those commenters favored allowing alternate identification numbers, citing concerns about the employee's security, privacy, and wanting to protect employees from potential identity theft. Some commenters suggested we only allow the last four digits of the SSN to be used. Those opposed to the proposed changes thought the only modification to part 40 should be to allow FMCSA-regulated employees to use their CDL numbers. Those commenters thought allowing others to use their driver's license number would result in violations unrelated to FMCSA-required testing erroneously being reported to the FMCSA's Clearinghouse. Finally, some of the commenters asked what to do when presented with a form of identification that has ''expired''.

Switching to using the last four digits of the SSN would not resolve the concerns about privacy and identity fraud adequately because some part of the SSN would still be used. In addition, for laboratories that receive thousands, and in some cases tens of thousands, of CCFs each day, it is not uncommon for those labs to receive multiple CCFs with the same last four digits.

We acknowledge the concerns about violations being incorrectly entered into the FMCSA Clearinghouse if an employee who is not regulated by the FMCSA provides their driver's license number. Some States use the same number format for a CDL as for any private driver's license number issued by the State. In some States, the CDL holder does not have a separate private license for driving their own car—only the CDL is issued. However, the essence of the concern is not so much about the number being used as it is about the entry of incorrect data into the FMCSA's Clearinghouse by program participants.

We have weighed the various considerations raised by the commenters and have adopted the proposed language in each section because the confusion the commenters are concerned about can be addressed with the program participants who may incorrectly enter data into the FMCSA's Clearinghouse. We will not remove the option for an employee to provide their SSN because that specific term currently appears on the CCF. In the future, if that term is ever removed from the CCF, which belongs to HHS, we would consider amending these part 40 provisions to exclude the SSN.

The new definition ''SSN or Employee No.'' will allow a collector, MRO, SAP, Breath Alcohol Technician (BAT), Screening Test Technician (STT) or other service agent or employer to utilize only the CDL number and State of issuance for FMCSA-regulated drivers tested under part 382, and to allow the CDL number to be used as an option on tests conducted under the authority of the other DOT agencies. The definition also allows any other State- or federally issued identification number to fulfill the part 40 requirement for a unique identification number.

Since States often do not differentiate between CDL numbers and private driver's license numbers, we will continue to remind employers and collectors to be very specific about the exact DOT agency regulation under which the employee will be tested. An employer directly, or through its service agent, must check the block for the ''Specific DOT Agency'' on Step 1.D. of the CCF. The name of each agency is provided in Step 1.D. (*i.e.,* FMCSA, FAA, FRA, FTA, PHMSA, USCG). When the employer sends the employee to the collection site, the employer must be clear with the collector as to what specific DOT agency regulates the test, as required by § 40.14(g). The collector, in turn, is expected to ensure that the correct DOT agency is checked, unless the employer has already checked the box. If unsure, without delaying conducting the actual test, the collector should contact the employer to ask what specific DOT agency regulates the test. Checking the correct block in Step 1.D.'s ''Specific DOT Agency'' block is as important as checking the correct box for the ''Reason for Test'' in Step 1.E. Employers and collectors are, and should be, aware that not knowing the correct reason for the test may subject an employee wrongfully to a direct observation collection or may fail to ensure that an employee is subject to a direct observation when they need to be observed. Similarly, checking the wrong box in Step 1.D. will have potentially incorrect consequences if the employee has a non-negative result. We will continue to educate and remind employers and collectors to appreciate the need for identifying the correct DOT agency on the testing form.

If an employee is wrongfully identified as an FMCSA-regulated employee during the collection process, the MRO is likely to discover this in the verification interview for a non-negative result. For example, during the verification interview some MROs simply ask the employee what they do for the employer. In any case, if the MRO finds the FMCSA box was incorrectly checked, the MRO must not report the verified non-negative result to the FMCSA's Clearinghouse. The only employees whose results are ever reported to the FMCSA's Clearinghouse are those employees who have taken an FMCSA-regulated test.

Similarly, if the employer is determining whether or not a collection site refusal has taken place and finds that the FMCSA box was incorrectly checked, the employer must not report the refusal to the FMCSA's Clearinghouse. Since only the employer or the MRO can enter a violation into the FMCSA's Clearinghouse, these are the only program participants who can correct their own entries, including when they have incorrectly identified an employee as an FMCSA-regulated individual when they are not.

Finally, we recognize the issue of employees using expired forms of identification at the collection site has been an ongoing problem. As we have advised for several years, we want collectors to know it is acceptable to accept an expired photo ID issued by a Federal, State, or local government agency, if the ID has not been expired for more than 1 year. This information is contained in the current Office of Drug and Alcohol (ODAPC) Urine Collection Guidelines and will be added to the ODAPC Oral Fluid Specimen Collection Guidelines.

Medical Review Officer Reversal of Test Cancellations

In part 40, there are many instances where an MRO would cancel a drug test result. These are set forth in § 40.133 (when verifying an invalid result without a donor interview), § 40.145 (if there is a legitimate explanation for an adulterated or substituted result), § 40.159 (for various specific explanations for an invalid result), § 40.161 (after laboratory rejection of a fatal flaw or an uncorrected flaw); § 40.187 (if a split fails to reconfirm or bottle B is unavailable for testing); § 40.191 (if there is a refusal to go for a medical examination where there is no contingent offer of employment on a pre-employment test); § 40.193 (where there is an acceptable medical explanation for an insufficient specimen); § 40.195 (if a medical examination reveals clinical evidence of drug use), and § 40.199 (after the laboratory reports a fatal flaw). We did not propose any of these types of cancellations as grounds for reversing a cancelled test.

Instead, the proposal addressed situations where a test is cancelled due to paperwork errors, which would be correctable flaws, but which were not corrected before the MRO sent the cancellation to the employer. Those are specifically found in §§ 40.203 and 40.205. In the preamble to the NPRM and in the proposed regulatory language of § 40.207(d), we gave the example of the MRO reversing the cancellation of a test where the missing or delayed paperwork is subsequently found and provided to the MRO. We also said that we did not intend for MROs to reverse the cancellation of a test that was rejected for testing by a laboratory.

There were several comments on this proposal. The commenters supportive of the proposal understood this as an administrative fix to allow an MRO to uncancel a test result involving a correctible error the MRO decided was not timely corrected. Many of those who opposed the proposal were concerned about DOT allowing MROs to reverse cancellations that were related to the fairness and accuracy of the test. Those were not the intended cancelled tests subject to the proposed change. Even so, we understand the questions in the preamble for public comment could have led commenters to conclude otherwise. The comments received have helped to shape a better final rule for this provision, which we have adopted with modifications.

Some MROs and other service agents said they already thought MROs could reverse a cancelled test. They did not see a need for a change because reversing cancelled tests was already part of their MRO practice. It is for exactly this reason we needed to consider modifying the regulation because these MROs had no authority to reverse cancellations. Throughout the history of part 40, there has not been a regulatory provision that allows an MRO to ''uncancel'' a test that the MRO has cancelled. We proposed a new paragraph § 40.207(d) to allow an MRO to reverse the cancellation of a test in very specific and limited circumstances.

The American Trucking Association supported the change as a useful ''administrative fix'' that would save money for random tests. They gave a solid example of the impact of the problem when they said: ''the employee is sent for a random test; the paperwork for the collection site is lost, so the MRO cancels the test; the paperwork is recovered, and the test is counted toward the employer's random testing requirement.'' As such, the proposal is a ''rational administrative fix that will not have a detrimental impact on safety . . . to address situations in which administrative errors require a driver to retake a drug test unnecessarily.''

The Association of American Railroads and American Short Line and Regional Railroad Association supported the proposal. They said this ''proposed amendment would be helpful in situations where an employer requires a negative result (*e.g.,* a pre-employment, return-to-duty or follow-up test), and would avoid the burdens and inconvenience of requiring an employee to travel for, or otherwise accommodate a test, more than once.''

Several consortia/third party administrators (C/TPAs) agreed with the proposal. One C/TPA referred to ''circumstances that missing paperwork is located after the MRO has cancelled the result. This would allow the MRO to then report the result.'' To illustrate the benefits of the proposal, the commenter described a frequently occurring scenario they encounter: ''a delay in receiving information that was inadvertently omitted from the custody and control form. In these situations, if the test has already been cancelled, a driver must be sent back to the collection facility to provide a new sample constituting a significant additional cost for motor carriers and drivers. Allowing un-cancelling of tests is a commonsense solution to an unintended consequence.''

Some who supported the proposal wanted the Department to ensure it would be used in narrow circumstances. They supported reversals of cancellations only in tests cancelled for administrative errors that are correctible flaws. We added language to the final rule, in the form of a parenthetical, to note correctible flaws arising under §§ 40.203 and 40.205 would be examples of what is reversible.

Several commenters, including the National Drug and Alcohol Screening Association (NDASA), C/TPAs, collector trainers, and a transit agency noted an existing issue within part 40: an MRO cannot cancel a test without having Copy 1 and Copy 2 of the CCF in the MRO's possession, per §§ 40.129(b), 40.161(a) and (c). These commenters said, if the reason the MRO is cancelling the test is because the CCF paperwork is missing, then part 40 should allow the MRO to cancel the test without holding either or both Copies 1 and 2 of the CCF. One commenter recommended we allow the MRO to cancel the test by noting on the bottom of Copy 1 that Copy 2 is missing. Another commenter suggested allowing the ''MRO to issue a report that the test is cancelled if the MRO has not received a legible [CCF].''

In response to the concerns from these commenters about an MRO's inability to cancel a test without the proper paperwork, we have made changes to part 40. In § 40.129(b), as a logical outgrowth of the comments, we have struck the words ''test cancelled'' so that cancelled tests do not require both Copies 1 and 2, as the other verified non-negative results listed would require. We have modified §§ 40.161(a) and (c) to allow an MRO to use either copy or to issue a report, if Copy 1, Copy 2, or both are missing. Also, we have made a technical amendment to insert quotation marks around ''rejected for testing'' and the word ''laboratory'' in § 40.161(c). As in §§ 40.127(c)(1) and 40.129(b)(1), we remind the MRO of the obligation to try to obtain Copy 2 or any other CCF copy containing the employee's signature before cancelling a test. If a copy of the CCF with the employee's signature cannot be obtained, then the MRO can use the report format set forth in § 40.163(c)(1) through (9).

The commenters who opposed the proposal to allow an MRO to uncancel a test included organized labor (*e.g.,* the Transportation Trades Department (TDD), the Airline Pilots Association (ALPA), and the National Air Traffic Controllers Union), Quest Diagnostics, and others. One commenter thought this would affect so few tests that it was not worth doing. Another opposing commenter objected to allowing laboratories to cancel tests and requested that the proposal restrict the MROs to a 30-day window for reversing a cancelled test. Another commenter

said the proposal will ''undermine the finality of these MRO administrative determinations, and raise practical concerns with undoing such actions.'' That commenter also wanted DOT to create a process for appealing MRO decisions, which is outside the scope of this rulemaking. One commenter said the proposal ''could in effect increase the frequency of drug testing beyond what is reasonable and justified. We are also concerned that it would create administrative burdens to the employees being tested who would not have the same finality they currently have if a test is canceled.'' Another commenter was concerned that, ''If an individual is told the test is cancelled, they may decide not to take steps to protect themselves (that they would otherwise have done had they been notified of an 'uncancelled' test), only to later learn that the test has been 'uncancelled'.''

We see no reason to limit the MRO's reversal to 30 days, but have maintained the proposed requirement for an MRO to consult ODAPC if the reversal of the cancellation occurs more than 60 days after the test was cancelled. We do not have exact data on the number of cancelled tests this will impact each year because, as we said earlier and the commenters supported, many MROs were already reversing cancellations because they mistakenly thought they had this authority.

Quite often the cancellations occur when an MRO is unable to get the information needed from the collection site. Often, MROs cannot reach the collector. Sometimes, the MROs must contact a general call center and wait days, or longer, to reach the collector who did not send the needed paperwork (*i.e.,* Copy 2 or a memorandum of correction). This delay in reaching the collector should be eliminated by the change to § 40.40 to require the collector to provide the telephone number where they can be reached more directly and promptly. Ensuring the MROs and their staffs have timely access to the collectors is likely to result in fewer cancellations. So, this is effectively a two-pronged approach to addressing the cancellation problem.

Allowing an MRO to reverse a result cancelled for administrative reasons will not increase the frequency of drug testing because there currently are many reasons an employee may be called back for a second test when an MRO cancels a test. Also, reversing the cancellation of a test would not reduce the finality of an employee's expectations because, if a second test is needed because of the reversal of the cancellation, an employee would not necessarily know if and when to expect a second test. Examples of this include when a split specimen is lost or damaged, then the employee must come back in for another test; or when a laboratory reports an invalid result and the MRO tells the employee to report for another collection. At times, if a negative result is needed (*i.e.,* pre-employment, return-to-duty, or follow-up), a cancelled test actually causes an employee to return for an unanticipated second test. This final rule will reduce the instances of those second tests.

An employee must make themselves available for an additional test when the employer directs them to go. Thus, the finality of a test has never been tied to the employee's expectations.

As for the concern that an employee ''may decide not to take steps to protect themselves'', we respectfully submit that the employee would not lose the right to have a split specimen tested or to request a litigation hold on the actual urine specimen. We hope this information eases that concern.

Another industry association and a C/TPA opposed the proposal because the employer may perform another test after the first is cancelled on a pre-employment, return-to-duty or follow-up test. On a similar note, another commenter said ''the ability to 'un-cancel' a test will cause significant confusion, particularly for those cases where a negative result is required (*e.g.,* for a pre-employment test) and the donor has likely already submitted to a second test.'' To avoid this problem, some commenters suggested only allowing an MRO to uncancel a test when the ''cancelled test did not qualify for recollection, [then] the MRO should have the option to invoke the same consultation requirement we have in [§] 40.149(a)(4).''

We believe part 40 already addresses these concerns. In a test where a negative result is not required (*i.e.,* random, reasonable cause/suspicion, or post-accident), the employer has no authority to send the employee for a second test after the first test is cancelled, unless the result of the first test was cancelled due to an invalid result. In a test where a negative test result is required (*i.e.,* pre-employment, return-to-duty, or follow-up), the employee should have been sent for a second test after the cancellation. Under § 40.162, an MRO is provided clear directions for handling multiple verified results for the same testing event, which the MRO can apply to reconciling a second test result with the reversed cancellation.

In the proposal, we included a requirement for a party seeking to reverse a cancellation to consult ODAPC if the decision is being made more than 60 days after the cancellation. This is the same consultation requirement we have in § 40.149(a)(4), where we allow an MRO to reopen a verified test after 60 days. Providing this information helps ODAPC to provide advice to MROs regarding what to consider and potential concerns. We received several supportive comments on this part of the proposal and have finalized it, as proposed.

V. Section-by-Section Analysis

The Department made a deliberate decision not to create a separate subpart of part 40 or to designate another part of Title 49 of the United States Code to house oral fluid testing. Since many of the provisions of part 40 can be applied to urine, oral fluid and other potential future testing matrices, we proposed to integrate new provisions concerning oral fluid testing within the current part 40 structure. In other sections, we proposed to revise current sections and their titles to specify they would only apply to urine testing.

§ 40.3 What do the terms used in this part mean?

We proposed to delete the definition of ''screening drug test'' because the term is not used in part 40. For consistency with HHS terminology, we have removed the defined term ''invalid drug test'' in the definitions section, § 40.3, and have updated the wording in the definition of ''invalid result'' to be consistent with the current language in the HHS mandatory guidelines for both urine and oral fluid. We have also updated §§ 40.123(c) and 40.129(a) and (d) to use the term ''invalid result''.

To harmonize part 40 with the HHS Guidelines and to update part 40, we have added seven defined terms. We have added ''alternate specimen'' as an authorized specimen of a type other than the one previously collected (*e.g.,* in a case where the initial collection was urine, oral fluid would be an alternate specimen). ''Cutoff'' is the quantitative point distinguishing a need for further testing or whether a laboratory result, for example, is positive or negative (*e.g.,* 2 ng/ml is the confirmatory test cutoff for a positive vs. negative oral fluid result reported by the laboratory for THC). We have added definitions for ''oral fluid specimen'' and ''urine specimen.'' We have added a sentence to the definition of ''oral fluid specimen'' to explicitly state that an oral fluid collection is a direct observation collection. ''Specimen'' is the generic term for any fluid, breath or material collected from someone for a

drug or alcohol test. We have added ''Undiluted (neat) oral fluid'', using the same language HHS uses in Section 1.5 of its Oral Fluid Mandatory Guidelines. We have also added a definition for the FMCSA's Commercial Driver's License (CDL) Drug and Alcohol Clearinghouse (Clearinghouse). For the reasons explained in the Principal Policy section, we added a new definition for ''SSN or Employee ID No.''.

We have modified seventeen definitions in § 40.3. For the most part, the changes are not substantive, and conform part 40's wording with that of the HHS guidelines. For example, ''collection container'' refers to vessels used in all collections, whether of urine or oral fluid. In the definition of ''specimen bottle,'' we added that the term could include ''tube'' or ''vial'' used in oral fluid testing.

One commenter requested we change the definition of ''split specimen'' to allow two separate specimen collections. This would be inconsistent with OTETA's requirement for a single specimen to be collected from and subdivided in the presence of the tested individual. Thus, we have adopted the proposed definition of ''split specimen'' with no changes.

Most of the comments were supportive of the proposed changes. Thus, we have adopted the proposed changes to § 40.3.

§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?

The Department has made minor changes to paragraphs (b), (c), and (d) of this section for clarification in the context of oral fluid testing. For example, paragraph (d) is applicable only to urine testing, since oral fluid testing is not part of the normal medical examination procedure to which the paragraph applies.

We have redesignated the current paragraphs (e) and (f) as new paragraphs (f) and (g). We have added a new paragraph (e) to specify that a drug or alcohol test administered as directed by a medical examiner, exclusively as part of a medical examination required for an employee to qualify for a certificate or license, is not a DOT drug or alcohol test under part 40 and related DOT agency drug and alcohol testing rules. For example, if a certified medical examiner decided to give a motor carrier driver a drug test as part of an examination for medical card purposes, that would be a ''non-DOT test.'' An employer could request a required DOT pre-employment test be conducted when the medical examination is being conducted, as currently permitted under 49 U.S.C. 31306(d).

We have added a new paragraph (h) to further emphasize that DOT drug and alcohol tests are authorized to be conducted only on safety-sensitive employees as designated in the agency drug and alcohol testing regulations. DOT-regulated tests must not be conducted on non-regulated persons (*i.e.,* those who do not perform DOT-regulated safety-sensitive duties). DOT testing is a legal warrantless search and seizure permitted by the Fourth Amendment of the Constitution and is only applicable to regulated persons. The DOT's strong interest in maintaining transportation safety, when weighed against an individual's right to privacy, allows DOT's regulated testing to pass Constitutional scrutiny. See *Bluestein* v. *Skinner,* 908 F.2d 451 (9th Cir. 1990); *Skinner* v. *Railway Labor Executives' Assn.,* 489 U.S. 682 (1989); *Treasury Employees* v. *Von Raab,* 489 U.S. 656 (1989). There is no Federal transportation safety interest in using this testing for individuals other than safety-sensitive employees. Consequently, DOT testing cannot be conducted on employees not regulated by the DOT agencies. Companies do not have the authority to conduct DOT-regulated testing on non-regulated employees. DOT regulations also do not allow non-DOT testing to satisfy an employer's obligation to meet its minimal annual random testing rate for DOT testing.

Some individual commenters supported the proposed modifications to paragraphs (d), (e), and (f). Other commenters noting the changes to § 40.13 were also supportive. We have finalized the proposed changes.

§ 40.14 What information must employers provide to collectors?

We received one comment in support of the modification we proposed to § 40.14(b). We have adopted this change to add clarity and to recognize that, in the motor carrier industry, FMCSA requires the CDL to be used for purposes of the Drug and Alcohol Clearinghouse (Clearinghouse) (*see* 49 CFR 382.705).

We have adopted our proposal to add a new paragraph (k) for ''the specimen type to be collected''. We had proposed to add paragraph (l) to specify if a urine test is to be directly observed. Although there were no comments on paragraphs (k) and (l), we have decided to remove the proposed paragraph (l) because it is redundant with current paragraph (i).

§ 40.21 May an employer stand down an employee before the MRO has completed the verification process?

Under part 40 and the corresponding DOT agency regulations, an employer can request a waiver to ''stand down'' an employee from performing safety-sensitive functions based on a laboratory confirmed non-negative result (*i.e.,* positive, adulterated, substituted or any combination thereof) until the MRO issues the employer a verified result. The authority to stand down an employee is very limited and requires an employer to obtain an actual waiver from the DOT agency before implementing a stand down policy.

As with any laboratory-confirmed positive, the MRO may verify the final result as negative (*e.g.,* if an employee offers a legitimate medical explanation such as a legal prescription). We proposed to add a new paragraph (c)(2)(vii)(C) of this section to prevent the employer to send an employee back in for another test using a different specimen type after receiving a verified negative result. We did not want the employer to order a second test using a different methodology to see if the window of detection could later impact the result. If the MRO cancelled the test (*e.g.,* per the requirements of § 40.159), then the employer can send an employee in for an alternate specimen collection.

We received one comment on this proposal. The combined commenter, a C/TPA and MRO practice, asked us to clarify in the final rule preamble that this applies to more than laboratory positives. Specifically, it also applies to laboratory-confirmed adulterated and substituted results. We have made this distinction in the preamble, as it already exists in § 40.21(b). Other than making this change, we have finalized the changes as proposed.

§ 40.23 What actions do employers take after receiving verified test results?

We proposed minor changes in this section to account for the use of oral fluid or urine in the event of an invalid specimen. In § 40.23(f), we proposed flexibility in allowing the subsequent direct observation collection to either be an oral fluid collection or a urine collection under direct observation. In paragraphs (f)(1) and (5), we offered language to acknowledge a urine collection would need to be directly observed. As written, it is clear oral fluid collections are directly observed.

We received two comments. One commenter supported allowing the employer to choose an alternate specimen type for the directly observed collection. The other commenter said an employee could deliberately cause their urine test to be invalid, then refrain from drug use for a few days and test negative on an oral fluid test. This commenter was concerned employees

would use the windows of detection for the different methodologies to their advantage.

While we recognize the concern of the second commenter, we want to emphasize that oral fluid is a scientifically valid form of testing for the DOT-regulated drug testing program. Our program is deterrence-based. With established cutoffs, we do not seek to detect the presence of every drug, we only seek to detect drugs at their cutoffs and deter illegal drug use. Since HHS has determined oral fluid testing is scientifically viable and forensically defensible, we are willing to leave it to the determination of the individual employers to select the methodology acceptable to them under given circumstances. For this reason, we encourage employers to look at all aspects of using urine drug testing versus oral fluid drug testing as their choice for a particular test, in accordance with part 40.

In consideration of the comments and for the reasons set forth above, we have finalized the proposed changes to § 40.23.

§ 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?

Beginning January 6, 2020, FMCSA implemented its Clearinghouse regulation, set forth in part 382, subpart G. As part of those requirements, FMCSA-regulated employers with drivers subject to the drug and alcohol use and testing regulations set forth in part 382 to query the Clearinghouse drug and alcohol database for information about an employee's past drug and alcohol violations that occurred while the driver was employed by another FMCSA-regulated employer. The Clearinghouse regulations apply only to employers and employees subject to the requirements of part 382.

Until January 2023, FMCSA-regulated employers had dual requirements. They had to conduct a pre-employment query of the Clearinghouse, as required by § 382.701(a), and continue to follow the procedure of § 40.25, as set forth in § 382.413, to request a prospective employee's drug and alcohol violation information from previous DOT-regulated employers.

We have added § 40.25(a)(2) to reflect that, beginning January 6, 2023, the requirements changed for FMCSA-regulated employers, who now must rely solely on querying the Clearinghouse, in accordance with § 382.413(b), to determine whether an applicant violated FMCSA's drug and alcohol testing regulations while employed by other FMCSA-regulated employers. For example, after January 6, 2023, a motor carrier vetting a prospective employee is required to check the Clearinghouse to determine whether the driver's previous FMCSA-regulated employer(s) reported drug and alcohol testing program violations by that driver.

However, since the Clearinghouse does not include drug and alcohol violations committed by employees of other DOT agency-regulated employers, FMCSA-regulated employers must continue to comply with the requirements of § 40.25 when hiring an employee who has been employed by another DOT agency-regulated employer.

Under the new § 40.25(a)(3), we remind FMCSA-regulated employers to request the information about the employee listed in paragraph (b)–(j) of this section from any other DOT agency-regulated employer for whom the employee previously worked, if the employee was subject to another DOT agency's drug and alcohol testing program. If an applicant's past employment was with an employer regulated by, for example, the FTA or the FAA, the gaining motor carrier employer must continue to comply with the requirements of § 40.25 by requesting the required information directly from those employers, in accordance with § 382.413(c). This is necessary since drug or alcohol violations incurred while the driver was employed by a DOT agency other than FMCSA will not have been recorded in the Clearinghouse.

Although FMCSA-regulated employers must query the Clearinghouse for an employee's drug and alcohol testing information, employers regulated by the other DOT agencies do not have access to the Clearinghouse but must find out this important safety information for employees who previously worked for motor carriers. For example, if an FAA-regulated employer sends a § 40.25 inquiry to a motor carrier, the motor carrier must respond to that inquiry in accordance with § 40.25(h). Thus, the Clearinghouse will address motor carrier inquiries, but each FMCSA-regulated employer is required to retain the records and be ready to respond to § 40.25 inquiries from other DOT-regulated employers.

We did not receive any substantive public comments on these changes, which merely conform to FMCSA's requirements. We have finalized the proposed changes.

§ 40.26 What form must an employer use to report Management Information System (MIS) data to a DOT Agency?

We proposed a simple editorial change, substituting a reference to appendix J for a reference to appendix H. This conforms to a re-designation of the appendix letters but would make no substantive changes to the section or form. We did not receive any public comments on this change. We have adopted this change as proposed.

§ 40.29 And Similar Sections

We proposed deleting several sections (§§ 40.29, 40.37, 40.113, 40.169, 40.189, 40.217, and 40.313), which listed other sections of part 40 touching on a given topic (*e.g.,* employer responsibilities in § 40.29). These lists of cross-references were intended to assist readers in finding other relevant information before part 40 was searchable electronically. In the more than 20 years since we placed these sections into part 40, electronic search tools have become sophisticated and ubiquitous, making these sections no longer necessary.

A small number of commenters said they liked these cross references, but the majority of commenters said that the cross-references have outlived their usefulness because of electronic search options. One commenter said, ''Please continue to make decisions about organization of part 40 based on logic, without regard to previous editions of the rule. Those of us who look at it every day need to do our jobs and learn the new numbers.'' Another commenter noted, ''it would not be a burden if the cross referencing was removed because the titles of the Subparts clearly identify the subject matter and the title/s of the section/s under those Subparts are worded in the format of a question with the answers found in that section.''

Therefore, we have adopted the changes. We removed the cross-reference sections of §§ 40.29, 40.37, 40.113, 40.169, 40.189, 40.217, and 40.313, as proposed.

§§ 40.31 and 40.35—Collectors and Their Qualifications—

We have updated § 40.31 to include oral fluid collectors who can collect DOT drug testing specimens. We have added a new § 40.35 to separately specify the requirements for collectors of urine and oral fluid specimens, respectively. Adding this section required renumbering existing § 40.35 to become § 40.36. We have paralleled the new § 40.35 as closely as possible to our existing training requirements for urine specimen collectors in § 40.33. We have added language to parallel § 40.213(b) for training on the specific devices.

In addition, we have included a clarification for both urine and oral fluid collectors prohibiting relatives, close friends, and certain employees (*e.g.,* co-worker or immediate supervisor) from conducting collections. This is consistent with existing guidance in the Department's Urine Specimen Collection Guidelines. We received substantive public comment on these changes. Several comments supported the following proposed wording: ''a collector must not be related to the employee being tested (*e.g.,* spouse, ex-spouse, relative) or a close personal friend.'' Other commenters, including Quest Laboratories, NDASA, and the Substance Abuse Program Administrator's Association (SAPAA) agreed with the exact wording proposed. An aviation employer, Flight Safety International, said they thought the list of specific relationships listed is too limited and would prefer the following wording: ''the collector shall have no conflict of interest with regard to the donor's result''.

On SAP commenter asked that we not allow supervisors or managers to serve as collectors. The Aircraft Mechanics Fraternal Association asked us to clarify whether management is included in the category of those prohibited from collecting a specimen. The Passenger Vessel Association supported the existing prohibition on collections by immediate supervisors in the current § 40.31(d) is sufficient. This commenter said: ''While the limitations proposed in 49 CFR 40.31(d) are problematic for vessels that are often operated by a small number of crew members with a strict supervisor/subordinate organization, that same paragraph finishes with caveat 'unless no other collector is available and you are allowed to do so under DOT Agency drug and alcohol regulations,'. . .'', which this commenter supported.

We agree with the Passenger Vessel Association and other commenters, who supported the wording of the newly renumbered § 40.31(d). We did not change this long-standing provision cautioning against collection by the immediate supervisor of the employee being tested, which is now found in § 40.31(d) (formerly in § 40.31(c)).

Regarding the qualifications for oral fluid collectors in § 40.35, those who commented generally supported the proposal and we have, therefore, adopted it as proposed. One C/TPA wanted to see training similar to urine specimen collectors plus completing the manufacturer's training for each oral fluid testing device the collector will use. A large C/TPA and MRO practice said all collectors should be trained and qualified to perform both oral fluid and urine testing, and device-specific training should come from the manufacturer. One commenter, who performs a large number of trainings annually, said we should look at this the way we view alcohol testing training, which means there needs to be comprehensive part 40 training plus device-specific training. One commenter suggested we call any qualified oral fluid collector a ''Drug Screening Collector Technician (DSCT)'' to be consistent with Breath Alcohol Technicians and Screening Test Technicians. This commenter also recommended having oral fluid collectors: join the ODAPC list serve; be trained to all steps of the CCF, and in problem collections, fatal flaws, and collection site integrity; undergo five error-free mock collections; and have a requirement to requalify every five years. Similarly, NDASA and several C/TPAs wanted oral fluid collector training to include all of the proposed training elements, which mirrored the urine collector training with additions specific to oral fluid collections. SAPAA also commented in favor of device-specific training. Several commenters said there should not be five error-free mock collections per device.

Regarding creating a model training course for oral fluid testing and urine testing similar to the one we have for alcohol testing, we did not propose to create and require such model courses in this rulemaking. However, we will take the requests of these commenters into consideration in formulating future guidance.

We asked for comment about who should be considered appropriate for monitoring the mock collections necessary to qualify an oral fluid collector. We modeled the criteria for the oral fluid monitor after what we have set for urine collections in § 40.33(c): one who has regularly conducted DOT drug test collections for a period of at least one year; has conducted collector training under this part for at least one year; or has successfully completed a ''train the trainer'' course. The commenters supported keeping the same requirements for the mock collection monitors for oral fluid as for urine. Several commenters noted it would be inadvisable for the Department to allow individuals who have been collecting only non-DOT specimens to automatically qualify to train oral fluid collectors under part 40 but did not provide a reason for their rationale. Other commenters asked if virtual training and virtual mock collections were permissible. Both have been allowed for urine collector initial training, error correction training and for requalification training. Consequently, both will be permitted for oral fluid collector initial training, error correction training and for requalification training.

One commenter asked about whether there must be two or three individuals involved in the mock proficiency demonstrations. Whether they are in-person or virtual, we have always required at least two individuals to interact during the mock collections, while a best business practice is to have a third person act as the donor, so that the trainee could have the experience of ''collecting from an employee'' without actually collecting a specimen during the training. We believe this is an extremely important requirement because collectors must deal with real people and real specimen collections. If the monitor and trainee are the only participants in the mock proficiency collections, then the monitor must also perform the role of the donor—by interacting meaningfully with the collector trainee to make certain the trainee gets the experience of both uneventful and problem collections. The easiest way to achieve this result is for there to be a third person playing the part of the donor. However, if there are only the monitor and the trainee, but the monitor meaningfully plays the roles of the cooperative and uncooperative donors, the intent of part 40 is fulfilled.

There were comments recommending oral fluid collectors be trained by the manufacturer(s) of the respective oral fluid device(s) the collector intends to use. Some recommended collectors take the manufacturer's online course to get qualified to use each specific device. Others distrusted having specific device training done through the manufacturer's website because they said that would increase costs. One commenter said not to allow manufacturers to train for their own devices because the manufacturer would introduce bias, but a third-party conducting training would not have that bias. One commenter suggested the collector instructor take the manufacturer's device-specific training and use that as the basis for training others. Similarly, a couple of commenters recommended using specific training approved by the manufacturer for its own device. Labcorp strongly encouraged us to require ''collectors to complete manufacturers' training on each collection device that will be used for DOT-regulated collections as individual devices have unique features with

respect to proper placement in the mouth, timing, and specimen sufficiency indicators.'' One C/TPA said train the trainer courses will be widely available, as they are for urine testing, and oral fluid device manufacturers may take the lead on this. Other commenters discussed the user-friendly nature of the devices (*i.e.,* they usually come with instructions for use or those instructions can easily be read on the manufacturer's website prior to the collection).

We agree with the commenters who were hesitant about specifically requiring the manufacturer's training be used. Considering the user-friendly nature of the devices and that instructors will be teaching oral fluid collectors to use each device the collector is expected to deploy, we amended the proposed language. We have adopted the requirement for a collector to obtain ''training to proficiency in the operation of the particular oral fluid collection device(s) you will be using.''

The collector must demonstrate proficiency for each device. We acknowledge several commenters did not want proficiency demonstrations for each device on which a collector is instructed. However, we disagree because the point of the initial proficiency demonstration is to prove the collector was trained on a particular device to full proficiency. If the collector will use more than one device, then the collector needs to prove initial proficiency on each device.

The collector must check the expiration date of the device in each mock collection because using an expired device or failing to enter the ''Split Specimen Device Expiration Date'' on Step 4 of the CCF would be a fatal flaw under § 40.199. Since the collector will use an oral fluid device that will collect a single specimen, which is then subdivided in the presence of the donor, only one device is to be used. The collector must make the entry on the option marked ''Split Specimen Device Expiration Date'' instead of the option marked ''Primary/Single Specimen Device Expiration Date''. We have been clear that part 40 does not allow the use of a ''primary'' collection device, meaning one of two collection devices. In addition, part 40 does not allow for a ''single specimen'' collection device because all devices must be capable of collecting both a primary and split specimen. For DOT-regulated collections, all devices will collect a split and have an expiration date. The collector will enter the expiration date of the single device in Step 4 of the CCF, on the line marked ''Split Specimen Device Expiration Date,'' which appears directly above Step 5A. The collector would not fill in the ''Primary/Single Specimen Device Expiration Date'' in addition to the ''Split Specimen Device Expiration Date'' on the CCF.

We consider proficiency demonstrations to be extremely important. It is one thing to receive instruction on how to use a device, but demonstrating proficiency is literally where the ''rubber hits the road.'' If a collector cannot demonstrate proficiency on a device, then the instruction received on the use of the device will not remain with the collector in real world collections.

§ 40.33 What training requirements must a collector meet for urine collection?

There were no comments to changing the title of § 40.33 to reflect its focus on urine collectors. We also proposed a change to § 40.33(f) to clarify that damage to a specimen resulting in it being cancelled does not require retraining of the collector, unless the error actually occurred during the collection process. When a specimen is damaged by a delivery truck, sort facility, or other part of the transportation process, or is lost in transit, it is not the result of an error by the collector during the collection process. However, when such damage during the transportation process occurred, some MROs had required collector retraining.

Our proposal to clarify that a collector is not subject to the time and costs of retraining for errors outside the collection process, such as in transportation process events, was met with only supportive comments. In response to the following, we have adopted the change to § 40.33(f).

One commenter, NDASA, said, ''Unnecessary error correction has been required for far too many circumstances that are beyond the control of the collector, costing time and cancelled tests.'' A combined MRO and C/TPA comment supported the proposal, saying ''Previously this was too subtle of a distinction and collectors have been unnecessarily subjected to error correction training when a situation was not their fault. An example is when a bottle leaks in transit where fault is difficult to assign.'' In further agreement, Quest Diagnostics said, ''Similar to urine collections, problems that occur during shipping that are out of the collector's control should not be held against the collector.'' LabCorp also agreed with this proposed change.

Subpart D—Collection Sites, Forms, Equipment and Supplies Used in DOT Urine and Oral Fluid Collections

Some commenters appeared to be confused about testing oral fluid specimens for drugs versus testing saliva for alcohol misuse. Oral fluid drug testing and saliva alcohol testing are completely distinct from each other. The devices, procedures and outcomes are never interchangeable. The provisions applicable to oral fluid testing procedures were proposed as additions in subpart D. The saliva alcohol testing provisions in subparts K through L remain unchanged.

We proposed to reorganize subpart D to accommodate the addition of provisions pertaining to oral fluid drug testing. Sections applying to the DOT drug testing process generally, regardless of specimen type, come first. Renumbered §§ 40.40 and 40.41 contain the content of previous §§ 40.45 and 40.47, concerning the use of the official ''Federal Drug Testing Custody and Control Form'', which we continue to refer as the ''CCF'' in all DOT collections. The 2020 CCF and instructions for completing the CCF for both urine and oral fluid collections are available on the HHS website, *https://www.samhsa.gov.* The DOT has posted the 2020 CCF on our website, *https://www.transportation.gov/odapc.* Some commenters specifically requested ODAPC to provide Specimen Collection Guidelines for both oral fluid and urine, in one combined document. Since not every collector intends to perform both types of collections, we will provide an ODAPC Oral Fluid Specimen Collection Guidelines document, separate from our Urine Specimen Collection Guidelines, after the publication of this final rule.

We proposed changes to the sections of subpart D, including the title of the subpart, which contain the word ''urine'' or a derivative of that word, if those sections would apply to both urine and oral fluid testing. We added the words ''and Oral Fluid'' to the title of this section to emphasize subpart D applies both forms of DOT-regulated drug testing collections. We proposed the language ''any other appropriate contact information'' to permit the inclusion of email addresses or other means of contacting the appropriate parties in the redesignated § 40.44(c)(2). We asked for public comment regarding removing requirements related to fax numbers on the CCF, allowing the fax number if the parties have one, or whether fax numbers were still relevant.

We proposed a provision allowing the Designated Employer Representative's (DER) name and contact information to

be preprinted on the CCF. We asked the laboratories about the availability of space on the CCF to pre-print the information, as well as the logistics and timeliness of sending out updated CCFs with the new DER information. To recognize the responsibility of collectors, as well as collection site operators, for proper collections, we have added ''collectors'' to the title of § 40.43.

As amended, the newly reorganized §§ 40.42–40.45 covers urine testing (renumbered § 40.42 in the amended rule contains the material previously found in § 40.41, while renumbered §§ 40.44 and 40.45 contain the material previously found in §§ 40.49 and 40.51). To parallel with their urine testing counterparts, new §§ 40.47–40.51 have been added to address oral fluid testing, specifically.

We proposed to modify renumbered § 40.40 to clarify what address and telephone number a collector must provide on the CCF. In January 2002, ODAPC issued a Question and Answer (Q&A) explaining that the collection site address should not be a corporate or ''main office'' address. In addition, the Q&A stated that the collector's telephone number on the CCF should be the number to directly reach the individual collector and/or the collector's supervisor and not a corporate ''toll free'' number to a call center. With the modification to § 40.40, if an MRO, laboratory, employer or any DOT staff need to speak with the collector, the telephone number provided on the CCF must give access directly to that collector and/or the collector's supervisor during the collection site's business hours. The collector must not provide a number for a call center. Since this amendment makes the collection site address and collector's telephone number part of the regulatory requirements, we will withdraw the January 2002 Q&A because it is now unnecessary.

If CCFs had already been printed before this final rule was published, the call center number may be on the forms. Service agents (*i.e.,* C/TPAs and collectors) and employers can use these preprinted forms, but they need to cross out the incorrect telephone number and write in the correct telephone number and/or collection site address. There is no need to incur the cost of destroying these CCFs, but we would expect they will no longer be generated with the call center telephone numbers or incorrect addresses after this final rule becomes effective. However, we want to remind collectors and collections sites that they have the responsibility to keep their information current with the laboratories.

We did not receive comments strongly opposing the addition of email addresses, but there were strong proponents for and against using fax numbers. Some commenters said fax machines are outmoded by more secure electronic equipment. LabCorp supported removing the fax number requirement. One commenter said fax machines tend to produce less legible and sometimes illegible copies of the recipient because some labs use lighter ink on their CCFs. One commenter specifically supported replacing the requirement for fax numbers on the CCF with the option and space to include a either a fax number or email address to transmit the CCF to others. In support of using fax numbers, one commenter said faxes are ''still a consistent use of transmitting information in a secure manner. Not all organizations are set up with secure transmittal methods and fax still remains more secure than email and is used between clinics, labs and MROs as well as with employers.'' A large C/TPA and MRO practice supported the continued use of faxes: ''While some collection sites are getting rid of fax numbers, we do not have widely available access to their email addresses. Fax is still commonly used to communicate between collectors, MROs and labs. Confidential communications with collection site should be encrypted yet some of their systems will not allow for this. Faxing still plays a role in our business world and systems are available to keep the information secure in transit.'' Another C/TPA commenter wanting us to keep fax numbers echoed, ''maximizing the usage of electronic mail and other digital means for document transfer is the most efficient method of communication available today. However, fax communications are still prevalent in the industry, and at this point still an unfortunate necessity.''

In response to the comments, we have decided to keep the option of including a fax number on the CCF, but not require its use. Since many entities no longer use fax machines, it would be an unintended cost to require them to reinstate them. Consequently, in § 40.40(c)(2), we finalized the following proposed language: ''Fax numbers may be included, but are not required.''

There were only opposing comments on the idea of including the DER's name and contact information pre-printed on the CCFs. Laboratories, C/TPAs, MROs, and collector trainers said that DERs change too frequently to pre-print a specific name on the CCF, and to fill that information in on the CCF at the time of the collection. One commenter said that, even on an electronic CCF, it can be confusing to need to change the actual DER's name if it is pre-set in the electronic system. Many commenters said pre-printing this would be a waste of money and time because the pre-printed DER names and contact information would need to be crossed out and the correct information written over the cross-outs. This would lead to further confusion.

Consequently, we have not included any requirement for pre-printing the DER's name. It was interesting and informative for us to know that using an electronic system would have difficulties adapting to changing DERs.

We asked for public comment on the use of the term ''dry mouth'' in § 40.48(c)(1). We explained ''dry mouth'' is shorthand, similar to the term ''shy bladder'' used for urine collections, for a situation in which an employee is unable to produce a sufficient specimen. We received no comments on this point, although many commenters had already adopted the term ''dry mouth'' in their own comments.

One commenter with a nationwide collection network said ''multiple oral tests can be conducted simultaneously when in a controlled/supervised environment. All while ensuring the integrity of the individual tests.'' That was the only comment opposing the proposal to require the collector to only collect from one employee at a time. We are concerned the distraction of conducting multiple collections at the same time could compromise the security of the collection and potentially impact the fairness and accuracy of the oral fluid test. Consequently, we have adopted this provision to allow the collector to conduct only one collection at a time.

§ 40.49 What materials are used to collect oral fluid?

The Department proposed that all oral fluid collection devices must meet the requirements being set forth in a new appendix B, which is consistent with OTETA's requirement that the specimen must be subdivided from the original specimen in the presence of the employee being tested. *See* 49 U.S.C. 45104(5) (aviation industry testing), 49 U.S.C. 20140(c)(5) (rail), 49 U.S.C. 31306(c)(5) (motor carrier), and 49 U.S.C. 5331(d)(5) (transit). Importantly, we noted not all the devices HHS would allow for the OFMG will be allowed for DOT-regulated collections under 49 CFR part 40 because many would not be consistent with OTETA.

Some commenters said DOT and HHS should not allow different devices. One commenter said HHS should only use devices meeting the needs of the DOT program. Another commenter said laboratories charge four dollars per oral fluid collection device, and since every collection would require two devices to create a split specimen, they thought DOT's proposal would save money by mandating a single device, even though it was a sub-dividable device.

Although we discussed the requirements of OTETA in the preamble to the NPRM, one commenter did not realize it was a statutory requirement, saying DOT did not have data to support using a single specimen collection device that gets subdivided. An industry association said it could not find the language in OTETA. One commenter said there was no need to subdivide the specimens, simply use a single collection device, as is done in non-DOT testing. A couple of commenters misunderstood OTETA's requirements and thought that a single specimen subdivided was a concept that DOT created separately from the statute. Several commenters suggested the mouth could be the collection container, thereby allowing separate specimens could be collected from different parts of the mouth to collect a subdivided specimen. Others said the Department did not understand OTETA's requirements and were thereby creating an obstacle that would delay oral fluid testing because the Food and Drug Administration (FDA) could take one to two years to approve new devices. Incidentally, some of these same commenters participated in the public comment period for proposed changes to the HHS OFMG and said it would not be a problem to change the devices and obtain FDA approval in under one year, even on an annual basis, if needed. (*See* 87 FR 20522, Apr. 7, 2022). That inconsistency was notable, when compared to the comments some of the same commenters filed to this docket.

When Congress passed OTETA in 1991, it designated DOT as the agency to interpret and carry out the requirements of the statute. The Secretary of Transportation, with certain delegations to the aviation, rail, motor carrier and transit administrations, was charged with continuing its existing drug testing regulations, but enhancements were articulated in OTETA. One of those enhancements was to require ''that each specimen sample be subdivided, secured, and labelled in the presence of the tested individual.'' *Id.* The Senate Committee Report explained the testing programs were to include ''procedures designed to safeguard individual rights and testing procedures which shall . . . Provide that each specimen sample be subdivided, secured, and labeled in the presence of the tested individual . . .'' Senate Report: Omnibus Transportation Employee Testing Act of 1991, S. Rpt. 102–54, pp. 20–21 (May 2, 1991). In addition, the Senate Report explained, ''These safeguards are critical to the success of any testing program. They are designed to ensure that an individual's basic rights to privacy are protected and that there is accountability and accuracy of testing.'' *Id.*

Having a single specimen collected and subdivided in the presence of the tested individual is the core issue in the decisions we have made regarding what device features would be acceptable in the DOT oral fluid testing program. Congress clearly articulated collecting a single specimen that is subdivided in the presence of the tested individual is a critical safeguard for the individual and it provides assurance of the accountability and accuracy of the testing program. Furthermore, the safeguard of a single specimen subdivided in the presence of the individual being tested is a right OTETA ensured for individuals being tested. As we said in our 2000 preamble to the plain language rewrite of part 40, ''When Congress guarantees a right to employees (and we believe we must treat all DOT-regulated employees in our program alike, even if they are not covered by the Omnibus Act), our obligation as a Federal agency is to faithfully execute that legislative decision.'' (65 FR 79467 Dec. 19, 2000).

Requiring a device that permits a single specimen to be collected and subdivided in the presence of the donor is both a statutory requirement and a reasonable expectation. The Department is acting within its authority to carry out such reasonable and clear requirements in legislation entrusted to it.

Assuming in the alternative that the statute is not considered to be clear on its face, the DOT is the Federal agency charged by Congress to interpret OTETA and we are utilizing our ability to interpret the statutory authority vested in us. The precedent for this ability to interpret statutes has been supported for almost forty years in the cases following *Chevron* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984). In *Chevron,* the leading case on the authority of agencies to interpret statutes through rulemaking, the Supreme Court articulated the following standard:

> When a court reviews an agency's construction of the statute it administers, it is confronted with two questions. First, always, is the question of whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction of the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute. (Id. at 842–43).

In applying the Chevron analysis, courts will strike down an agency regulation or interpretation when there is something in the statute specifically precluding the action the agency had taken. Actually, OTETA confirms the Department's broad authority to carry out its drug and alcohol testing responsibilities. When the intent of Congress is clear, as is the case here, no further inquiry is necessary.

Thus, the Department is acting within its statutory authority to carry out such reasonable requirements in legislation entrusted to it. The statute unambiguously provides that samples for drug testing must be subdivided, or ''split.'' To the extent that that the statute requires interpretation, the DOT's implementation of the statute is reasonable and is, therefore, entitled to deference. *See Chevron* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984).

Consequently, as we proposed, all devices meeting the requirements in Appendix B will allow a single specimen to be subdivided in the presence of the donor. For example, a device could allow two specimens to be collected simultaneously using a single collection device, which directs the oral fluid into two separate collection tubes; or a specimen could be collected with a single device, which is inserted into the mouth and can be subdivided into two separate collection tubes. We would also allow a device to have two pads joined together for the collection in the same part of the mouth, as long as they can be separated in the presence of the employee being tested. We do not agree with the creative suggestion of allowing the mouth to be the collection container.

We have made slight modifications to the proposed rule language in Appendix B to encompass this broader intention of what is acceptable under OTETA. We think it is reasonable to allow a device with either one or two pads that can be subdivided and sealed in the presence

of the employee to be consistent with OTETA.

One commenter who is a collector pointed out that there is already at least one patented device that would meet the requirements of OTETA. This commenter said she has experience using that device and it is far superior to others on the market. She noted problems with other oral fluid collection devices ''such as: inadequate specimen for multiple drug confirmations; sample-adequacy indicators are not reliable indicators of specimen volume as donors attempting to 'beat' the test often suck on the device to draw saliva out of the paddle or swab; absorbent material in paddles/swabs have no consistency in sample volume collected; there is no standardization of oral fluid collection devices that a offers a reproducible, sufficient (1 mL) sample . . .'' As manufacturers develop new devices capable of being subdivided in the presence of the donor, we expect that any such problematic issues with oral fluid collection devices will be resolved.

We have included below, in the Section-by-Section analysis of Appendix B, more comments regarding the specifics of what we proposed for collection device kits. A full discussion of the specific comments can be found there.

§ 40.61 What are the preliminary steps in the drug testing collection process?

We proposed changes to § 40.61(a) to remind C/TPAs for motor carrier owner/operators of the C/TPA's respective nondelegable duty to make a determination of whether a refusal has occurred when an employee fails to timely report for a test that is not for pre-employment. We received only supportive comments. We have adopted the changes and have added similar language to this section to remind employers of their duty to make a determination on refusals. We have added language in the final rule to reiterate the responsibility for the employer or C/TPA of the owner/operator to make the actual refusal determination required under §§ 40.191(a)(1) and 40.355(i) and (j).

There were no comments regarding modifying § 40.61(b)(1) and (3), to use the term ''drug testing'' or ''drug test'' in place of ''urine,'' since the provision applies to the testing of either specimen type. We have adopted these changes as proposed.

We proposed to split the existing § 40.61(b)(3) into (b)(3) and a revised (b)(4), and there were no comments. We have revised § 40.61(b)(3) to prohibit collection of any kind of specimen from an unconscious donor. The revision to § 40.61(b)(4) includes the remaining sentences of the current § 40.61(b)(3), with a change to the final sentence of proposed subparagraph § 40.61(b)(4). The final sentence in § 40.61(b)(4) emphasizes the actual employer must decide whether a given circumstance constitutes a refusal, as is required by § 40.355(i). When a directly observed test is needed, either a directly observed urine collection or oral fluid collection will suffice, and the collector will note on the CCF whether a directly observed urine or oral fluid test was conducted under § 40.61(f)(5)(i).

There was a comment to § 40.61(f)(5)(i). The commenter said 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.'' We agree that this instruction should come from the DER. That instruction should be provided in advance of the tests when possible. These are the kinds of details employers and collection sites should be discussing in their regular course of business. We disagree that it should be a regulatory requirement.

DOT-regulated entities are required to use HHS's OMB-approved CCF. DOT worked closely with HHS on the current CCF, which incorporated changes necessary as a result of HHS's establishment of scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The majority of changes to the CCF were made to allow the collection of oral fluid specimens, which have not been authorized in the DOT drug testing until this final rule and will not be fully implemented until HHS certifies at least two laboratories.

In response to the HHS revisions to the CCF, we proposed changes to §§ 40.61(e) and 40.79(a)(1) (formerly § 40.73(a)(1)). The instructions for completing the old CCF were provided on the back of Copy 5 of that form. These instructions are not provided on the revised CCF. Instead, instructions for completing the form can be found on the HHS and DOT (ODAPC) websites. We proposed amending § 40.61(e) to instruct the collector to tell the employee they can find instructions for completing the CCF on specific HHS and DOT websites. We received the following comments to these changes.

Airlines for America (A4A) supported the amendment to require the collector to ''notify the employee that instructions for . . . the CCF can be found at the HHS . . . and DOT . . . websites.'' Quest Diagnostics suggested, ''a printed and legible copy of the instructions for completing the CCF should be available to both the donor and collector to follow as part of the collection process during all collections. Provision of a printed copy should be a collector's responsibility in the event electronic access is not available.'' While we agree with the spirit of this latter comment and would encourage collectors to have a legible copy of the CCF instructions available, we envision it as a good business practice and not a regulatory provision. To require paper copies of this to be provided to each donor seems to be an unnecessary paperwork burden to employers and their collection personnel. Having a laminated copy available at the collection site is also a good idea. As long as these directions are available electronically through the DOT and HHS websites, they will be available to all employees. We have finalized § 40.61(e) as proposed.

We received a comment from a labor organization asking for a new requirement to be added to § 40.61(b). Specifically, they asked us ''to add a requirement that for union represented employees to be informed by the collector that the employee being tested has the right to have a union representative present during the process.'' It is unlikely that collectors would know this information. We consider this comment outside the scope of this rulemaking, but it can be addressed in individual collective bargaining agreements between unions and their employers.

Also, we proposed amending redesignated § 40.79(a)(1) to note the employee must provide all information required in Step 5 of the revised CCF. This information includes the donor's printed name and signature, date of the collection, date of birth, daytime and evening phone numbers, and email address (if the donor has one they are willing to share).

One commenter asked that we not require the collector to make a remark on the CCF if the donor's email address, date of birth, or telephone numbers are not in Step 5 of the CCF. This commenter said requiring this notation as a remark on the CCF ''could have a catastrophic impact on the collection process, expose employers to privacy complaints, create unnecessary test cancelations, increase administrative costs, and add another point of potential conflict between the donor and collector.'' The commenter thought the requirement to provide two phone numbers and an email address would be a violation of the employee's privacy

rights. However, the commenter did not have an issue with providing the donor's name, SSN and date of birth.

We disagree that additional information on the CCF is a violation of the employee's privacy. If the information required in Step 5 of the CCF is not properly completed by the employee, the collector has a duty to attempt to get the employee to provide the information or note in the remarks section that this was not done. As with all problems at the collection site, it is best to document them as soon as possible.

One commenter, NDASA, asked about situations in which the employee does not have a second phone number. This commenter asked that we allow the collector to write ''Not applicable'' or some derivation of that phrase on the CCF, to note the absence of the second number was not available and not simply an oversight. That is a reasonable suggestion and common-sense approach. We have not included this in the regulatory text. Instead, we will include it in our collection guidance. We have finalized § 40.79(a)(1) as proposed.

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

We proposed to modify § 40.63(a) to remind collectors to ensure that all items in Step 1 of the CCF are completed. Specifically, we proposed to add a parenthetical to remind collectors to check the box for the DOT agency in Step 1.D, and to write an address for the actual collection site in Step 1.G.

Quest Diagnostics commented in support of ''the reminder to collectors to check the box for the DOT agency in Step 1.D, and to write an address for the actual collection site in Step 1.G.'' Similarly, industry trade associations supported the change. There were no opposing comments. We have adopted the changes as proposed.

§ 40.65 What does the collector check for when the employee presents a urine specimen?

We proposed to modify § 40.65 to ensure that when an immediate re-collection under direct observation is needed (*e.g.,* because the temperature of a urine specimen is out of range or there are signs of tampering), regardless of whether the first specimen was urine or oral fluid, the required directly observed collection could be either urine or oral fluid. For example, if a directly observed collection is needed after a urine collection, the second could be either an oral fluid collection (inherently directly observed) or a urine collection carried out under the direct observation procedures set forth in § 40.67. After the second collection is done, each specimen collected must be sent to the appropriate laboratory (*i.e.,* a laboratory certified by HHS for that specimen type). We asked for public comment about who should make the decision as to the methodology for the second collection.

ARCpoint Labs, a nationwide network of collection sites, commented that the collector should be the one ''to determine the type of second collection that is performed. This will allow maximum flexibility based on environment, oral/urine kits available for that client, and the collectors experience.'' This commenter also pointed out that moving from a urine collection to an oral fluid for the purpose of obtaining a directly observed collection would remove the need to conduct a more invasive urine direct observation.

Conversely, Labcorp, which is an HHS-certified laboratory and owner of a large network of collection sites, opposed ''allowing the collector to independently determine when an alternate specimen should be collected or requiring that the collector contact the employer each time an alternate specimen type is collected.'' Labcorp also said the identification of what specimen type is used and when it should be used should not be in the regulation and should be in the agreement between the employer and the collection site. A C/TPA requested that a ''collector should have clear instructions on when the type of sample can be switched.'' Similarly, the New York City Department of Transportation recommended advance communication between the DER and the service agent ''to ensure that an alternate methodology is authorized with devices and laboratories as designated. In the event an alternate methodology is needed, the collector should contact the employer (DER) and/or service agent (TPA/MRO) immediately. They will make the decision on which device to use.''

We agree there should be clear communication between the employer and their service agent(s) who conduct the collection to ensure there is a process set up in advance. That process would determine whether the collection would either continue with the same methodology as the collection began or switch to the alternate methodology to complete the second test (*e.g.,* under direct observation or to complete the test when there is a shy bladder scenario). As Labcorp noted, moving to oral fluid for a directly observed collection is less invasive than moving to a urine collection under direct observation.

When there is a need to determine whether an alternate specimen should be used, it is advisable for an employer to have a standing order in place to deal with such situations. The different specimen type could be chosen by the employer (through a standing order or a discussion with the collector) or its service agent (*i.e.,* if there is no standing order and the collector cannot contact the DER) to complete the collection process for the testing event.

As several commenters supported, this should all be discussed and arranged in advance. We do not believe this is something the Department should regulate. The employer and its service agents are in the best position to assess the costs and logistics of the collection, set up the appropriate contracts with collectors and laboratories, and determine the most effective way to conduct a second collection under direct observation. The proposed language sets up the performance standard for the second collection to be accomplished without interfering in these contractual relationships between employers and their service agents. Consequently, we have finalized the proposed language without further changes.

§ 40.67 When and how is a directly observed urine collection conducted?

We proposed to modify the title of the section to add the word ''urine''. This clarifies its applicability solely to how and when directly observed urine collections will occur. We received no comments on this point and have adopted the change to the title.

One commenter asked why we did not include permission for an employer to send an employee in for an immediate recollection if the employer discovered a direct observation should have been conducted but was not. The commenter pointed out the employer could do this only when the service agent noted this for the employer. We agree with this commenter and, as a logical outgrowth, we have added a § 40.67(a)(4) to permit this and to tie in the action expected of the employer when a service agent notifies the employer under § 40.67(n) that a required direct observation was not done.

We proposed minor changes to § 40.67(c) and (d). We received a public comment requesting an additional modification to the proposed § 40.67(d). That commenter asked for a language change to have the collector inform the employee a direct observation is

necessary because the specimen did not meet Federal guidelines. We will not make that change because we believe it will cause confusion between the HHS guidelines and DOT's regulation, part 40. We have finalized the changes to § 40.67(c) and (d).

In the most substantive proposed change to § 40.67, we offered an amendment to § 40.67(g) to address situations where a same gender observer is not available for the collection of urine specimens. We requested and received public comment on whether a licensed or certified medical professional legally authorized to take part in a medical examination in the jurisdiction where the collection takes place should be permitted to be opposite gender observers. We explained that we were proposing this option to reduce the circumstances in which an observed urine collection might be delayed for lack of a same-gender observer.

We received a significant number of comments on proposed § 40.67(g). Some commenters thought that it would be a good idea to allow certain specified medical professionals to be direct observers regardless of gender because a same-gender observer is not always present in a collection site, and others mentioned how transgender and nonbinary gender individuals pose a challenge for finding a same-gender observer.

The majority of commenters on this subject opposed the proposal. The opposing comments included concerns about sexual advances, stress to donors, and accusations of assault that would lead to liability for medical professional serving as the observer. Some commenters asked that we leave the same gender direct observation provision exactly as it is in § 40.67.

While we acknowledge the concerns of the commenters who opposed the proposal, we agree with the commenters who wanted to see some changes made to accommodate situations where a same-gender observer cannot be easily provided and in the less common situations of transgender and nonbinary gender individuals who will be subject to a direct observation collection. Oral fluid testing offers a completely appropriate solution for all of these scenarios because every oral fluid collection is a directly observed collection without the need for a same gender individual to perform that observation.

Consequently, we have not added the proposed provision to allow a different gender direct observer who is a medical professional. If a directly observed urine collection is required, the burden remains on the employer to provide the same-gender observer if the collection site cannot do so, or to permit an oral fluid test. The responsibility of ensuring the collection takes place has always been the employer's requirement. If the employer has a standing order that all directly observed collections will be conducted as oral fluid, then there is no need for the collector to call the DER. Otherwise, the collector will use the telephone number listed on the CCF where the DER can be reached at any time of the day or night the testing is being conducted. If a collector cannot find a same-gender observer, the collector needs to let the DER know that one must be immediately provided for the collection, unless an oral fluid standing order exists.

In the case where the employee identifies as transgender or nonbinary gender, the burden remains on the actual employer to ensure the direct observed collection will take place. We have added § 40.67(g)(3) to require that when a same gender collector cannot be found, unless the employer has a standing order to allow oral fluid testing in such situations, the collector must contact the DER and either conduct an oral fluid test because the collection site is able to do so or send the employee to a collection site acceptable to the employer for the oral fluid test. Even if an employer does not usually utilize oral fluid testing, that employer should have agreements or arrangements either directly, or through its C/TPA, for oral fluid testing to be used for directly observed collections of transgender or nonbinary employees. In the alternative, the employer could establish in-house collections for such situations. We encourage employers to arrange for oral fluid testing in advance, in order to plan for such contingencies.

We want to clarify that the collector does not enter the reason for the direct observation in the ''Remarks'' section of the CCF if the employer is sending the employee in for a required directly observed collection (*e.g.,* a return-to-duty test, a follow-up test, a test where the MRO has instructed the employer to send an employee in for a directly observed collection). The ''Remarks'' section would be used only when the collector moves to a directly observed collection and the employer did not know about it in advance (*e.g.,* temperature out-of-range, or signs of tampering). Thus, we have amended § 40.67(e)(2) to change a cross-reference to § 40.67(b) to become a cross-reference to § 40.67(c)(2) through (4). This is because § 40.67(e)(2) is an instruction to collectors to follow through with an entry on the ''Remarks'' line on a CCF when an event under § 40.67(c) takes place. This has nothing to do with § 40.67(b), so this cross-reference has been corrected. We also proposed to make a technical amendment to § 40.67(c)(1) to strike the reference to paragraph (b) because it is an incorrect reference. There were no comments opposing any of these edits to § 40.67, so we have adopted them, as proposed.

§ 40.69 How is a monitored urine collection conducted?

There were no comments on the proposed new introductory language in § 40.69(a) to emphasize a monitored collection will be conducted if the collector is using a multi-stall restroom and the collector cannot secure all sources of water and other substances that could be used for adulteration and substitution (§ 40.42(f)(2)(ii)). Also, there were no comments about the proposed edits to § 40.69(e) to update cross-references in part 40 that were renumbered. We have adopted these changes as proposed.

§ 40.71 How does the collector prepare the urine specimens?

The final rule makes a minor clarifying change, instructing the collector of a urine specimen to check both the boxes for ''urine'' and ''split specimen'' on the CCF. We received one comment, which requested we add the words ''after the collection'' for the purpose of reminding the collector to check the boxes under Step 2 after the collection takes place. We agree this would be helpful. We have adopted the change to § 40.71(b)(1), with this modification.

§§ 40.72–40.74—Collection Procedures for Oral Fluid Testing

These three new sections establish the collection procedures for oral fluid testing. They are consistent with the HHS OFMG (84 FR 57554, Oct. 25, 2019).

There were many substantive points discussed in the comments that were extremely helpful to the Department. Commenters in the medical field, collectors experienced in non-DOT collections, laboratories, associations, and others discussed practical tips, potential problems and other factors for us to consider. In response to those comments, we made the following changes explained below.

The American College of Occupational Medicine (ACOEM) questioned whether oral fluid collectors would be well-enough trained to determine whether a donor is ''cheeking'', which they said is ''a practice of hiding medication or

contraband in the mouth between the cheek and gums.'' This association, with a membership of very knowledgeable health care professionals, warned of ''substitute saliva (complete with the proper amount of albumin or immunoglobulin biomarker) which is far easier to conceal and maintain at body temp than 30 cc of urine'' and the rise of other products to cheat oral fluid testing. They also asked whether collectors would ''be trained to carefully examine the entire mouth, *i.e.,* using a dental mirror, to assure that the donor has not concealed an adulterant or substitute saliva sample in their mouth?'' ACOEM also encouraged us to include such instructions in our Oral Fluid Collection Guidelines to ''make sure that the proper initial inspection process of the oral cavity is included.''

To ensure proper training can be done, we must first ensure the regulatory text is clear and provides the necessary details. Consequently, we chose to address the substantive concerns about substituting and adulterating tests here, in § 40.72(a), instead of the collector training provisions of the regulation.

We agree with ACOEM about the potential for adulterating, substituting, or otherwise interfering with an oral fluid test exists, even though all oral fluid tests will be directly observed. The final rule requires the employee to open their mouth and allow the collector to fully inspect the oral cavity. The collector is required to check the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen. In § 40.72(a), we have provided the examples of ''candy, gum, food, or tobacco'', which is not an exclusive list because there could be more items that are inadvertently present in a donor's mouth. However, we also included in § 40.72(a) that the collector needs to be checking for anything that could be used to adulterate, substitute, or alter the specimen. As this commenter suggested, we will provide further guidance on inspecting the oral cavity within our oral fluid collection guidelines to remind collectors to conduct oral fluid testing in well-lit areas and recommend, as a best business practice, the collector have a flashlight available for oral cavity inspection.

In response to the concerns of ACOEM and other commenters, we have amended the proposed § 40.72(a)(1) and created a new § 40.72(a)(2). Specifically, we have added ''If the collector finds indication(s) of anything identified above, the collector will ask the employee to lift their tongue and/or separate their cheek from their gum to permit full inspection.'' Although we do not believe every oral cavity inspection will require the employee to lift their tongue and/or separate their check from their gum, we want to provide this as an option for the collector to utilize within their discretion. We also added a sentence to allow the employee to cleanse their hands if they need to touch their own mouth to allow further inspection by the collector.

On the specific subject of tobacco, one commenter asked how oral fluid testing ''interacts chemically with employees who will use tobacco products via dip, smoke or chew prior to testing and of course various mouth washes to cover up.'' The HHS looked at this specific subject when formulating its OFMG. See 84 FR 57565 (Oct.25, 2019). The dark brown juice resulting from some forms of tobacco use can cause discoloration that may interfere with initial testing. This is part of the reason why there is a wait period prior to collection, so the employee can clear their mouth of any material that might stain the collected oral fluid.

In § 40.72(a)(3), the Department continues to emphasize the actual employer must make the refusal determination after the collection site notes the circumstances in the Remarks section of the CCF and reports these to the DER. Determining whether a refusal has occurred is a non-delegable duty of the employer per § 40.355(i). The collector will provide information to the employer to reach a determination about whether a refusal has occurred.

We asked for public comment about whether the collector or the laboratory should check the expiration date on the device used. The comments, including laboratories, industry associations, C/TPAs and collectors were overwhelmingly in support of having the collector check the date and record it, as in the proposed language in § 40.72(d)(3). Many pointed out the collector could discard an expired device and proceed with a new device at the collection site, with no impact on the collection. Conversely, if the laboratory were responsible for checking the expiration date on the oral fluid collection device and the device were expired, then the test would need to be cancelled. Consequently, in this final rule, we have required the collector to check the expiration date on the device and document it on the CCF.

It is important to note the CCF is a document designed by HHS and is not customized to the DOT-regulated drug testing process. HHS allows two separate devices to be used to collect a primary and a secondary specimen. For the reasons set forth in the *Principle Policy* section regarding the requirements for a single specimen to be collected and subdivided in the presence of the donor, the collector will not use two separate devices. Consequently, we have added a new § 40.72(d)(5) to specify the collector must enter the expiration date of the device being used on the CCF line marked in Step 4 of the CCF.

We chose the option designated as ''Split Specimen Device Expiration Date'' instead of the option marked ''Primary/Single Specimen Device Expiration Date'' for entry of the DOT-regulated test's expiration date because part 40 does not allow the use of a ''primary'' collection device, meaning one of two collection devices, nor does it allow for a ''single specimen'' collection device because all devices must be capable of collecting a primary and split specimen. Consequently, to avoid confusion, we require the collector to enter the device expiration date only in the second option in Step 4 of the CCF because it is entitled, ''Split Specimen Device Expiration Date'' and all devices will collect a split and have a single expiration date.

Some commenters asked whether an expired collection device would be a fatal flaw. We had proposed that in § 40.199(b)(8). We have adopted that change, as proposed. We have also added a new § 40.199(b)(9) to create a fatal flaw when the collector fails to note the expiration date for the device in Step 4 of the CCF and the laboratory confirms that the device was expired.

A commenter suggested we include a new provision to allow corrective action when a collector checked the expiration date on the device but forgot to check the box in Step 2 of the CCF to indicate the device was not expired. The documentation to prove the collector checked the expiration date is the collector's notation in Step 4 of the CCF, where the collector will document the expiration date for the oral fluid collection device. Consequently, we agree with the spirit of the suggestion and have amended § 40.208 to add the situation where a collector has entered the collection device expiration and merely forgot to check the box in Step 2. We have also added language to address when the collector enters the expiration date in the wrong spot, as the ''Primary Specimen Expiration Date'', instead of entering the date as the ''Split Specimen Device Expiration Date'' in Step 4 of the CCF. By adding these points to § 40.208, we have made these omissions the basis for creating a memorandum for the record, but the absence of this corrective

documentation will not cause the cancellation of the test.

Commenters, including laboratories and oral fluid device manufactures, supported the provision in § 40.72(b) to have the employee rinse with 8 ounces of water, if something was in the mouth. Several of these commenters noted a rinse with 8 ounces of water for the purpose of clearing the mouth is consistent with current instructions and practices in non-DOT testing.

More than one commenter was hesitant to say consuming water would remedy a dry mouth responsible for an insufficient specimen volume. Quest Diagnostics said, ''the use of water may, but is unlikely, to have a material impact on the amount of oral fluid collected.''

The commenters were supportive of the 10-minute wait and offered comments to enhance the proposal. A4A suggested ''DOT provide a mechanism or guidance regarding the performance-based documentation of the 10-minute period so that collectors may demonstrate compliance with the wait time.'' Since § 40.72 requires the 10-minute wait occur in every collection, the Department will not require the collector to document this on the CCF. However, the commenter raises a fair point about addressing this in guidance. Consequently, in the ODAPC Oral Fluid Specimen Collection Guidelines, we will include more suggestions for best business practices for a collector to use to demonstrate their compliance.

A commenter asked whether the collector failing to give the employee water and wait 10 minutes in a ''dry mouth situation'' would be a ''fatal flaw.'' It would not be a fatal flaw because fatal flaws are laboratory issues. Similarly, in urine testing, we did not classify failure of a collector to make fluids available to an employee during the shy bladder process in § 40.193 as a ''fatal flaw'' in § 40.199.

Regarding proposed § 40.73, one commenter questioned what we meant by referring to conducting collections ''correctly''. We recognize there are differences among the various oral fluid collection kits on the market today and those that will be developed in the future. We expect all oral fluid specimen collectors to follow both the part 40 requirements for collections, as well as the manufacturer's instructions on how to collect the specimen. Each device will have its own instructions, and when we refer to conducting the collection ''correctly'' in this section, we mean using the oral fluid device in the manner described by its manufacturer. The oral fluid collection must be done under the observation of the collector. In addition, the employee must properly position the device. We have added a new § 40.73(c)(1) to reflect these requirements.

We received a comment from Quest Diagnostics regarding § 40.74. Specifically, this commenter ''agrees with the requirement for a minimum of 1 mL of neat saliva for both the ''A'' and ''B'' (split) specimens.'' In addition, after further consultations with HHS, we realized we had drafted this provision too narrowly. There may be scientifically valid and forensically defensible devices that HHS determines do not need a minimum measure of 1 mL of neat saliva. Therefore, we have added the following language to § 40.74(b), ''or an otherwise sufficient amount of oral fluid to permit an HHS-certified laboratory to analyze the specimen(s).'' With this additional language added, we have adopted the amended § 40.74.

As an overall concern, a commenter suggested we refer to the individual being tested as the ''donor'' and not the ''employee'' in §§ 40.72–40.74. To be consistent with the urine collection procedures, we will continue to refer to the individual being tested as the ''employee.''

Subpart F

We are reorganizing subpart F (§§ 40.81–40.97), which addresses drug testing laboratories, to create a logical progression of urine drug testing, oral fluid drug testing, and provisions common to both. This reorganization involves renumbering several provisions and, in some cases, adding language to specify where a provision applies only to urine drug testing. For example, the title of renumbered § 40.86 would be changed to read ''§ 40.86 What is urine validity testing, and are laboratories required to conduct it?'' We have made a technical amendment to the second footnote in the newly renumbered § 40.86.

As an outgrowth of the public comments, we have added new fatal flaws for the laboratories in § 40.83(c)(8) and (9). We have not included a requirement for the laboratories to enter the expiration date on the CCF, as the CCF currently indicates and as commenters objected to in response to the NPRM. Instead, the laboratory must reject a specimen if the collector used an expired device at the time of collection or the collector failed to enter the expiration date in Step 4 of the CCF, but only if the laboratory confirms the device was expired. This mirrors the fatal flaws added to § 40.199(b)(8) and (9). Importantly, it is not the Department's expectation that every laboratory must check every vial for an expiration date. Instead, the laboratory will check the vials only when the collector has not entered the expiration date on the CCF or has entered an expired date. In those hopefully infrequent instances, by checking the date on the vials and ensuring that the expiration date has not passed, the laboratory is saving the test and not declaring it a fatal flaw.

In addition, we asked for comment on decreasing the amount of time laboratories would be required to keep non-negative specimens from 1 year to 90 days, as required by § 40.84 (formerly § 40.99). We explained the change was intended to reduce storage burdens on laboratories. The proposed change would not have affected the 2-year record retention HHS requires for documentation supporting the laboratory's analysis of a non-negative specimen and it would not have changed a litigation hold placed upon the specimen and the paperwork.

We received many comments on this proposal, with the vast majority of those opposing the change. Several commenters in favor of the change said employees challenge the results within 90 days and those commenters recognized that the litigation hold would mean that the specimen would be retained for what is sometimes years. Others said that they appreciated the cost and logistical benefits of having laboratories retain the specimens for a shorter time but suggested 180 days instead of 90 days. Those commenters said the introduction of oral fluid collections will pose additional costs on the laboratories for housing two different kinds of specimens under different preservation methods, so a reduction in time was welcomed.

Those opposing the change cited many substantive arguments for why they thought reducing the time to 90 days would disadvantage employees who want to challenge their result. The most persuasive of the opposing comments noted how an employee who has a non-negative test result needs more time to understand the process and retain counsel who, in turn, would formally place a litigation hold upon the specimen.

We agree with the commenters that 90 days may be too short for the specimen retention where there is no litigation hold. Although we did not propose 180 days as the hold period, we acknowledge that it is a logical outgrowth of the comments. We could adopt that period of time. However, it would be more helpful if we had further insight from public comment on that specific point. Although multiple

commenters suggested 180 days would be better, we did not receive any rationale for the 180 days. Consequently, we have not made any change at this time to the one-year retention period for non-negative test result and have withdrawn the proposed language. In a future rulemaking, it is possible we may consider posing a 180-day retention period instead of a one-year period, but we would want full public comment on such a proposal.

The most notable new portions of subpart F are §§ 40.91–40.93, which cover cutoff concentrations and specimen validity testing (SVT) for oral fluid specimens. These three new sections are drawn from the HHS OFMG and are intended to be consistent with the HHS provisions. For information on the parallel HHS provisions and the HHS rationale for putting them into effect, see the OFMG (84 FR 57554).

One commenter questioned whether HHS had set the correct cutoffs to be as sensitive to the presence of the drugs for which we test as the urine cutoffs are sensitive. While this commenter acknowledged DOT must follow HHS for the science, including the cutoffs for screening and confirmation for oral fluid testing, the commenter was concerned about whether there could be a lack of equivalence between the urine and oral fluid test results and the ultimate fairness of any difference between the two methodologies.

OTETA requires the DOT to follow HHS on the science of drug testing, as the commenter noted, and we must defer to HHS for their scientific determinations. We consulted with HHS regarding this commenter's concerns and were told there were many variable factors that impact the ability to detect a person's drug use. Those factors include biological differences, route of administration, diet and, for urine, hydration status. In addition, whether someone is an occasional drug user or a chronic drug user will impact detection, regardless of methodology. For example, someone's body mass index (BMI) may impact their urine test results for marijuana because THC adheres to fat cells. So, someone with a lower BMI may be less likely to test positive on a urine test than someone with a higher BMI. We have always accepted the impact on drug testing of the various factors mentioned above. Similarly, we acknowledge these factors will impact both urine and oral fluid testing in the future. Since the DOT-regulated testing program is deterrence-based, we acknowledge our focus is on prevention. When an employee abstains from using drugs because they know they will be drug tested, the true result is a benefit to both the individual and to transportation safety. There may be some situations where urine testing may not detect the same drug use as oral fluid does, or vice versa. However, HHS has set the cutoffs for both methodologies to ensure accuracy and fairness. In this approach, HHS and DOT have made the decision to forfeit detecting every single possible positive test result in favor of ensuring accuracy and fairness to each employee tested. Far from a possible ''arbitrary and capricious'' approach suggested by the commenter, it is our carefully weighed decision to ensure accurate and fair testing.

Quest Diagnostics submitted a comment in support of the SVT provisions of §§ 40.92 and 40.93. This commenter agrees with allowing SVT, as long as DOT is consistent with HHS requirements and ''the specific analyte(s) or whether it is performed at all should be left to the discretion of the laboratory.''

In the text of § 40.97, several requirements for laboratories are specified to apply only to urine testing, as they have no application to oral fluid testing. We restated § 40.97 in its entirety, given the number of individual changes made for this purpose. We did not receive any comments opposing these editorial changes, which were not intended to modify the substance of the provisions in question. We have finalized those changes.

We proposed a new data element in § 40.97(c)(1)(i)(I) to require a laboratory to report the collection device expiration date in a laboratory results report for the MRO. An industry association and a major laboratory opposed the addition of this data element. We disagree with the commenters and have included this data element because it applies only in the circumstance where a laboratory wants to report negative results to an MRO in report format. If the laboratory chooses to use Copy 1 of the CCF, the collection device expiration date is included on the CCF and no additional data element is needed. If a laboratory chooses to issue a report for one or more negative results, then the data elements in § 40.97(c)(1) must be included.

An additional major laboratory wanted the collector and not the laboratory to check the expiration date, saying that having the laboratory check the expiration date would be another 20,000 hours of work for laboratories each year. We agree, as we stated in the preamble for § 40.72(d)(3), the collectors and not the laboratories will have that responsibility. However, we see two different issues on the expiration date, neither of which should generate 20,000 hours of laboratory staff time annually. The first issue is who will be responsible for checking the expiration date? This will be the collector per § 40.72(d)(3). The second issue on the expiration date is its importance as a data element, but only if the laboratory chooses to generate its own report to the MRO instead of reporting the result on Copy 1 of the CCF. An expired device could be the grounds for a fatal flaw, but if the laboratory sends a report instead of sending the MRO Copy 1 of the CCF, on which the collector has already provided the expiration date of the device, the MRO would not know about the fatal flaw. Thus, if the laboratory wants to generate a report instead of using Copy 1 of the CCF, then the expiration date needs to be included to ensure the MRO gets the same data as if Copy 1 of the CCF were transmitted by the laboratory. Since the report is optional for laboratories, they could choose to revert to Copy 1 of the CCF for reporting each negative result to the MROs with no burden at all.

In § 40.111, we proposed to add language to paragraphs (a) and (d) to clarify that in their statistical reports to employers and DOT, laboratories need to submit reports to employers for the specimens for which the laboratory tests. Also, we proposed language in § 40.111 to state a laboratory withdrawing from National Laboratory Certification Program (NLCP) certification is required to file with both employers and the DOT an aggregate statistical summary for the last semi-annual reporting period in which it conducted DOT-regulated testing. This data is important to the Department because it helps DOT identify trends regarding non-negative results (*e.g.,* positives, adulterated, substituted and invalid) and cancelled tests. We received one supportive comment regarding these changes and have adopted them as proposed.

Subpart G—Medical Review Officers

With the addition of oral fluid testing, for the most part, MROs would continue to do their work as they have done under the current regulation. Conferring with laboratories, verifying test results by interviewing donors, and the other aspects of the MROs remain the same because this final rule adds an additional methodology, but does not change the basics of the MRO's role. We asked for public comment on whether existing and/or new MROs should receive additional training specifically with respect to their role in oral fluid testing and, if so, what subjects should such training cover. While we agree it

is important for MROs to learn about the science of oral fluid drug testing, the commenters said this is already covered in MRO training.

Several very experienced MROs and practices weighed in on this subject. One large MRO practice did not want to see additional training, but the other commenters did. An active MRO and MRO trainer said, ''Yes training is needed, especially in light of detection windows, cutoffs and collection processes.'' Corporate Medical Services commented, ''MRO training should be enhanced to include Oral Fluid Specimen information during initial training and recertification training, but that the training should not be required prior to reviewing oral specimen for MROs who are currently certified.'' The American Association of Medical Review Officers (AAMRO) said they already instruct on non-DOT oral fluid testing in their online training and their current materials follow the HHS final rule on oral fluid testing. They intend to incorporate any requirements of this DOT final rule. AAMRO said, ''key areas of concentration will be on managing 'shy mouth' and understanding the factors that can result between conflicting urine and oral fluid confirmed results.'' Vault Health Workforce Screening, another MRO practice wants to see oral fluid testing addressed in MRO training and certification. This commenter also noted ''[t]he MRO is required to subscribe to ODAPC's list serve. Through this they are notified of the new regulation once finalized. This would provide them the information on the collection and laboratory process that additional training prior to their re-certification should not be needed.'' We appreciate that perspective on the usefulness of the ODAPC list serve.

Additional commenters on this subject included SAPAA and Quest Diagnostics, who both said there should be additional training required for MROs to include the following, ''differences in laboratory procedures (*e.g.,* cut-off levels) between urine and oral fluid testing, the differences between the detection of parent drugs vs. metabolites where urine and oral fluid differ, differences in windows of detection, and any additional requirements for the interpretation and reporting of codeine and morphine positive results in oral fluid testing.'' Quest Diagnostics urged the Department to require MRO training, echoing the SAPAA comment and adding ''While it would not be practical to immediately augment the training of all MROs, the recognized certification and/or training entities should consider making available oral fluid modules to augment the training of currently certified MROs without having to wait for the next recertification cycle.''

We agree with the commenters who said MROs should be trained on the various aspects of oral fluid testing. We particularly like the approach of suggesting the MRO training organizations offer oral fluid modules to augment the training of MROs who are already current on their training certification requirements. As Vault Health Workforce Screening noted, the MROs will be notified through the ODAPC list serve, and mandatory training for MROs is not needed before their next certification date.

We only proposed to modify a few MRO provisions in subpart G. Specifically, in § 40.121, we have deleted the word ''urine'' from subparagraph (c)(1)(i) because future training for MROs should also include familiarization with oral fluid testing. By removing the word ''urine'' from § 40.121(c)(1)(i), we have opened the section on MRO qualification training to include oral fluid matters. We will not require MROs to undergo recertification training, but strongly suggest MROs seek supplemental information about oral fluid testing by the time HHS certifies at least two laboratories to conduct oral fluid testing.

In § 40.127, concerning MRO reviews of negative results, we proposed specifying that MROs need not review more than 500 negative results ''of all specimen types combined'' in any quarter. This is to clarify that, by adding oral fluid testing to the regulation, we do not intend to increase MROs' negative test result review requirements. We received only supportive comments on this proposal and have included it in this final rule.

In § 40.129(d), we proposed deleting ''drug test report'' and adding the word ''result'' following ''invalid test.'' In § 40.135(d), we proposed deleting the word ''test'' and adding the word ''result.'' This would keep the language of that paragraph internally consistent and consistent with the definition of the term ''invalid result'' in § 40.3. In § 40.139(b), we proposed to add the cutoffs for oral fluid laboratory-confirmed results. This is important because there are different cutoffs for the MRO to consider when the specimen is oral fluid versus urine. These cutoffs trigger a clinical examination for the use of the naturally occurring opiates, codeine and morphine. In addition, in § 40.139(c), we proposed to delete a reference to ''urine,'' since the provision would apply to all DOT drug tests. We received no comments on these changes and have adopted them as proposed.

We proposed a change to the MRO's responsibilities regarding contacting the pharmacy to verify the authenticity of a prescription in accordance with § 40.141(b). For more than twenty years, MROs have been required to personally contact pharmacies to verify a prescription that an employee has cited as a potential legitimate medical explanation for a laboratory-confirmed positive test. We proposed to allow MRO staff to make these inquiries. This would increase efficiency, lower costs, and assist MRO office workflow. No part of the MRO's verification interview of the donor would be changed, only the subsequent checking with the pharmacy to authenticate the prescription. The proposal only addressed the communication between the MRO's staff and the pharmacy to ensure that the prescription the donor provided is or is not authentic.

We received several comments in support of this proposal to change § 40.141(b). Most of the commenters agreed that this would increase efficiency and decrease costs because MRO time would not be spent waiting to speak with pharmacists. One MRO practice characterized calling the pharmacy as ''an administrative task to 'confirm' the information that was presented to the MRO during the interview.'' AAMRO suggested the MRO provide their staff ''with an outline or script and form for documentation. It would also be a good idea for the MRO to monitor a number of these calls to assure the staff call is appropriate.'' ACOEM was unsure this change would be effective because pharmacists are already hesitant to speak with the MROs, who are actual physicians. If a pharmacist does not want to speak with the MRO, they would be less likely to speak with staff. Instead, this commenter wanted the Department to instruct pharmacies that HIPAA does not apply, and they must communicate with the MRO.

We agree with the suggestion that MROs should conduct some oversight of their staff by providing instructions on what to say and occasionally monitoring some of these staff calls. We have added language to § 40.141(b) to set a performance standard for MROs to ensure oversight and quality control measures. While HIPAA does not apply to MROs, who are functioning in DOT-regulated drug testing, a search and seizure process under the Fourth Amendment to the U.S. Constitution, pharmacists are functioning under HIPAA because they are providing healthcare services, often covered by

insurance. Thus, we cannot direct pharmacists to comply. However, as always, under § 40.137(c), the burden of proof is on the employee to establish a legitimate medical explanation. If the pharmacist will not speak with the MRO or the MRO staff, then the MRO practice needs to let the donor know to authorize the pharmacist to communicate the information needed to verify the authenticity of the prescription. If the donor does not do this, then the MRO must report the verified non-negative result because the MRO could not authenticate the prescription, thus the donor did not provide a legitimate medical explanation that could be authenticated per § 40.137(c). Of course, the MRO has the discretion to reopen the verification within 60 days, if the employee is able to provide them access to the pharmacy. After 60 days, the MRO must continue to notify ODAPC before reopening the verification.

We have adopted two clarifying changes to § 40.145 on which we received no comments. In § 40.145(g)(3), we have deleted the word ''urine'' and substituted ''drug,'' since in this context we apply the requirement to test in an HHS-certified laboratory to any such test, whether urine or oral fluid. In § 40.145(h), have added the word ''urine'' after ''substituted''.

In § 40.151(a), we proposed clarifying the language to direct MROs not to accept the result of any drug test not collected and tested under part 40 procedures. If an employee goes to their own doctor the next day and requests a drug test, the MRO must not consider the results of that non-DOT test. We also proposed to delete language referring to DNA tests since use of those tests is prohibited elsewhere in the regulation (*see* §§ 40.153(e) and 40.331(f)). In § 40.151(b), we proposed to change ''urine'' container to ''collection'' container in recognition of the advent of oral fluid testing. In § 40.151(g), we proposed to delete the reference to ''MDEA'', since it was removed in a previous rulemaking (82 FR 52229 (Nov. 13, 2017)), after HHS deleted MDEA from the drug testing panel. MDEA is a Schedule I drug in the amphetamines class and was previously a required confirmatory test analyte before HHS removed it from the HHS Mandatory Guidelines.

In § 40.151(i), we proposed a technical amendment to replace the wording ''with no detectable creatinine'' with ''when the creatinine level is below the laboratory's limit of detection.'' This would ensure consistency with the requirement for laboratories to provide a numerical value for a substituted result (*see* § 40.97(e)(2)). Also, it is our understanding that all HHS-certified laboratories must have an established limit of detection for creatinine of 1mg/dL or less. Thus, when a laboratory reports a creatinine concentration level at less than its limit of detection, MROs can be assured it falls below the creatinine concentration of 2mg/dL for a substituted specimen and an individual cannot physiologically produce such a urine specimen.

We received only one comment regarding our proposed changes to § 40.151. SAPAA said it ''appreciates the clarification language as it will allow the MRO to point to a clearer explanation in the regulations when they receive donor objections.'' With this supportive comment and no others, we adopted all proposed changes to § 40.151.

In § 40.159(a)(1) we proposed to correct the reference to § 40.96(c) to become § 40.96(b) and we proposed adding a new sentence to § 40.159(a)(5)(ii), which would require re-collection when an invalid test is cancelled. The added sentence would direct that an alternate specimen be collected if practicable (*e.g.,* oral fluid, if the specimen was urine). This could result in a more efficient process and reduce the likelihood of multiple invalid specimens resulting from use of the same specimen type.

We received a comment from a C/TPA and MRO practice regarding § 40.159(a)(5)(ii), in which they said, ''We agree with the concept of changing specimen methodology if possible, but feel that it is the employer's decision to do so.'' An industry association specifically supported the new sentence in § 40.159(a)(5)(ii), ''which would require recollection when an invalid test is canceled. However, clarification that the proposed addition applies only to results canceled without a valid medical explanation or where a negative result is required is needed.'' Since § 40.159(a)(5) already makes this clarification, no further rule language is needed and we have adopted it as proposed.

In § 40.163(c)(2), we proposed a small change, substituting ''employee'' for ''donor.'' In § 40.163(e), we also proposed minor wording changes to clarify what records the MRO needs to retain after having reported a result and to clarify that when completing Copy 2 of the CCF, either the MRO must sign and date it (for both negatives and non-negatives) or MRO staff must stamp and date it (for negatives only).

A C/TPA and MRO practice specifically agreed with the changes to § 40.163(e) saying, ''We agree with stressing that the MRO needs to sign and date the CCF copy 2 for non-negative results. The MRO staff may stamp negative test results. All tests must have signed/stamped MRO copy.''

We have adopted the changes to § 40.163 as proposed.

Subpart H, Split Specimen Tests

We proposed a change to § 40.177 to add a reference to the sections pertaining to oral fluid testing. In § 40.179, we proposed to change referenced section numbers in accordance with renumbering and new oral fluid provisions elsewhere in the regulations. In § 40.181, we proposed changing referenced section numbers in accordance with renumbering and new oral fluid provisions elsewhere in the regulations. Another change to § 40.181 is to refer only to urine testing, since the creatinine and specific gravity apply only to urine testing. In § 40.187, we proposed to change references to Appendix D to Appendix F in accordance with the redesignations. We received no substantive comments regarding these changes and have adopted them, as proposed.

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

§ 40.261 What is a refusal to take an alcohol test, and what are the consequences?

The Department proposed edits to § 40.191(a) to add what can constitute a refusal in an oral fluid collection to part 40's existing refusals provisions. The revisions included wording changes to take oral fluid testing into account (*e.g.,* in paragraph (a)(8)), ''fail to permit an inspection of the employee's oral cavity, or fail to remove objects from his or her mouth''), as well as specifying situations that are applicable only to urine testing (*e.g.,* in paragraph (a)(9)), ''fail to comply with an instruction to permit inspection to allow the observer to determine whether there is a prosthetic device in use'').

Like the pre-employment urine and alcohol collection processes, the oral fluid pre-employment collection process generally would not begin until the device is unwrapped. If an employee does not appear for a pre-employment drug test or leaves the collection site before receiving or unwrapping the device, this is not a refusal under § 40.191(a)(1) and (2). However, as in urine testing, certain blatant conduct by the employee at the collection site could constitute a refusal before the collection device is chosen under § 40.191(a)(8). For example, if an employee arriving for a pre-employment test engages in

disruptive or combative conduct at the collection site, a collector could report a refusal event to the employer for determination under § 40.191(a)(8). Also, if the employee shows they are possessing or wearing a prosthetic or other device that could be used to interfere with the collection process, and this becomes evident before the specimen container is unwrapped, a collector could report a refusal event to the employer for determination under § 40.191(a)(10).

Importantly, when an employee is undergoing a pre-employment test and the collector switches to an alternate device, it is considered a continuation of the original collection and is not subject to the pre-employment exception for leaving the collection site before the second device is opened. For example, if a collector begins with one specimen methodology (*e.g.,* urine) and switches to oral fluid (*e.g.,* because the employee was unable to provide a sufficient specimen), the employee must not leave the collection site without refusal consequences.

In addition, we would like to remind employers that, under the existing § 40.23(g), if they receive a cancelled test result on a pre-employment test, the employer must direct the employee to provide another specimen immediately. This second specimen collection is a continuation of the original pre-employment test. This means, as we said in our 2001 final rule on refusals, ''once the collection has commenced, the donor has committed to the process and must complete it.'' 66 FR 41948 (Aug. 9, 2001). As such, the employee must take the second pre-employment test and does not have the ability to decide not to continue this pre-employment testing requirement. In our 2003 final rule on the Drug and Alcohol Management Information System (MIS), we referred to the second test as ''the subsequent collection'' and we reminded employers to report only one pre-employment test result (68 FR 43950, Jul. 25, 2003). Accordingly, the employer would count the second test result as the result of record for this pre-employment test on the DOT's MIS form.

We have revised drug testing refusals § 40.191(d) and added a new § 40.261(c)(1) to alcohol testing refusals to clarify an often-misunderstood point about who has the authority to determine if conduct at the collection site constitutes a refusal to test. Employers often automatically treat as a refusal any situation in which the collection site notes a refusal in the remarks section of the CCF. This is not correct. The new § 40.191(d) emphasizes the role of the collector in a refusal is to notify the employer about the circumstances the collector believes constitute a refusal, but the employer must decide whether a refusal occurred. The new § 40.261(c)(1) specifically spells out the respective responsibilities of the alcohol testing service agent(s) in reporting and the DER in making decisions about whether a situation during an alcohol test constitutes a refusal to test.

Under the long-existing § 40.355(i), making collection site refusal decisions is a ''non-delegable'' duty of the actual employer. Service agents, such as collectors, BATs or STTs, are not and never have been authorized to make this decision. The service agent's role is to provide information to the employer concerning the circumstances of the event. Then the employer, who must make the ultimate decision should, as a matter of responsible decision-making, contact the collector or BAT to gather information and consider anything the employee brings to the employer's attention. Taking the entirety of the circumstances into account, the employer should then make the decision about whether a refusal occurred. The employer also has the discretion to consider information from the employee to determine if the evidence satisfactorily excuses the employee's conduct. For FMCSA-regulated owner-operators, C/TPAs stand in the shoes of those employers for the purposes of determining whether the individual refused a test (§ 382.705(b)(6)).

In this final rule, we emphasize the already existing employer's role in making determinations about collection site and other non-MRO-determined refusals (*e.g.,* failure to appear for a test, failure to take an additional test, etc.). We think it bears repeating that refusals are violations that cannot be overturned in a decision about personnel actions. An arbitration, grievance, State court or other non-Federal forum cannot overturn the employer's determination of a refusal on a DOT-regulated test. When a case proceeds to one of those forums, it is because the employee wants an adverse personnel action reversed. None of those forums has jurisdiction over DOT-regulated Federal drug or alcohol testing, the determination of a refusal under part 40, or the regulatory consequences that exist to ensure transportation safety is served. In the part 40 final rule from December 2000, (65 FR 79470–71), we said, as has been true from the beginning, all the Department requires is that an employee who violates the rule not perform safety-sensitive functions until and unless he or she successfully completes the return-to-duty process. Decisions about discipline and termination are left to the discretion of the employer or labor-management negotiations. Where employer policy, or labor-management negotiations, have delegated personnel decisions of this kind to an arbitrator, the Department intends that the arbitrator's decision determines the personnel action that the employer takes. The Supreme Court has affirmed these principles. *Eastern Associated Coal Corporation* v. *United Mine Workers of America, District 17, et al.,* 531 U.S. 57 (2000). Of course, an arbitrator cannot order an employer to return an employee to the performance of safety-sensitive functions until the employee has successfully completed the return-to duty process. Nor can an arbitrator or an employer change the laboratory's findings about a specimen or an MRO's decision about whether there is a legitimate medical explanation for a test result.

Therefore, we have added a second sentence to §§ 40.191(c) and 40.261(b), to remind the employee and employer that the consequences specified under DOT agency regulations for a violation cannot be overturned or set aside by an arbitration, grievance or State court tasked with adjudicating the personnel decisions the employer decides to take against the employee. As we said in the December 2000 preamble, the employee must successfully complete the federally required return-to-duty process regardless of what the decision is on the personnel action. This ensures safety is not compromised. Importantly, a refusal is a willful violation of the Department's drug and alcohol safety regulations and is completely separate and apart from employment decisions the employer makes.

Some commenters asked for examples of what would not be grounds for an employer to determine a refusal. Of course, the universe of examples is too vast to capture. However, here are a few examples that are not meant to be exhaustive, they are only a tiny fraction of what is possible. Example 1: An employee provides an insufficient quantity of urine, begins the ''shy bladder'' process, but the process is cut short because the collection site sent the employee away because they were closing before the employee had three hours to produce a sufficient urine specimen per § 40.193(b)(2). If the collection site nevertheless reports this to the employer as a refusal, the employer could determine there was no possibility the employee could have completed the test, and therefore could conclude there was no refusal. Example

2: When an employee leaves a collection site due to a documented family medical emergency, the employer could determine the employee's departure from the collection site did not constitute a refusal. Example 3: If an employer sends an employee to report for a DOT-regulated test, but the collection site is closed or is about to close and sends the employee away, the employer would take this into consideration in determining that a refusal did not occur. Example 4: If an employer requests an applicant take a pre-employment test, and the employee does not show for the test, this is not a refusal under part 40 and the employer would appropriately not consider this to be a refusal to test. In all of the examples above, an employer would not report a ''refusal'' in response to a records request made by a prospective employer under § 40.25. Similarly, an FMCSA-regulated employer would not report a ''refusal'' to the Clearinghouse.

If the employer determines that a refusal did not occur, the employer would treat the test as an administratively closed non-event. The employer would not ''cancel'' the test and would not enter it on the MIS report required by DOT. For random, post-accident and reasonable cause/suspicion tests administratively closed as a non-event by the employer, no further action is required, and the employee would not be sent back in for another test. For those testing events that require a ''negative'' test result (*e.g.,* return-to-duty, follow-up, pre-employment), the employer would send the employee back for another collection. In all cases, the employer should document the event and the evidence relied upon to explain why the employer concluded a refusal did not occur.

The Aircraft Owners and Pilots Association (AOPA) said it ''supports the change to § 40.191 that clarifies the employer does not need to automatically treat as a refusal any situation in which the collection site notes a refusal in the remarks section.'' AOPA also asked for clarification in the regulation to indicate ''what the testing center must explain to an individual.''

For decades, it has been a requirement of Federal law, per §§ 40.191(a)(2) and 40.261(a)(2), for an employee to ''remain at the testing site until the testing process is complete.'' With this explicit statement of the requirement to remain at the testing site, we have never put additional requirements on the collector to explain to the employee what the employee's legal requirements are. ODAPC has provided guidance stating the following: ''There is no requirement for a collector to inform an employee that the failure to remain at the collection site is a refusal. Therefore, if the collector does not inform an employee that failure to remain at the collection site is a refusal, it does not mean that the collector has given the employee permission to leave the collection site. If an employee leaves prior to the completion of the testing process, the employer must decide whether the employee's actions constitute a refusal.'' *https://www.transportation.gov/sites/dot.gov/files/docs/resources/partners/drug-and-alcohol-testing/323471/july-2014-part-40-questions-and-answers.pdf.* In response to AOPA's comment for clarification, we have added the following to § 40.191(a)(2) and (3), ''The collector is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal.'' For consistency and as a logical outgrowth of the comment, we have also amended § 40.261(a)(2) and (3) to add the same language.

Two commenters asked for specificity about § 40.191(a)(2) because it deems one ground for determining a refusal is an employee's failure to remain at a ''testing site'' until the process is complete. One commenter noted part 40 does not state ''what constitutes a 'testing site' for this purpose. Is it the waiting room? Is it the building? Is it the building and grounds?'' Another commenter asked for more explanation from the Department about whether it would be a refusal for an employee to step out of a waiting room or to leave a building during a collection.

Since part 40 covers the regulated industries of aviation, motor carriers, transit, railroads, pipelines and is applied to the maritime industry, it would be nearly impossible to define what a ''testing site'' is for every industry and in every circumstance. It could be the clinic in a major airline's hub, the area around a portable toilet in an oil field, an occupational health clinic offering drug tests, or somewhat of an improvised collection site near the scene of an accident. In recognition of the differences among and between these transportation industry employers and the testing sites they and their contractors use, we will continue to defer to the respective employers to make the determination about what is reasonable to construe as the ''testing site'' in a particular circumstance, as they determine whether or not their employee's behavior constituted a failure to remain at that testing site.

One commenter opposed the changes to §§ 40.191(d)(1) and 40.261(c), saying collectors should be the ones to determine whether or not a collection site refusal has occurred. This commenter said most employers ''do not know what to do when the collector informs them that there was an attempt to tamper during the collection. The only witness to the tampering is often only the collector.'' Conversely, another commenter who is a seasoned collector and collector trainer said, ''Thank you for clarifying that collectors do not have the authority to make these. I appreciate the two very common and distressing examples (collection site closing, family emergency for employee) and the clarification that employers have discretion in these cases.''

Several commenters were pleased with the additional clarity we proposed to add to §§ 40.191(d)(1) and 40.261(c) to remind employers that making collection site refusal decisions continues to be their ''non-delegable'' duty. Quest Diagnostics, which includes multiple HHS-certified laboratories and more than a thousand collection sites in the United States, said it ''appreciates the clarification that it is only the employer who can make the determination that a donor refused to take a DOT drug test. While a collector can inform the donor that an employer may view the donor's action as a refusal to test, that decision rests with the employer.''

One commenter noted the importance of the employer making ''the determination regarding a test refusal after seeking comments from the collectors involved in the process.'' Other supportive commenters requested we go further and not say ''the collector could report a refusal to the employer for determination . . .'' A collector training company said this language ''implies that the collector has the ability to make the determination. They suggest better language would be: ''note the actions that may constitute a refusal on the Remarks line . . .' [and they want] ''more directive language'' for employers who must make refusal determinations. Several commenters asked us to amend this proposed rule text ''to be clear the collector will 'notify' an employer of the employee's actions'', so the employer will make the determination of whether or not a refusal has occurred. One commenter asked for more directive language for employers who must make refusal determinations.

In response to the comments, we have amended §§ 40.191(d)(1) and 40.261(c)

to include the language some requested to more clearly indicate that collectors do not determine refusals. Both sections now state, ''As the collector, you must note the actions that may constitute a refusal in the 'Remarks' line (Step 2), and sign and date the . . . [CCF for drug testing or ATF for alcohol testing].'' We think we have been sufficiently directive to employers in adding the following to §§ 40.191(d)(1) and 40.261(c)(2): ''the employer has the sole responsibility to decide whether a refusal occurred.''

More than one commenter asked for guidance on how a collection site should handle an employee who is sent back to the collection site after the employer determines that a refusal did not occur. Because every collector is different and every employee is different, this would be difficult for the Department to include in guidance. What collection site(s) an employer uses would be up to the employer. If another collection site is available for the subsequent collection, the employer might want to choose this collection site for the second collection.

Another commenter asked for advice about ''What actions by the donor prior to selecting the collection device constitutes a refusal in a Pre-employment setting? Which do not?'' The preamble to the final rule establishing exceptions for refusal determinations when a donor leaves a collection site in pre-employment tests merits reiterating. It stated that i]n the pre-employment test context, there can be situations in which an employee could legitimately leave a collection site before the test actually commences (*e.g.,* there is a long wait for the test and the employee has another obligation). By the commencement of the test, we mean the actions listed in § 40.63(c), in which the collector or employee selects a collection container. Once the collection has commenced, the donor has committed to the process, and must complete it. If the employee then leaves before the process is complete, or takes another action listed in this section as a refusal, the consequences of a refusal attach. However, if the employee leaves the site before the test commences, then the employee is in the same situation as someone who does not appear at all for the pre-employment test. The consequences of a refusal do not attach in this situation (§ 40.191(a)(2) and (3)). 68 FR 41948 (Aug. 9, 2001).

However, in a pre-employment situation there could be a refusal to test prior to selecting a collection container. In § 40.191(a)(8) and (10), there are no exceptions for pre-employment tests. These sections address conduct at the collection site that is disruptive or that involves bringing in substituting or adulterating products. Consequently, there could be refusals reported to an employer for a pre-employment applicant. Here are some specific examples, although not an exhaustive list: refusing to empty one's pockets; refusing to wash one's hands; acting disruptively at the collection site; threatening or attempting to bribe collection site personnel; bringing to a collection site a bag of urine or any device that could be used to substitute or adulterate a urine specimen.

§ 40.193 What happens when an employee does not provide a sufficient amount of specimen for a drug test?

We proposed the addition of oral fluid testing to paragraph (a), adding insufficient specimen provisions for oral fluid testing, parallel to the existing insufficient urine specimen procedures. Due to the differences between the two types of specimen collections, the oral fluid insufficient specimen collection procedure is shorter in duration than the insufficient urine specimen collection procedure (*e.g.,* in an oral fluid collection, there is no need for a three-hour wait period). In paragraph (e), we proposed adding examples of conditions that might succeed as medical explanations of providing an insufficient quantity of oral fluid (*e.g.,* autoimmune diseases), as well as examples that would not constitute a valid medical explanation (*e.g.,* unsupported assertions of dehydration). Although one commenter opposed listing any examples of conditions that could be legitimate medical explanations because MROs should be able to ascertain legitimate conditions, we have kept the examples as proposed. In addition, another commenter said MROs are not qualified to assess the legitimacy of shy bladders or dry mouth, but we disagree and will continue to have MROs, who are fully qualified physicians, assess the legitimacy of the conditions underlying an individual's inability to provide a sufficient specimen under any approved testing methodology.

With an alternate specimen methodology now available, an employer may authorize a collector to use a different type of specimen collection process in an insufficient quantity case. If a urine specimen is insufficient, the collector could follow up with an oral fluid collection, or vice-versa. In a case involving an insufficient urine specimen, following the insufficient urine specimen procedures would become unnecessary since an oral fluid collection would be performed. We asked for public comment on these changes and whether allowing a donor to rinse with up to 8 ounces of water is an appropriate amount of fluid for rinsing for the purposes of both §§ 40.72(b) and 40.193(b)(2). We also asked for comment about the questions of who would decide what methodology to use after an insufficient specimen occurs, and when and how such a decision would be made. Since so many oral fluid tests occur each year in non-DOT testing, we were eager to learn from those with experience on what we should know.

We received robust public comment on the above-mentioned subjects and have discussed these in detail in the *Principle Policy* section of this final rule. As explained in the *Principle Policy* section, the Department will not mandate the use of the same or the alternate testing methodology for an insufficient urine specimen (''shy bladder'') or an insufficient oral fluid specimen (''dry mouth''). While not required, it would be prudent for an employer to offer more than one methodology to address such scenarios.

The Department agrees there are several advantages to switching from a urine collection to an oral fluid collection when an employee has presented an insufficient specimen. For example, once an employee provides an insufficient urine specimen, they would have up to three hours to provide a sufficient specimen (during which time the employee should be monitored). If at the end of the three-hour period, the employee still did not provide a sufficient specimen, the employee is required to prove (via a medical evaluation by a referral physician) they have a medical condition to explain their inability to provide a sufficient specimen.

We also acknowledge the commenters' concerns that shy bladder situations merit attention, as we have articulated in our discussion of § 40.193 below. Employers have legal obligations separate and apart from part 40 for providing reasonable accommodations for employees with disabilities. If an individual has a condition rendering that person unable to produce urine falling within the parameters of a disability, this should not be considered to be an effort to evade a test.

Whether the reason for failing to provide a sufficient specimen is substantiated by a medical condition or not, there is a cost (*e.g.,* lost work) to the employer for having the employee wait for up to three hours. Similarly, there is a cost for the medical evaluation which, in most instances, is at the employee's expense. The availability of oral fluid

drug testing means the costs associated with the three-hour wait and the medical evaluation could be avoided while still affording the employee the opportunity to provide a specimen.

Some commenters opposed allowing an insufficient urine collection to go to an oral fluid collection. These commenters were concerned employees who had used drugs several days before the test would withhold their urine in the hopes of having an oral fluid with a shorter window of detection. Some commenters wanted the decision of whether to proceed with another urine collection or to change to an oral fluid collection left to the discretion of the collector after the initial insufficient urine specimen. Since the collector could assess the facts at the collection site, the collector would be the better judge of the best method of testing to deploy.

The majority of the commenters supported the option of changing to a different collection methodology if the employee demonstrates (at the onset) that she or he cannot provide a sufficient specimen. For the reasons outlined above, the Department agrees with those commenters in theory, but we have not mandated that change in drug testing methodologies.

For employers including oral fluid drug testing in their DOT-regulated drug testing program, the Department will allow the employer to switch to an oral fluid collection when an employee does not provide a sufficient urine specimen on their first attempt. Similarly, the Department will allow the employer to switch to a urine collection when an employee does not provide a sufficient oral fluid specimen on their first attempt. Under § 40.193, the employer has this option and the employer should communicate this option to the collector or the collection site in advance of any collection. The employer will need to ensure the collector is a qualified urine and/or oral fluid collector.

In either scenario when there is a successful collection under § 40.193, there is no requirement for the employer to send the employee for an evaluation of the first insufficient specimen type. In the rare circumstance when the employee is not able to provide a sufficient oral fluid specimen after the insufficient urine specimen or vice a versa, the employee would be required to only have an evaluation for the collection of the specimen type attempted under § 40.193. To be clear, the employer must send the employee for only a dry mouth medical evaluation if the employee has not provided a sufficient oral fluid specimen following an insufficient urine specimen. The MRO will only proceed with the dry mouth evaluation and not proceed with the shy bladder evaluation. Similarly, the employer must not send the employee for a dry mouth evaluation if the employee has not provided a sufficient urine specimen following an insufficient oral fluid specimen. The MRO will only proceed with the shy bladder evaluation and not proceed with the dry mouth evaluation. Only a shy bladder medical evaluation is to be done at that point. The final rule reflects this requirement.

Employers should strongly consider having oral fluid as an alternate methodology available for employees who need a reasonable accommodation because of a physiological or pre-existing psychological condition that renders the employee unable to provide a urine specimen. Similarly, if an employee needs a reasonable accommodation for dry mouth, it is advisable for the employer to have urine testing available.

In situations where the employee provides a suspect urine specimen (*e.g.,* temperature out of range, excess foaming, etc.), which leads to a successful oral fluid specimen collection, or vice versa, the collector would send both specimens to the respective laboratories for testing. In this scenario, the MRO would report the multiple verified results from one testing event in accordance with § 40.162. For example, if there were two negative results, a single negative result would be reported to the employer; if there were a negative and a verified non-negative result, only the verified non-negative result would be reported.

In addition, we asked for public comment as to whether the collector should use the same CCF when switching collection methodologies from urine to oral fluid or vise-a-versa. Some commenters thought this would be more efficient. Others thought it was too confusing to list a urine collection on the same form as an oral fluid collection is listed, even if there is an explanation in the ''Remark'' space on the CCF.

We agree with the commenters who said documenting the insufficient first specimen on the same CCF used for the second collection with a different methodology is likely to cause confusion. The laboratory for the urine collection might not be the same laboratory listed on the CCF for the subsequent oral fluid collection. If the specimen from the second collection is sent to the wrong laboratory, it will add confusion and delay, as the specimen will need to be rerouted to the correct laboratory. Not all HHS-certified laboratories for urine collections will be HHS-certified for oral fluid collections, and vice-versa.

For example, the CCF is designed for the collector to complete and document either an oral fluid or a urine collection process (*e.g.,* Step 2 identifies the specimen type, the specimen labels can be used for either type of specimen container). The CCF from a urine-only testing laboratory contains account and billing information only for the employer's urine drug testing account. The CCF from an oral fluid-only drug testing laboratory will contain account and billing information for the employer's oral fluid drug testing account. The CCF from a laboratory that conducts both urine and oral fluid drug testing would contain account and billing information for the employer's urine and oral fluid drug testing accounts. The collector will use a new CCF when switching collection processes. The rule text will reflect the need for the collector to ensure a correct CCF is used. The rule text will also reflect the requirement to document, in the ''Remarks'' section of the CCF, the reason for the changed collection process. It will not be a fatal flaw or correctable flaw if the collector does not make notes in the ''Remarks'' section.

Oral Fluid Insufficient Specimen (''Dry Mouth'') Specifics

Since oral fluid testing and ''dry mouth'' for insufficient oral fluid specimens are new concepts for DOT-regulated testing, the commenters asked many relevant questions. We appreciate the time people took to call out the details because their thoughts and concerns have made this a better final rule.

Some commenters asked exactly how ''dry mouth'' will be determined. The commenters also wanted to know how many attempts and/or how much time would a donor be given before the collector would end the collection and send it on to the DER to provide the contact information for an evaluation by a referral physician.

In § 40.48(c)(1), we use the term ''dry mouth'' to indicate an insufficient oral fluid specimen. This is shorthand, similar to the term ''shy bladder'' used for urine collections, for a situation in which an employee is unable to produce a sufficient specimen. An employee may tell a collector they think their mouth is dry before the collection begins. If the employee states their mouth is dry, then § 40.72(b)(1) requires the collector to give the employee up to 8 ounces of water to rinse their mouth. The employee may drink the water. The collector must then wait 10 minutes

before beginning the specimen collection. Incidentally, the commenters who responded to our question whether 10 minutes was an appropriate waiting time responded unanimously in support of this amount of time. Apparently, it is the industry standard.

It is a dry mouth scenario if the oral fluid device indicates the employee has not provided a sufficient specimen. If dry mouth occurs after the initial collection is attempted, this will begin a one-hour period to allow a sufficient specimen. Also, this necessitates a second oral fluid collection within one hour, or the employer could have a standing order to require the collector to move on to an alternate methodology (*i.e.,* urine) to complete the collection process for the testing event.

Some commenters asked how many attempts at providing an oral fluid specimen should be made before a finding of dry mouth is determined and a referral physician is needed. We were asked to consider conducting research concerning dry mouth. Some commenters wondered if we would require a specific period of time for attempts for an oral fluid collection. In addition, we were asked to describe or define what we meant in § 40.193(b)(2)(i) by requiring that the employee ''remain at the collection site, in a monitored area designated by the collector, during the wait period.''

We proposed procedures to go into effect 15 minutes after an employee fails to produce a sufficient specimen and the procedures would continue for one hour. We have adopted this proposal in § 40.193(b)(2)(i). If an employer has provided for an alternate methodology to be used in oral fluid insufficient specimen situations, then the collector would move on to the alternate methodology, which is currently urine. If the employer does not have this option, then the collector would follow the steps set forth in § 40.193(b)(2)(i) when the employee demonstrates an inability to provide a specimen after 15 minutes of using the collection device. As in urine testing, the time clock begins after the 15 minutes and when the employee attempts but is unable to provide a sufficient quantity of specimen. If the employee states they could provide a specimen after drinking some fluids, the collector must urge the employee to drink (up to 8 ounces) and wait an additional 10 minutes before beginning the next specimen collection (a period of up to one hour must be provided, or until the donor has provided a sufficient oral fluid specimen, whichever occurs first). The employee is not required to drink during the hour and their choice not to drink is not a refusal. The collector must provide a full hour for the employee to attempt another oral fluid collection. If the employee still cannot provide a sufficient specimen, then the collector must note this in the ''Remarks'' line in Step 2 of the CCF, and immediately contact the DER to begin the referral physician process for the dry mouth medical evaluation.

We will not be conducting our own studies on dry mouth but will continue to follow HHS for the science of oral fluid testing, as required by OTETA. In addition, a referral physician would evaluate the employee to obtain and provide to the MRO information about whether a ''medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen'', per § 40.193(d)(1). We rely on the referral physician and the MRO to remain versed in the current medical studies to make these important determinations, as they have done for more than 30 years in shy bladder urine testing cases.

To ''monitor'' an employee during a wait period in an oral fluid collection, we mean the employee must be supervised or observed for security and integrity of the collection process. This ensures they cannot take any actions to interfere with the integrity of the specimen they are required to provide. It does not need to be the actual collector who monitors the employee during the wait period. In fact, in § 40.48(c)(1), we say that the collector can conduct a collection for another employee during this wait period.

§ 40.195 What happens when an individual is unable to provide a sufficient amount of specimen for a pre-employment follow-up or return-to-duty test because of a permanent or long-term medical condition?

The only change we proposed in § 40.195 was in the title, where the more general ''specimen'' is substituted for ''urine,'' in view of the addition of oral fluid testing to the program. However, there were several commenters who wanted an oral fluid test conducted whenever there is a permanent or long-term medical situation.

Section 40.195 is the mechanism for an MRO to rule out the drug use of an employee who has been found under the clinical evaluation in § 40.193 to have permanent or long-term medical condition that renders that employee otherwise unable to produce a sufficient amount of urine required to yield a negative drug test result. A negative drug test result is required for a pre-employment, return-to-duty, or follow-up test. Historically, § 40.195 has not applied to random, post-accident, reasonable cause, or reasonable suspicion tests.

We anticipate most employers will embrace oral fluid testing for employees they know have permanent or long-term medical conditions that affect one's ability to urinate. However, we have not mandated that employers use oral fluid testing for employees with such medical conditions. It would be prudent for an employer to consider various cost factors for an oral fluid test versus a urine test in a shy bladder scenario. In addition, if an alternate methodology is not used, then when a negative drug test result is needed, there is the cost of having yet another evaluation for clinical evidence of drug use so that the MRO can determine whether a ''negative'' result can be issued under § 40.195. While an employer may not want to use two different testing methodologies on a regular basis, the situations of an inability to provide a sufficient specimen for either a urine test or an oral fluid test are excellent reasons for an employer to have a second methodology in place to plan for such contingencies.

One commenter acknowledged § 40.195 ''has long provided relief to employees with permanent or long-term medical conditions preventing the provision of a sufficient urine specimen in the cases of pre-employment, follow-up, or return-to-duty tests, in which a negative test is required.'' This commenter urged the Department to go further to allow an employee to bypass a urine specimen collection by producing documentation of their ''long-term medical conditions preventing giving a complete specimen [regardless of test type].''

While the Department agrees with the spirit of this commenter's point, we do not agree with allowing an employee to produce documentation to avoid a urine specimen collection. Individuals who are unable to produce a sufficient urine specimen, regardless of whether their condition is short-term or long-term, have the potential to undergo an oral fluid specimen collection instead of a urine collection, as long as their employer allows oral fluid testing. Prudent employers should take this into consideration when determining what testing methodologies to allow.

§ 40.197 What happens when an employer receives a report of a dilute urine specimen?

The only textual change in § 40.197 in the proposed rule is in the title, where the word ''urine'' would be inserted because this section concerns situations

that arise only in urine testing. We received no comments regarding this change and have adopted it as proposed.

§ 40.199 What problems always cause a drug test to be cancelled?

We proposed to add a new fatal flaw for use of an expired oral fluid collection device, in § 40.199(b)(8). In § 40.199 (b)(7) of, we proposed to replace the term ''urine'' with ''specimen,'' to reflect the addition of oral fluid testing to the program.

OraSure, a long-established oral fluid device manufacturer, agreed that the use of an expired device should be a fatal flaw. Quest Diagnostics also agreed with the addition of the new fatal flaw and said ''the use of an expired device (at the time of collection) should be considered a fatal flaw and collector error.''

We have adopted the proposed changes to § 40.199 without further change.

§ 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

In §§ 40.199(b)(7) and 40.201(f), we proposed to replace the term ''urine'' with ''specimen,'' reflecting the addition of oral fluid testing to the program. We received no comments on this proposal and have finalized it as proposed.

§ 40.210 What kinds of drug tests are permitted under the regulations?

The proposal acknowledged that oral fluid and/or urine specimens can be collected, and must be tested at HHS-certified laboratories. No other specimen methodologies are currently permitted. Furthermore, we proposed an employer can use one or the other, but not both urine and oral fluid methodologies at the beginning of the testing event. We offered an example ''if an employee is sent for a test, either a urine or oral fluid specimen can be collected, but not both simultaneously.''

ALPA agrees ''with DOT's proposal to require an employer to use one or the other methodology at the beginning of a testing event—but not both simultaneously.'' A consortium and MRO practice also supported ''using one method of testing at the beginning of the testing event, not both simultaneously.''

In § 40.210, we also discussed what to do if a problem arises that would require a second collection. Such problems would include when the employee provides a specimen that is an insufficient quantity of urine, has a temperature out of range, or is an insufficient oral fluid quantity. We asked for comment on whether the employer and/or its service agent would be the correct one(s) to make the decision as to which methodology to use in the second collection.

One commenter suggested using urine first in all collections and to use oral fluid testing if a second collection is needed. Another commenter said it would be easier to finish the testing event by using the same methodology for the second collection. The International Paruresis Association cautioned against continuing with a second urine collection after the employee produced an insufficient urine specimen unless the employee requested this. Another commenter asked ''how things would proceed when the alternate specimen was available only at a different collection site. How would the change of venue be handled? Would someone have to accompany or supervise the employee in transit between Site 1 and Site 2?'' Questions such as these are valid and will be best handled in the collection guidelines for both urine and oral fluid.

The remaining comments on this provision delved into the choices between having the employer and service agent make the choice as to what to do when a second collection is needed. NDASA said the employer should decide what methodology to use for the initial specimen ''and only in cases where an alternative is required to complete the collection, should the service agent make a determination.'' The New York City Department of Transportation commented in support of allowing either the employer or service agent to make a decision about the second collection. An MRO practice, Cynergy, said the employer's ''policy should dictate what is permitted if there is a problem in the collection that necessitates a second collection.''

Under § 40.210 we have retained the flexibility for either the employer, the service agent, or both working together, to decide what methodology to use for a second collection after a problematic first collection. We think the ideal is for the employer's policy to dictate what methodology should be used for the first test and for the second test, should a problem arise. However, if there is no standing order and the collector cannot contact the DER, then the service agent will need to make the decision as to the methodology to be used for the second test. Thus, we have adopted § 40.210 with minor changes to emphasize the flexibility discussed above.

§ 40.225 What form is used for an alcohol test?

We made a conforming change to § 40.225 and redesignated appendix G to be appendix I. We received no comments on this change.

§ 40.283 How does a certification organization obtain recognition for its members as SAPs?

In § 40.283, we made a conforming change redesignating appendix E to appendix G. We no comments received on this change.

§ 40.285 When is a SAP evaluation required?

In § 40.285, the word ''urine'' would be removed if oral fluid testing is added. Having received no comments on this change, we have finalized it.

§ 40.291 What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has violated DOT Agency drug and alcohol testing regulations?

As discussed in the *Principal Policy* section of this final rule, the Department proposed to permit SAPs to conduct evaluations or assessments remotely by amending § 40.291(a)(1) and (3) to remove the requirement that SAP evaluations be only ''face-to-face'' and to explain what is required for remote evaluations. The changes we adopted are fully discussed and resolved in the *Principal Policy* section.

§ 40.293 What is the SAP's function in conducting the initial evaluation of an employee?

For the reasons discussed in the *Principal Policy* section of this final rule, we have removed the words ''face-to-face'' from paragraph (a) this provision to remote evaluations. In the context of remote evaluations and other issues of concern to SAPs, many commenters raised points that we have decided merit changes to § 40.293, as a logical outgrowth of their comments.

Specifically, some commenters expressed concerns about SAPs who are conducting remote assessments without following the requirements of subpart O of part 40. The commenters said some SAPs are not evaluating employees individually and are simply taking their money. The commenters asserted these purportedly noncompliant SAPs are regularly or even exclusively requiring employees to complete online education, regardless of the substance abuse issues the individual employee presents. Additional commenters said some SAPs offer low pricing for their services online and, before evaluating employees, allegedly promise the employees will only need to complete online education to satisfy the return-to-duty requirements, when some of these employees actually may need treatment

after an assessment and clinical evaluation is performed.

We appreciate that these concerns are serious, but we believe they potentially apply to all SAPs, not only those SAPs who conduct remote assessments. It is important to break out the individual points raised by the commenters, in order to explain what is already addressed in the existing subpart O of part 40, what we will not address through regulatory changes, and what we can address through rulemaking, as a logical outgrowth of these comments.

First, under § 40.293(a), each SAP must perform an assessment and clinical evaluation for each employee. Any SAP who is not performing an assessment and clinical evaluation for an individual employee is in direct violation of § 40.293(a). There is no modification to § 40.293(a) needed because the current regulatory language is clear.

Second, if a SAP prescribes online education for most or all of the individual employees that SAP evaluates, then the SAP would be in violation of § 40.293(b) through (d). These sections discuss the appropriate education and/or treatment the SAP would determine is necessary for each employee. In the final rule establishing subpart O, the Department said: ''For someone who performs safety-sensitive transportation functions, the very fact of a violation indicates a disregard of safety that must be addressed, corrected, and monitored in order to ensure safe performance of those functions in the future.'' 65 FR 79470 (Dec. 19, 2000). As a gatekeeper of transportation safety, the SAP has an essential duty to evaluate each employee and consider the employee's violation(s) in order to determine what help that individual needs and how to best address safety through getting the employee the help they need for their unique circumstances. If the SAP were to prescribe the same education and/or treatment requirement for every employee, the SAP would be violating part 40 and failing to fulfill their role as a gatekeeper of safety and enormous responsibility to the public.

The Department recently became aware that some SAPs were providing return-to-duty timelines to employees who violated the DOT drug and/or alcohol regulations before conducting the required initial assessment and evaluation of the employee. In response, we issued a list serve to remind SAPs of their regulatory responsibilities and the SAP's role in evaluating each individual employee and directing that employee to get the specific help the employee needs. *https://content.govdelivery.com/accounts/USDOT/bulletins/3304b9a*.

The SAP process was carefully designed to utilize the clinical evaluation and assessment skills and expertise of the SAP practitioner to evaluate each specific individual employee. The SAP must address the employee's needs for rehabilitation for the sake of the employee and give the employee the tools the employee needs to return to the performance of safety-sensitive duties. Consistent with sound clinical and established SAP standards of care in clinical practice, and utilizing reliable alcohol and drug abuse assessment tools, the SAP must conduct an assessment and evaluation, either in-person or remotely. As stated in ODAPC's SAP Guidelines, ''The evaluation should be comprised of a review of the employee's psychosocial history, an in-depth review of the employee's drug and alcohol use history (with information regarding onset, duration, frequency, and amount of use; substance(s) of use and choice; emotional and physical characteristics of use; and associated health, work, family, personal, and interpersonal problems); and an evaluation of the employee's current mental status.'' *https://www.transportation.gov/odapc/substance-abuse-professional-guidelines*.

In accordance with § 40.293, the SAP must provide a comprehensive assessment and clinical evaluation unique to the employee. As required by § 40.293(b), the SAP must make a recommendation for education and/or treatment that will, to the greatest extent possible, protect public safety in the event that the employee returns to the performance of safety-sensitive functions. Providing estimated return-to-duty dates without such individual assessments and recommendations unique to the individual is yet another concern recently arising.

As a logical outgrowth of the proposal to add an option for remote evaluations and, in response to the concerns about some SAPs failing to individually evaluate, assess and recommend education or treatment, and a follow-up testing plan unique to the needs of each and every employee evaluated, we have added a new paragraph to § 40.293(e). This additional paragraph requires a SAP to use their professional judgment to individualize their assessment, clinical evaluation, education and/or treatment recommendations, and follow-up testing recommendations unique to each employee. In the regulatory text, we provided the example of not having the SAP require the same and/or substantially similar education, treatment and/or follow-up testing plan for most of the employees you assess. If the SAP prescribes the same treatment for every marijuana positive as a result of the SAP's personal philosophy about marijuana use and not as a result of evaluating and clinically assessing the needs of the individual employee, then the SAP is not exercising their professional judgment. If the SAP requires only online training for every employee who comes to the SAP, then the SAP is not individualizing their assessment and, actually, may not even be making an evaluation and assessment. Thus, this would certainly not fall within the bounds of using their professional judgment.

The SAP has highly respected roles and serious responsibilities under the DOT's regulations. The SAP is the key to ensuring the employee receives the education or treatment they need to have meaningful rehabilitation and treatment. In addition, the SAP has the extremely important responsibility of being the gatekeeper for transportation safety. The SAP is required to use their professional judgment to evaluate and assess the employee and direct the employee to get the individualized help they need. When the SAP role is carried out faithfully, the employee gets the help they need toward the road to recovery and toward being able to return to safety-sensitive functions in a way that will not pose a threat to safety. In short, the individualized evaluations and assessments carried out through the SAP's professional judgment as a safety gatekeeper ensure employees get the help they need, and transportation safety is protected and preserved.

Finally, as to costs a SAP advertises or charges, the Department will continue to remain silent, as we do on other questions of who pays and how much one would pay for services rendered to meet the requirements of part 40. Any SAP can charge a fee they determine is appropriate. Since the Department remains silent on all pricing issues, the marketplace controls what SAPs can reasonably charge and what individual employees with part 40 violations are willing to pay. We do not see a reason to intervene in this free market, which has been working successfully for more than 20 years.

§ 40.301 What is the SAP's function in the follow-up evaluation of an employee?

As discussed in *Principal Policy* section of this final rule, we have removed the words ''face-to-face'' from paragraph (b)(2) this provision. We have added the words ''meeting the

requirements of § 40.291(a)(1) of this part'' to allow remote evaluations.

§ 40.307 What is the SAP's function in prescribing the employee's follow-up tests?

In the SAP comments, there were discussions about follow-up testing, and as a logical outgrowth, we are clarifying several points. A follow-up testing plan contains the SAP's recommendation for the number and duration of follow-up tests to be conducted by the employer. The SAP can recommend drug follow-up testing and alcohol follow-up testing for a single drug violation or a single alcohol violation if the SAP determines that is necessary.

However, the SAP has no authority to determine the dates when the testing is to be done, that is up to the employer. The SAP can indicate the follow-up tests should be done close in time to certain triggering events for the employee (*e.g.,* birthdays, anniversaries of deaths, long weekends, etc.) or the SAP can choose not to make such suggestions.

The key to successful follow-up testing is that it is not announced to the employee in advance. If the employer, the SAP, or another service agent provides the follow-up testing plan to the employee, the employee can anticipate how many tests will take place and ''plan'' the period of time they need to abstain from illegal drug use or alcohol misuse to successfully complete their follow-up tests. Thus, it was always the intent that no one provide the follow-up testing schedule to the employee. We have added a new paragraph (g) to clarify this.

§ 40.311 What are the requirements concerning SAP reports?

For the reasons discussed in the *Principal Policy* section of this final rule, we have adopted the proposal to add the words ''and format (*i.e.,* face-to-face or remote)'' to § 40.311(c)(4), (d)(4), and (e)(4). In addition, we have amended § 40.311 to direct SAPs to note on their SAP reports whether a given evaluation occurred face-to-face or remotely.

Also as discussed in the *Principal Policy* section, we have adopted the proposal to change ''SSN'' to ''SSN or employee ID number'' in § 40.311(c)(1), (d)(1), and (e)(1) for consistency of terms in part 40 and to allow the use of additional identification numbers in SAP reports, instead of solely the SSN.

§ 40.327 When must the MRO report medical information gathered in the verification process?

In § 40.327, we proposed to add a clarification requiring MROs not to use the CCF to transmit information about safety concerns to employers or other authorized parties. Rather, a separate communication (*e.g.,* secure email or letter) must be used and will specify whether the MRO's safety concern relates to the use of a medication, the type of medical condition for which such a medication is typically prescribed, or some combination of the two. The purpose of providing this information is to allow the employer and/or any third parties to focus on the MRO's specific concern, rather than having to make an open-ended inquiry. This clarification echoes the Department's 2017 final rule preamble discussion that medical information is sent apart from the verified result report. (82 FR 52229, 52236; Nov. 13, 2017).

Several commenters, including NDASA and multiple MRO practices, supported this clarification. The Drug and Alcohol Testing Association (DATIA) commented in support of the proposal, saying: ''The MRO must take appropriate steps to balance public safety concern and the right to privacy of the individual that is subject to testing. We support fully the Department's 2017 final rule preamble discussion that medical information or any other communication regarding a safety sensitive concern should be processed and reported separately from the standard result report.''

Another major industry association opposed the proposal and appeared to be confused about what is currently required. The association said MROs should continue to report a significant safety risk with a negative test result. However, MROs have not been permitted to report the two simultaneously since 2017. Under § 40.135(e), MROs have been required to wait five business days between reporting a negative test result and reporting a significant safety risk they have determined under § 40.327 regarding an employee who does not hold DOT-regulated medical certification. *See* 82 FR 52236 (Nov. 13, 2017).

One MRO practice thought the clarification would allow the MRO ''to discuss specifics with the DER, avoiding more vague references to safety concerns thus enabling a more focused fitness for duty process.'' This commenter supported the proposal.

There is no duty of confidentiality between the MRO and the employee, as every MRO must declare to each employee. Instead, per § 40.135(d), the MRO is ''required to provide third parties drug testing information and medical information affecting the performance of safety-sensitive duties that the employee gives . . .'' Under § 40.135(d)(2), this includes ''information on medicines or other substances affecting the performance of safety-sensitive duties that the employee reports using or medical conditions the employee reports having.'' Thus, with informed consent, the employee provides such information to the MRO who can share it with the employer. However, what the employer does with such information may impact the Americans with Disabilities Act or other Federal, State or local civil rights laws and responsibilities. These are matters outside the jurisdiction of the DOT. Employers should consult with their counsel to understand how they can use such information received by the MRO without violating the Americans with Disabilities Act, the Rehabilitation Act of 1973, or other State or Federal laws. We are adopting § 40.327 as proposed.

§ 40.345 In what circumstances may a C/TPA act as an intermediary in the transmission of drug and alcohol testing information to employers?

As a conforming change, we have updated the reference from appendix F to appendix H, § 40.345. There were no comments on this point.

§ 40.355 What limitations apply to the activities of service agents?

In § 40.355(n) (Example 3), we have removed the word ''urine'' to allow the section to apply to both approved methodologies for testing. We received no comments on this proposed change.

We received one comment regarding § 40.355(a), which we had not proposed to change. The commenter asked us to include the term ''treatment provider'' in list of the entities that must not require an employee to sign a consent form. The commenter noted the term ''treatment provider'' is included in the DOT's HIPAA statement (*https://www.transportation.gov/odapc/hipaa-statement*), and in the Release of Information section of the DOT's Substance Abuse Guidelines (*https://www.transportation.gov/odapc/substance-abuse-professional-guidelines*). In the HIPAA statement, we say ''SAPs need no written authorizations from employees to conduct SAP evaluations, to confer with employers, to confer with MROs, to confer with appropriate education and

treatment providers, or to provide SAP reports to employers.'' We state this because SAPs are performing a role as a safety official within the bounds of part 40 and not as a health care provider. Thus, it would not be appropriate for us to instruct treatment providers, who are likely covered under HIPAA when they accept insurance payments, to communicate with third parties without the consent of their patient/client. It would also be outside the jurisdiction of the Department to do this. On page 10 of the SAP Guidelines, we instruct SAPs to provide information to treatment providers, but we lack jurisdiction to require treatment providers to provide information to SAPs.

Section 40.355(a) would not restrict a SAP from asking an employee to execute a HIPAA waiver with the treatment provider to provide the SAP with information about treatment progression and conclusion. That information is essential to the SAP being able to determine whether the employee has successfully complied with the education and/or treatment. Without this information, the SAP cannot complete the follow-up evaluation of the employee. It is in the best interests of the employee to execute such a release for the treatment provider to communicate. If the employee does not provide the appropriate releases and the information is not conveyed to the SAP, then the employee will not be permitted to return to work. We think this natural progression of the process has been successful and we have not made the suggested change.

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

We proposed to amend § 40.365 to say a PIE could occur because a SAP failed to conduct an evaluation using the means provided in § 40.291(a)(1), rather than because there was no face-to-face evaluation. NDASA and several other commenters concurred with the change. We have adopted it as proposed.

Appendices

Appendix A, concerning urine collection kits remains unchanged. We have added a new Appendix B, establashing standards for oral fluid collection kits, based on material in the HHS OFMG and consistent with OTETA requirements for a split specimen. The remainder of the appendices have been renumbered and reordered, as explained below. For a summary of these changes, see the redesignation table.

Appendix B

Appendix B describes the requirements for the contents of an oral fluid collection kit. Where we could conform to the HHS OFMG, we did so. We differed from HHS in some aspects of the collection kits because OTETA requires a single collection that must be subdivided in the presence of the employee. This necessitated unique requirements for DOT-regulated entities. For a full discussion of the comments in support of and opposing our approach in appendix B, as well as the Department's responses, see the section-by-section analysis above for § 40.49.

In viewing the public comments and in consultation with HHS, we restructured appendix B, section 1(a) to address future devices that may be invented, as well as neat collection devices that currently exist in what we now have as appendix B, section 1(a)(1). We have a new appendix B, section 1(a)(2), similar to what we proposed, for devices utilizing a buffering solution. We have removed some specific language from the proposal regarding quantities of specimens and percentages of undiluted (neat) oral fluid because these do not need to be included in part 40. An oral fluid collection device will not be permitted to be used in the DOT-regulated drug testing program unless HHS has approved a certified laboratory to deploy a particular device. In other words, unless HHS has approved an HHS-certified laboratory to use a particular oral fluid collection device, that device will not be used. So, it is unnecessary and inconsistent for part 40 to create device or volume specifications separate from those of HHS. This is part of the scientific aspect of drug testing we defer to HHS.

Alere Toxicology provided comments including language edits with which we agree and have added to the final rule language, with slight modification. Specifically, this commenter recommended a change in appendix B, section 1(a) of ''specimen bottle or tube'' instead of merely ''specimen bottle.'' They also suggested a change to appendix B, section 1(a) to add ''a single pad or dual pads'' for a description of the single collection which can be subdivided into two separate collection tubes. We have added these to appendix B, section 1(a)(2) and have included a slight modification to make it clear that the dual pads must be joined for insertion together into the same spot in the mouth. This further clarifies details about the single collection device that would be subdivided in the presence of the donor, which we must require under OTETA.

We appreciate ALPA's comments, in which they supported the way we have described neat and wet collections in appendix B, section 1(a). They believe we have met OTETA on the requirements for these devices.

OraSure requested ''additional language should be added allowing for the use of a single device, consisting of 2 cotton fiber pads, placed back-to-back or side by side, which after the collection, can be split into an A & B samples.'' We agree and the language added to appendix B section 1(a)(2) described above should address this. OraSure asked us to leave room to allow entirely different types of devices ''that could be pad based or non-pad-based devices so long as they meet'' what we are asking for under OTETA. This is a reasonable request, and we have added the new appendix B, section 1(a)(1) to include devices that we have not contemplated as of this time.

Both buffered and undiluted (neat) specimen collection devices must have an expiration date. For clarity, we have added a parenthetical to appendix B, section 1(e) to indicate the expiration date is the shortest expiration date of any component. We recognize that this date could be more than a decade after an undiluted (neat) specimen collection device is manufactured. However, we proposed and there were no dissenting comments regarding the need for an expiration date. We want to ensure the integrity of the testing process and that collectors will always enter the device expiration regardless of whether the device is a buffered collection device or an undiluted (neat) specimen collection device.

We asked for public comments specifically regarding whether devices should be sufficiently transparent so the collector can observe whether there is anything unusual about the specimen collected and take action to perform a re-collection, if appropriate. We proposed language in appendix B, section 1(c) to ensure that transparency.

Several commenters including DATIA, OraSure, Quest Diagnostics, the New York City Department of Transportation, and others commented in favor of this proposal. Many commenters said the tubes should be sufficiently transparent, or at least semi-transparent, to assist collectors in detecting adulteration. Alere San Diego also agreed, saying ''the tube . . . should be sufficiently transparent to allow the collector the ability to ensure the sample is visible.'' We agree with these commenters.

In addition, some commenters wanted to see a minimum volume indicator built into the device or vials to ensure

the collector has gathered enough specimen for the laboratory to process. One commenter noted that there are at least two devices already on the market with an indicator showing whether enough fluid was collected. We agree with these commenters and have finalized the proposed language.

In appendix B, section 1(h), we proposed to require the tamper-evident bottle seals for bottles A and B ''not conceal printed information.'' NDASA urged that we not require the use of ''clear security labels'' because it would be a cost increase. In addition, NDASA said ''clear label materials are an untested technology, without evidence of how a clear label product could affect the collection device and its components. For the collector to verify the expiration date during the collection process and then adhere paper-based security seals which are already in use and industry standard, should suffice in the collection process.'' Quest Diagnostics also strongly stated we should not require transparent seals ''because of high costs of manufacturing the transparent seals (estimated at an increase of $300,000 annually) and the intended purpose would be for the lab to be better able to read the expiry dates, which the collectors should do.'' In addition, Quest Diagnostics noted, ''the current seals stand up to heat of travel and freezing in the lab, transparent labels may not do as well.''

We appreciate these concerns and observations. We will only require that the seals not conceal the printed information on Bottles A and B and that the seals not be damaged by the employee initialing or the collector signing them. This creates a performance standard, and we are not requiring more specific details for compliance with this provision.

We have amended the proposed appendix B, section 1(i) to state the oral fluid collection device ''must be approved by HHS for use by the specific HHS-certified laboratory that will test the specimen gathered by this device.'' As discussed above, if HHS approves the use of a particular device by an HHS-certified laboratory, we defer to that approval.

Appendix D

The resdesignated appendix D (the former appendix B) concerns semi-annual reports laboratories provide to employers. The new appendix D sets forth matters to be reported with respect to urine and oral fluid testing respectively. No comments were received on these changes, and they are adopted as proposed.

Appendix E

In the redesignated appendix E (the former appendix C), the Department proposed to amend the data elements that HHS-certified laboratories submit to DOT semi-annually. With this change, laboratories will continue to provide the DOT with the drug testing data but to be broken out by specimen type (*i.e.,* urine and oral fluid), DOT agency (*i.e.,* FMCSA, FAA, FRA, FTA, PHMSA, the US Coast Guard) and test reason (*i.e.,* pre-employment, random, reasonable suspicion/cause, post-accident, return-to-duty, other, and follow-up). The proposal required each laboratory to submit multiple data summaries as opposed to the one data summary they now provide. The additional data elements will assist the Department in evaluating the efficacy of testing by oral fluid versus urine. In addition, we anticipate developing a better understanding of any trends in drug testing by specimen type, DOT agency and/or test reason(s).

There were very few comments to the proposed biannual reporting changes. One DOT-regulated employer opposed the concept of collecting data from laboratories at all because the collectors make errors on the test type and the DOT agency they list on the CCF. This employer thought these mistakes would make the data unreliable. We also received public comments suggesting there would be cost associated with adding the proposed data elements, but no costs were quantified by the commenters.

While any change to searches set up for data collection may have an initial cost, the changes to the redesignated appendix C fall within data elements already collected by the laboratories. We did not ask for new data to be collected. It is our understanding that most, if not all of the HHS-certified laboratories capture these data elements either as a result of implementing the electronic Federal Drug Testing Custody and Control Form, or in their Laboratory Information Management System, as part of tracking the specimens and reporting out test results to the Medical Review Officer.

The Department has required laboratories to submit data biannually since 2018. This data has proven to be effective in analyzing drug use trends. Even though there could be some potential collector errors, there is still great utility for this data collection. Due to this value to DOT and since no quantifiable burdens were identified with adding the new data elements, we have adopted the changes as proposed.

Appendix F

Current appendix D, concerning reports on split specimen failures to reconfirm, will become appendix F under this final rule. We proposed to add the ''specimen type'' as another element to the information the MRO currently provides so we can track the two specimen types. We received no comments on this proposal, other than to agree with the redesignation of the appendices, and have adopted the changes to appendix D.

Appendix G

Current appendix E, on SAP equivalency requirements for certification organizations, would become appendix G. We received no comments on this proposal, other than to agree with the redesignation of the appendices, and have adopted it as proposed.

Appendix H

Current appendix F, concerning drug and alcohol testing information can be transmitted by C/TPAs, would become appendix H. We received no comments on this proposal, other than to agree with the redesignation of the appendices, and have adopted it as proposed.

Appendix I

Current appendix G, the Alcohol Testing Form, would become appendix I. We received no comments on this proposal, other than to agree with the redesignation of the appendices, and have adopted it as proposed.

Appendix J

Finally, appendix H, the MIS data collection form, would be found in appendix J. We received no comments on this proposal, other than to agree with the redesignation of the appendices, and have adopted it as proposed.

Miscellaneous Comments Outside the Scope

We received many comments outside the scope of this rulemaking. These included a request for a new provision to say, ''if a test is given to an employee who per the applicable agency rule should not have been subjected to that test, it must be treated for all purposes as a non-DOT test.'' We received several comments about the PIE process. A few commenters wanted to see an appeal process for any positive or refusal verified by an MRO, as well as any employer-determined refusals.

Another commenter wanted guidance or regulatory text to address how people should proceed if the donor or collector

appears to be ill at the time of the test. A standard approach cannot be applied because each situation is different. In § 40.61(b)(2) we already say that medical care for the employee is to be provided before the drug test is administered.

One commenter wanted us to have collectors and collection sites ''explicitly warn employees of the consequences of non-cooperation or leaving a collection site prematurely, which could be done via posters or words in the script collectors use to begin the process with employees.'' The requirement to follow the DOT's regulations is a matter of Federal law, so the collectors are not obligated to remind employees of their duties under the regulations that govern their work responsibilities. However, we are aware that many collectors, as a best practice do warn employees. In addition, ODAPC has issued several posters that collection sites and workplaces can post to remind employees ''What You Can Lose if You Refuse.''

NDASA made several suggestions that are outside the scope but are helpful suggestions for revisions to our collection guidelines. They suggested including in our guidelines the situations of ''donors who enter the facility claiming inability to provide a specimen before an attempt to provide is made, donors leaving before shy bladder is complete, the point at which the actual collection process begins, who may and may not determine a refusal to test.'' NDASA also suggested we ''produce an updated collector training video to include all specimen types.'' Another helpful suggestion was to clarify if the collector can rely on an expired identification as proof of their identity. We will address that in our collection guidelines.

We also received a comment requesting refusal training for all employers. This is outside the scope of part 40. Instead, the DOT agency regulations would need to include such requirements for their respective regulated employers.

Another commenter requested a strengthening of and expansion for the conflict-of-interest provisions in part 40. This issue is outside the scope of this regulation. Also, as this commenter mentioned, ''the provisions that already exist in § 40.101 regarding prohibited relationships and in other areas of part 40 that speak to improper actions on the part of a service provider, and retaliation for reporting improper actions to employers and regulators''.

Other comments outside the scope included requests to remove urine testing, add hair testing, include point of collection testing (without laboratory-based testing included), removing marijuana testing, and other matters involving the science of DOT-regulated testing. As we have said many times, OTETA requires DOT to follow HHS for the drugs for which we test, the scientific and technical aspects, and that we must use HHS-certified laboratories for the screening and confirmation of our regulated specimens. Thus, these comments are outside the scope of this rulemaking and have not been further addressed.

Common Preamble

While part 40 provides the regulatory provisions for how to administer drug and alcohol testing, the DOT agency regulations provide the specifics of what employers and employees are subject to testing and when to conduct the testing. In order to allow oral fluid drug testing across the DOT-regulated transportation industries, we must make some minor adjustments to some of the DOT agency regulations. Specifically, we are making conforming changes to 14 CFR part 120 (FAA), 49 CFR part 219 (FRA), 49 CFR part 382 (FMCSA), and 49 CFR part 655 (FTA), all of which are directly subject to the OTETA mandate to follow the HHS Mandatory Guidelines for the scientific and technical requirements for oral fluid testing under part 40. Without the changes explained in this Common Preamble, these DOT agencies would not be able to allow oral fluid testing. Consequently, this final rule addresses urine-specific provisions; adds, removes and modifies definitions; and makes other technical changes specifically set forth below. Incidentally, PHMSA has determined it does not need to make any changes to its drug testing regulations to permit oral fluid testing, thus there are no changes to 49 CFR part 199 in this final rule. Part 199 utilizes the testing procedures of part 40.

FAA

In 14 CFR part 120, the FAA has revised the definitions of ''Alcohol'' to be consistent with part 40. The FAA has corrected the definition of ''Refusal to submit to drug test'' to reference covered employees. It is important to note this is not a change in coverage, it is only a technical change to phrasing. The FAA has added the definition of ''Alcohol misuse'' to reference the alcohol misuse prohibitions under subparts C or D of part 120. The FAA has removed the following definitions because they are unnecessary and/or already defined in part 40: ''Alcohol Concentration (or content)'', ''Alcohol use'', ''DOT agency'', ''Verified negative drug test result'', and ''Verified positive drug test result''. Due to the removal of these definitions, several paragraphs of § 120.7 have been redesignated and the definitions of ''Covered employee'' and ''Employee'' have been updated. In §§ 120.119(b) and 120.219(b)(2), the FAA has changed references to ''Appendix H'' to become references to ''appendix J'' because those appendices are redesignated in part 40. In §§ 120.111(d) and 120.221(d), the FAA corrected references to ''employee'' to ''covered employee.'' All of these changes are conforming only and do not otherwise amend the underlying provisions of 14 CFR part 120.

Federal Railroad Adimistration (FRA)

FRA has made the followings changes to the regulatory text in part 219, which are solely for purpose of either conforming with part 40 or correcting an error in the regulatory text, and do not affect the substance of FRA's rule.

In 49 CFR part 219, FRA amended §§ 219.11(a)(2) and (h), 219.617(b)(2), 219.619, 219.621(a), and 219.903(a) to conform with changes made today to part 40. FRA's revisions have generally removed the term ''urine'' and replaced it with references to body fluid specimens to capture both the existing urine specimens and the new alternate oral fluids specimens.

FRA has made minor technical corrections to § 219.4. To conform with terminology used in part 40, FRA replaced the term ''return-to-service'' with ''return-to-duty'' in § 219.4(a) and (b)(1) and (2). FRA has further amended § 219.4(b)(2) to remove an incorrect reference to ''paragraph (d) of this section'' and replaced it with the correct reference to ''§ 219.104(d),'' which establishes the return-to-duty requirements this paragraph addresses.

FRA has also made the following technical changes to part 240—Qualification and Certification of Locomotive Engineers and part 242—Qualification and Certification of Conductors. The amended provisions previously used the word ''urine'' when referencing certain provisions of part 219 that a railroad must consider when determining whether a person may be or remain certified as a locomotive engineer or conductor. These changes are solely for the purpose of conforming with part 40 and do not affect the substance of FRA's locomotive engineer and conductor certification regulations. Specifically, in part 240, FRA is amending § 240.119(e)(4)(iv)(A) and (f)(1)(iii) to replace the word ''urine'' with the words ''body fluid.'' In part 242, FRA is amending § 242.115(e)(4)(iv)(A) and (f)(1)(iii) to

replace the word ''urine'' with the words ''body fluid.''

With respect to oral fluid and FRA post-accident toxicological testing, persons subject to part 219 should note that FRA's post-accident toxicological testing requirements in part 219, subpart C are not subject to the OTETA mandate and therefore do not follow part 40 procedures. *See* §§ 40.1(c), 219.205(a), and 219.701(a) and (b). This final rule allowing for oral fluid testing therefore does not apply to FRA post-accident toxicological testing, which still requires urine and blood specimens, as well as body fluid and tissue specimens for post-mortem tests. *See* §§ 219.203(a)(1), 219.205(a), and 219.207(a).

Federal Motor Carriers S* * * Administration (FMCSA)

In part 382, the FMCSA has amended §§ 382.107, 382.401(b) and (c), 382.403(b), 382.409(b), and 382.705(a) to conform with changes made to part 40. The revised text includes references to oral fluid specimens as an alternate to urine specimens and added the term ''oral fluid collectors'' as necessary. The FMCSA also updated references to sections of part 40 (*i.e.,* references to appendices) that were redesignated in the oral fluids final rule and has added references to a Medical Review Officer's reversal of canceled drug test results. These changes are conforming only and do not otherwise amend the underlying provisions of 49 CFR part 382.

Federal Transit Administration (FTA)

In 49 CFR part 655, FTA has amended § 655.53 to add ''oral fluid collector''. FTA has modified § 655.71 to explicitly add ''oral fluid specimen'' to conform with changes made today to part 40 to add oral fluid specimens as an alternate to urine specimens, a small technical change is being made to correct ''breathe'' to ''breath'', also. In §§ 655.47 and 655.61(a)(3), FTA revised the term ''employee'' to read as ''covered employee.'' FTA has made technical changes to conform with the rest of Parts 40 and 655, including amending § 655.5(c) to update their street address; revised § 655.15(e) by replacing ''illegal'' with ''prohibited''; and revised § 655.44(a)(1)(i) by correcting a reference to ''part 389''. These changes are technical or conforming only and do not otherwise amend the underlying provisions of 49 CFR part 655.

Good Cause for Adoption Without Prior Notice and Comment

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with prior notice and comment for rules when the agency for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking.

The changes being made to the regulations of FAA, FMCSA, FRA, and FTA are all conforming technical edits to conform with the OST part 40 regulations. Because the underlying part 40 regulations received the benefit of notice and comment, further public comment on the conforming edits is not necessary.

IV. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the internet—

1. Search *regulations.gov* (*https://www.regulations.gov*) for the docket number listed at the beginning of this document; or

2. Search the Office of the Federal Register's web page (*https://www.federalregister.gov*) for the RIN listed at the beginning of this document.

V. Regulatory Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review)

The Office and Management and Budget (OMB) has determined that the rulemaking action is not significant under Executive Order 12866 (''Regulatory Planning and Review''), as supplemented by Executive Order 13563 (''Improving Regulation and Regulatory Review''). Accordingly, OMB has not reviewed it under that order.

The final rule allows transportation employers and drug test collection sites to use oral fluid testing instead of urine testing for DOT-regulated drug tests. Compared with the baseline scenario in which employers must use urine testing for all drug tests, the rule may reduce costs for employers and collection sites, improve the effectiveness of drug testing, and reduce burdens for individuals undergoing testing. Oral fluid testing is optional in all but very rare cases, and DOT expects that employers would adopt it only when benefits exceed costs.

The extent of the benefits depends on the degree to which employers and collection sites adopt oral fluid testing. For non-DOT drug tests, an increasing number of companies utilize oral fluid testing. In 2022, 38% of respondents to a drug testing industry survey reported that their company already offered oral fluid testing.[3] An additional 48% expected that their company would offer oral fluid testing after SAMHSA and DOT establish guidelines. Some of the respondents may not be involved in DOT-regulated testing, but the results demonstrate industry interest in adopting oral fluid testing.

Cost Savings

Allowing employers to use oral fluid testing may result in cost savings for employers by reducing the time individuals need to spend undergoing testing. Most urine collections occur in separate collection facilities, requiring individuals to travel to and from the facilities. Oral fluid collection could occur at or near the workplace, reducing travel time.

Oral fluid testing may also reduce resources needed to administer tests. Collectors administering urine tests must secure the site to ensure the integrity of the testing process. Securing the site involves restricting access to water sources and ensuring that individuals cannot alter or switch urine samples. Oral fluid testing, in contrast, is directly observed and requires fewer resources to ensure testing integrity.

Oral fluid testing may offer a less time-consuming alternate to existing procedures when an employee cannot produce a sufficient urine specimen—for example, in a ''shy bladder'' situation or when specimens show evidence of tampering. Currently, employers must give individuals up to three hours to try producing a urine specimen again. If an individual still cannot produce a urine sample, the employer must refer the individual to a physician for further evaluation. The rule would allow employers to switch immediately to an oral fluid collection after the first failed attempt. Employers could similarly switch from oral fluid to urine collection if, for example, an employee has a ''dry mouth'' situation.

DOT estimated cost savings for employers in the NPRM but has not done so for the final rule. In the NPRM, DOT used testing costs from industry and projected adoption rates from the HHS rule on oral fluid guidelines to estimate annual net cost savings of $25.0 million by the fourth year. As detailed in ''Principal Policy Considerations,'' commenters disputed the information used. Some commenters asserted that an oral fluid test has slightly higher costs than a urine test, in

[3] Current Consulting Group. 2022. ''The 2022 Drug Testing Industry Survey.'' *http://www.currentconsultinggroup.com/wp-content/uploads/2022/07/2022-Drug-Testing-Industry-Survey.pdf.*

part because oral fluid collection kits use chemical buffering solutions with a limited shelf life. At the same time, economies of scale may lead to lower unit costs for oral fluid tests if the drug testing industry increases its volume of testing. Given the uncertainty of testing costs and lack of data on other aspects of testing, DOT has not estimated cost savings or other benefits for the final rule. Nonetheless, commenters acknowledged the potential for cost savings.

Improved Effectiveness of Testing

Allowing employers to use oral fluid testing may improve the effectiveness of drug testing. Oral fluid testing can detect the recent use of some drugs, including marijuana and cocaine,[4] [5] while urine drug testing has a longer window of detection. More effective drug testing could deter employee illicit drug use and reduce safety risks from drug use.

Reduced Burdens for Individuals Undergoing Testing

Oral fluid testing can reduce anxiety, discomfort, and other burdens for individuals undergoing testing because it is less intrusive and time-consuming than urine testing. For example, while most DOT-regulated urine tests are unobserved, a small number require direct observation. In observed tests, an observer of the same gender as the employee watches the employee urinate into the collection container. Allowing the alternative of oral fluid testing would reduce discomfort and other issues for individuals, including potential civil rights issues for transgender or non-binary individuals. Reducing the burdens associated with testing may also reduce barriers to transportation employment for individuals deterred by current testing requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of their regulatory actions on small businesses and other small entities and minimize any significant economic impact.

The Department does not expect that the rule would have a significant economic impact on a substantial number of small entities. The rule increases flexibility for small-entity transportation employers and drug test collection sites by allowing them to use oral fluid testing instead of urine testing to meet DOT testing requirements. Oral fluid testing is a voluntary option for the small entities. Accordingly, the Department certifies that the rule would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates

The Secretary has examined the impact of the final rule under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under section 202(a) of the UMRA because this rulemaking does not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by either State, local, and Tribal governments in the aggregate or by the private sector in any one year. In fact, by providing a lower cost alternative to urine drug testing, the final rule would reduce costs to regulated parties, including State and local entities (*e.g.,* public transit authorities, public works departments) whose employees are subject to testing.

Environmental Impact

The DOT has analyzed the environmental impacts of this action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, ''Procedures for Considering Environmental Impacts'' (44 FR 56420, October 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). This final rule amends the transportation industry drug testing program procedures regulation to include oral fluid testing. Paragraph 4(c)(5) of DOT Order 5610.1C incorporates by reference the categorical exclusions for all DOT Operating Administrations. This action is covered by the categorical exclusion listed in the Federal Transit Administration's implementing procedures, ''[p]lanning and administrative activities that do not involve or lead directly to construction, such as: . . . promulgation of rules, regulations, directives . . .'' 23 CFR 771.118(c)(4). The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Executive Order 13132: Federalism

The Secretary has analyzed the final rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Most of the regulated parties under the Department's drug testing program are private entities. Some regulated entities are public entities (*e.g.,* transit authorities, public works departments); however, as noted above, this proposal would reduce costs of the Department's drug testing program and provide additional flexibility for regulated parties. Accordingly, the Secretary has determined that the final rule does not contain policies that have federalism implications.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 9, 2000) requires Federal agencies to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive order, include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This final rule does not have tribal implications. Nor will they have substantial direct effects on Tribal governments, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175.

[4] Edward J. Cone and Marilyn A. Huestis. 2007. ''Interpretation of Oral Fluid Tests for Drugs of Abuse.'' *Annals of the New York Academy of Sciences* 1098, 51–103. *https://doi.org/10.1196/annals.1384.037.*

[5] Rebecca Jufer, Sharon L. Walsh, Edward J. Cone, and Angela Sampson-Cone. 2006. ''Effect of Repeated Cocaine Administration on Detection Times in Oral Fluid and Urine.'' *Journal of Analytical Toxicology* 30(7): 458–462. *https://doi.org/10.1093/jat/30.7.458.*

Paperwork Reduction Act

The PRA requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public. We will need a new data collection section for oral fluid specimens on the U.S. Department of Transportation Drug and Alcohol Testing MIS Data collection form (OMB No. 2105–0529), which DOT-regulated employers currently use to report their urine drug testing data annually. There will be no increase in the number of tests conducted. For those employers choosing to use oral fluid, in addition to urine testing, there will simply be a redistribution of the total number of tests split between the drug testing methodologies the employer uses. Thus, for the employers who choose to use both methodologies, we expect a nominal increase in the burden hours because they will have one more simple section to fill out on the form. The information collections for oral fluid testing are covered by HHS under OMB Control Number 0930–0158. Notwithstanding any other provisions of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a currently valid OMB control number.

Privacy Act

Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.) For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation (ICAO), it is FAA policy to conform to ICAO Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that its portion of this final rule does not conflict with any international agreement of the United States.

List of Subjects

14 CFR Part 120

Air carriers, Alcoholism, Alcohol abuse, Aviation safety, Drug abuse, Drug testing, Operators, Reporting and recordkeeping requirements, Safety, Safety-sensitive, Transportation.

49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

49 CFR Part 219

Alcohol abuse, Drug abuse, Drug testing, Penalties, Railway safety, Reporting and record keeping requirements, Safety, Transportation.

49 CFR Part 240

Administrative practice and procedure, Locomotive engineer, Penalties, Railroad employees, Railroad operating procedures, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 242

Administrative practice and procedure, Conductors, Penalties, Railroad employees, Railroad operating procedures, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 382

Administrative practice and procedure, Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Penalties, Safety, Transportation.

49 CFR Part 655

Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Grant programs—transportation, Mass transportation, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons stated in the preamble, the Department amends 14 CFR chapter 1 and 49 CFR chapters I through III and VI as follows:

Title 14—Aeronautics and Space

PART 120—DRUG AND ALCOHOL TESTING PROGRAM

■ 1. The authority citation for part 120 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101–40103, 40113, 40120, 41706, 41721, 44106, 44701, 44702, 44703, 44709, 44710, 44711, 45101–45105, 46105, 46306.

■ 2. Revise § 120.7 to read as follows:

§ 120.7 Definitions.

For the purposes of this part, the following definitions apply:

(a) *Accident* means an occurrence associated with the operation of an aircraft which takes place between the time any individual boards the aircraft with the intention of flight and all such individuals have disembarked, and in which any individual suffers death or serious injury, or in which the aircraft receives substantial damage.

(b) *Alcohol* means any substance specified in 49 CFR part 40.

(c) *Alcohol misuse* means any prohibited conduct referenced under subpart C or D of this part.

(d) *Contractor* is an individual or company that performs a safety-sensitive function by contract for an employer or another contractor.

(e) *Covered employee* means an individual who performs, either directly or by contract, a safety-sensitive function listed in §§ 120.105 and 120.215 for an employer (as defined in paragraph (g) of this section). For purposes of pre-employment testing only, the term ''covered employee'' includes an individual applying to perform a safety-sensitive function.

(f) *Employee* is an individual who is hired, either directly or by contract, to perform a safety-sensitive function for an employer, as defined in paragraph (g) of this section. An employee is also an individual who transfers into a position to perform a safety-sensitive function for an employer.

(g) *Employer* is a part 119 certificate holder with authority to operate under parts 121 and/or 135 of this chapter, an operator as defined in § 91.147 of this chapter, or an air traffic control facility not operated by the FAA or by or under contract to the U.S. Military. An employer may use a contract employee who is not included under that employer's FAA-mandated drug and alcohol testing program to perform a safety-sensitive function only if that contract employee is included under the contractor's FAA-mandated drug and alcohol testing program and is performing a safety-sensitive function on behalf of that contractor (*i.e.,* within the scope of employment with the contractor.)

(h) *Hire* means retaining an individual for a safety-sensitive function as a paid employee, as a volunteer, or through barter or other form of compensation.

(i) *Performing* (a safety-sensitive function): an employee is considered to be performing a safety-sensitive function during any period in which he or she is actually performing, ready to perform, or immediately available to perform such function.

(j) *Positive rate for random drug testing* means the number of verified positive results for random drug tests conducted under subpart E of this part, plus the number of refusals of random drug tests required by subpart E of this part, divided by the total number of random drug test results (*i.e.,* positives,

negatives, and refusals) under subpart E of this part.

(k) *Prohibited drug* means any of the drugs specified in 49 CFR part 40.

(l) *Refusal to submit to alcohol test* means that a covered employee has engaged in conduct including but not limited to that described in 49 CFR 40.261, or has failed to remain readily available for post-accident testing as required by subpart F of this part.

(m) *Refusal to submit to drug test* means that a covered employee engages in conduct including but not limited to that described in 49 CFR 40.191.

(n) *Safety-sensitive function* means a function listed in §§ 120.105 and 120.215.

(o) *Violation rate for random alcohol testing* means the number of 0.04, and above, random alcohol confirmation test results conducted under subpart F of this part, plus the number of refusals of random alcohol tests required by subpart F of this part, divided by the total number of random alcohol screening tests (including refusals) conducted under subpart F of this part.

§ 120.111 [Amended]

■ 3. Amend § 120.111 in the first sentence of paragraph (d) by adding the word ''covered'' before the word ''employee''.

§ 120.119 [Amended]

■ 4. Amend § 120.119 in the first sentence of paragraph (b) by removing ''appendix H'' and adding in its place ''appendix J''.

§ 120.219 [Amended]

■ 5. Amend § 120.219 in the first sentence of paragraph (b)(2) by removing ''appendix H'' and adding in its place ''appendix J''.

§ 120.221 [Amended]

■ 6. Amend § 120.221 in the first sentence of paragraph (d) by adding the word ''covered'' before the word ''employee''.

Title 49—Transportation

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

■ 7. 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.*

■ 8. Amend § 40.3 by:

■ a. Removing the definitions of ''Invalid drug test'' and ''Screening drug test'';

■ b. Removing the definition of ''Initial drug test (also known as ''Screening drug text'') and adding a definition for ''Initial drug test'' in its place;

■ c. Removing the definition of ''Limit of Quantification'' and adding a definition for ''Limit of Quantification (LOQ)'' in its place;

■ d. Adding in alphabetical order definitions for ''Alternate specimen'', ''Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse)'', ''Cutoff'', ''Oral fluid specimen'', ''Specimen'', ''SSN or Employee ID No.'', ''Undiluted (neat) oral fluid'', and ''Urine specimen''; and

■ e. Revising the definitions of ''Collection container'', ''Collection site'', ''Confirmatory drug test'', ''Initial specimen validity test'', ''Invalid result'', ''Laboratory'', ''Limit of Detection (LOD)'', ''Non-negative specimen'', ''Primary specimen'', ''Reconfirmed'', ''Shipping container'', ''Specimen bottle'', ''Split specimen'', ''Split specimen collection'', and ''Substituted specimen''.

The additions and revisions read as follows:

§ 40.3 What do the terms used in this part mean?

* * * * *

Alternate specimen. An authorized specimen, other than the type of specimen previously collected or attempted to be collected.

* * * * *

Collection container. A container used to collect a specimen.

Collection site. A place selected by the employer where employees present themselves for the purpose of providing a specimen for a drug test.

* * * * *

Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse). A database, administered by the Federal Motor Carrier Safety Administration, containing records of commercial motor vehicle drivers' violations of controlled substances and alcohol testing program requirements, as set forth in part 382 of this title, as well as their return-to-duty status.

* * * * *

Confirmatory drug test. A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify a specific drug or drug metabolite.

* * * * *

Cutoff. The analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

* * * * *

Initial drug test. The first test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Initial specimen validity test. The first test used to determine if a specimen is adulterated, diluted, substituted, or invalid.

Invalid result. The result reported by an HHS-certified in accordance with the criteria established by HHS when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards set by HHS; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part.

Limit of Detection (LOD). The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantitation (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

* * * * *

Non-negative specimen. A specimen that is reported as adulterated, substituted, positive (for drug(s) or drug metabolite(s)), or invalid.

* * * * *

Oral fluid specimen. A specimen that is collected from an employee's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands. An oral fluid specimen is considered to be a direct observation collection for all purposes of this part.

* * * * *

Primary specimen. In drug testing, the specimen bottle that is opened and tested by a first laboratory to determine whether the employee has a drug or drug metabolite in his or her system; and for the purpose of specimen validity testing. The primary specimen is the portion of the donor's subdivided specimen designated as the primary (''A'') specimen by the collector to distinguish it from the split (''B'') specimen, as defined in this section.

* * * * *

Reconfirmed. The result reported for a split (Bottle B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (Bottle A) specimen.

* * * * *

Shipping container. A container that is used for transporting and protecting specimen bottles and associated

documents from the collection site to the laboratory.

Specimen. Fluid, breath, or other material collected from an employee at the collection site for the purpose of a drug or alcohol test.

Specimen bottle. The bottle that, after being sealed and labeled according to the procedures in this part, is used to hold a primary (''A'') or split (''B'') specimen during transportation to the laboratory. In the context of oral fluid testing, it may be referred to as a ''vial,'' ''tube,'' or ''bottle.''

Split specimen. In drug testing, the specimen that is sent to a first laboratory and stored with its original seal intact, and which is transported to a second laboratory for retesting at the employee's request following MRO verification of the primary specimen as positive, adulterated or substituted.

Split specimen collection. A collection in which the single specimen collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

SSN or Employee ID No. This number serves as a unique identifier that must be used on the Federal Drug Testing Custody and Control Form (CCF) or Alcohol Testing Form (ATF) for a donor, on the MRO's reports, on SAP reports, or on other documents that are required under this part. For all purposes of this part, this term means: only the Commercial Driver's License (CDL) Number and State of issuance for drivers tested under the authority of the Federal Motor Carrier Safety Administration (FMCSA); and, for all drivers and other safety-sensitive employees tested under the authority of the other DOT agencies, this can be the individual's actual Social Security Number, a unique identifier issued by the employer, a State-issued identification card number, a State-issued driver's license number (including a CDL number) or any other State-issued or federally-issued identification number.

* * * * *

Substituted specimen. An employee's specimen not consistent with a normal human specimen, as determined by HHS (*e.g.,* a urine specimen, with creatinine and specific gravity values that are so diminished, or so divergent that they are not consistent with normal human urine).

* * * * *

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example: A collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Urine specimen. Urine collected from an employee at the collection site for the purpose of a drug test.

* * * * *

■ 9. Amend § 40.13 by revising paragraphs (b), (c), and (d), redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively, adding new paragraph (e), and adding paragraph (h).

The revisions and additions to read as follows:

§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?

* * * * *

(b) DOT tests must take priority and must be conducted and completed before a non-DOT test is begun. When conducting a urine DOT drug test, you must discard any excess urine left over from a DOT test and collect a separate urine void for the subsequent non-DOT test.

(c) Except as provided in paragraph (d) of this section, you must not perform any tests on DOT specimens other than those tests specifically authorized by this part or DOT agency regulations. For example, you must not test a DOT specimen for additional drugs. In addition, a laboratory is prohibited from making a DOT specimen available for a DNA test or other types of specimen identity testing.

(d) When a DOT urine drug test collection is conducted as part of a physical examination required by DOT agency regulations, it is permissible to conduct medical tests related to this physical examination (*e.g.,* for glucose) on any specimen remaining in the collection container after the DOT portion has been sealed into the specimen bottles.

(e) A non-DOT drug or alcohol test administered, as part of a physical examination, is not a DOT drug or alcohol test for purposes of this part and/or related DOT agency drug and alcohol testing rules, if that test was performed to determine if an employee is medically qualified for a license or certificate. Consequently, the results of such a test do not have consequences under this part.

* * * * *

(h) No one is permitted to conduct a DOT drug or alcohol test on an individual who is not a DOT-regulated employee, as defined by the DOT agency regulations.

* * * * *

■ 10. In § 40.14 by revising paragraph (b) and adding paragraph (k) to read as follows:

§ 40.14 What information must employers provide to collectors?

* * * * *

(b) SSN or Employee ID No.'';

* * * * *

(k) Specimen type to be collected (*i.e.,* oral fluid or urine).

■ 11. Amend § 40.21 by:

■ a. Removing the word ''and'' from the end of paragraph (c)(2)(vii)(B);

■ b. Redesignating paragraph (c)(2)(vii)(C) as paragraph (c)(2)(vii)(D); and

■ c. Adding a new paragraph (c)(2)(vii)(C).

The addition reads as follows:

§ 40.21 May an employer stand down an employee before the MRO has completed the verification process?

* * * * *

(c) * * *

(2) * * *

(vii) * * *

(C) For a verified negative result, the employee will not be required to submit an alternate specimen for the same testing action. For a cancelled result, the employee could be required to submit an alternate specimen on a re-collection; and

* * * * *

■ 12. Amend § 40.23 by revising paragraphs (f) introductory text and (f)(1) and (5) to read as follows:

§ 40.23 What actions do employers take after receiving verified test results?

* * * * *

(f) As an employer who receives a drug test result indicating that the employee's test was cancelled because it was invalid and that a second collection must take place under direct observation—

(1) You must immediately direct the employee to provide a new specimen under direct observation (either an oral fluid specimen or a urine specimen under direct observation).

* * * * *

(5) You must ensure that the collector conducts the collection under direct observation (either an oral fluid specimen or a urine specimen under direct observation).

* * * * *

■ 13. Amend § 40.25 by revising paragraph (a) to read as follows:

§ 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?

(a)(1) Yes, as an employer, you must, after obtaining an employee's written

consent, request the information about the employee listed in paragraphs (b) through (j) of this section. This requirement applies only to employees seeking to begin performing safety-sensitive duties for you for the first time (*i.e.,* a new hire, an employee transferring into a safety-sensitive position). If the employee refuses to provide this written consent, you must not permit the employee to perform safety-sensitive functions.

(2) If you are an employer regulated by FMCSA, you must comply with the requirements of this section by using the FMCSA's Drug and Alcohol Clearinghouse in accordance with 49 CFR 382.71(a). In addition, you must continue to comply with the requirements of this § 40.25 when checking an employee's testing history with employers regulated by a DOT operating administration other than FMCSA.

(3) If you are an employer regulated by FMCSA, with a prospective employee subject to drug and alcohol testing with a DOT agency other than FMCSA, you must continue to request the information about the employee listed in paragraphs (b) through (j) of this section. For example, if you are an employer regulated by both FMCSA and PHMSA, and you are hiring an employee to perform functions regulated by both DOT agencies, then you must query FMCSA's Clearinghouse to satisfy FMCSA's requirements and you must request the information listed in paragraphs (b) through (j) of this section to satisfy PHMSA's requirements.

* * * * *

§ 40.26 [Amended]

■ 14. Amend § 40.26 in the second sentence by removing ''Appendix H'' and adding in its place ''appendix J''.

§ 40.29 [Removed]

■ 15. Remove § 40.29.

■ 16. Amend § 40.31 by:
■ a. Revising the section heading;
■ b. Revising paragraph (b);
■ c. Redesignating paragraphs (c) and (d) as paragraphs (d) and (e);
■ d, Adding new paragraph (c);
■ e. Revising newly redesignated paragraph (d); and
■ f. Adding paragraph (f).

The revisions and additions read as follows:

§ 40.31 Who may collect specimens for DOT drug testing?

* * * * *

(b) A urine collector must meet training requirements of § 40.33.

(c) An oral fluid collector must meet the training requirements of § 40.35.

(d) To avoid the appearance of a conflict of interest, if you are the immediate supervisor of the employee being tested, you must not act as the collector when that employee is tested, unless no other collector is available and you are permitted to do so under DOT agency drug and alcohol regulations.

* * * * *

(f) Employees are not permitted to be their own collector.

(1) An employee who is a qualified collector is not permitted to be their own collector; another qualified collector must perform the collection in accordance with this part.

(2) To avoid a potential conflict of interest, a collector must not be related to the employee being tested (*e.g.,* spouse, ex-spouse, relative) or a close personal friend.

■ 17. Amend § 40.33 by revising the section heading, introductory text, and paragraph (f) introductory text to read as follows:

§ 40.33 What training requirements must a collector meet for urine collection?

To be permitted to act as a urine collector in the DOT drug testing program, you must meet each of the requirements of this section:

* * * * *

(f) *Error correction training.* If you make a mistake in the collection process that causes a test to be cancelled (*i.e.,* a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining. Errors that cause cancellation but occur outside the collection process (*e.g.,* when a specimen is crushed or otherwise damaged during the transportation process, or is lost in transit), the cancellation would not be the result of an error by the collector during the collection process and does not require the collector to be retrained.

* * * * *

§ 40.35 [Redesignated as § 40.36]

■ 18. Redesignate § 40.35 as § 40.36.

■ 19. Add a new § 40.35 to read as follows:

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

To be permitted to act as an oral fluid collector in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Basic information.* You must be knowledgeable about this part, the current ''DOT Oral Fluid Specimen Collection Procedures Guidelines,'' and DOT agency regulations applicable to the employers for whom you perform collections. DOT agency regulations, guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE, Washington DC, 20590, 202–366–3784, or on the ODAPC website (*https://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: *https://www.transportation.gov/odapc/get-odapc-email-updates.*

(b) *Qualification training.* You must receive qualification training meeting the requirements of this paragraph (b). Qualification training must provide instruction on the following subjects:

(1) Training on the testing procedures of this part;

(2) Training to proficiency in the operation of the particular oral fluid collection device(s) you will be using.

(3) All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;

(4) ''Problem'' collections (*e.g.,* situations like ''dry mouth'' and attempts to tamper with a specimen);

(5) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(6) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(c) *Initial proficiency demonstration.* Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections for each device you will use.

(1) The five mock collections for each device must include one uneventful collection scenario, one insufficient specimen quantity scenario; one scenario in which the employee has something in their mouth that might interfere with the collection; one scenario in which the employee attempts to tamper with the specimen; and one scenario in which the employee refuses to sign the CCF. For each of the five mock collections, the collector must check the expiration date of the device, show it to the employee, and record the date on the CCF used. The collector must ensure, when applying the labels, they do not cover the expiration dates.

(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.'' 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.

(d) *Schedule for qualification training and initial proficiency demonstration.* You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

(e) *Refresher training.* No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c).

(f) *Error correction training.* If you make a mistake in the collection process that causes a test to be cancelled (*i.e.,* a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining.

(1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (c)(2) of this section.

(2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(3) As part of the error correction training, you must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections. The mock collections must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were ''error-free.''

(g) *Documentation.* You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

§ 40.37 [Removed]

■ 20. Remove § 40.37.

■ 21. Revise the heading for subpart D to read as follows:

Subpart D—Collection Sites, Forms, Equipment and Supplies Used in DOT Urine and Oral Fluid Collections

§ 40.41 [Redesignated as § 40.42]

■ 22. Redesignate § 40.41 as § 40.42.

§ 40.45 [Redesignated as § 40.40]

■ 23. Redesignate § 40.45 as § 40.40.

■ 24. Amend newly redesignated § 40.40 by:

■ a. Revising the section heading and paragraphs (a) and (b), (c) introductory text, and (c)(1) through (4); and

■ b. Removing the words ''social security number (SSN) or other employee identification (ID) number'' and adding in their place ''SSN or Employee ID No.'' in paragraph (d).

The revisions read as follows:

§ 40.40 What form is used to document a DOT collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every collection required by the DOT drug testing program. You may view this form on the Department's website (*https://www.transportation.gov/odapc*) or the HHS website (*https://www.workplace.samhsa.gov*).

(b) You must not use a non-Federal form or an expired CCF to conduct a DOT collection. As a laboratory, C/TPA or other party that provides CCFs to employers, collection sites, or other customers, you must not provide copies of an expired CCF to these participants. You must also affirmatively notify these participants that they must not use an expired CCF.

(c) As a participant in the DOT drug testing program, you are not permitted to modify or revise the CCF except as follows:

(1) You may include, in the area outside the border of the form, other information needed for billing or other purposes necessary to the collection process.

(2) The CCF must include the names, addresses, telephone numbers and any other appropriate contact information (*e.g.,* an email address of the employer and the MRO), including the DER's name and contact information. All of this information must be preprinted, typed, or handwritten. Fax numbers may be included but are not required. The MRO information must include the physician's name and address, as opposed to only a generic clinic, health care organization, company name, or post office box. This information is required, and an employer, collector, service agent or any other party is prohibited from omitting it. In addition, a C/TPA's name, address, telephone and fax numbers, and any other appropriate contact information should be included, but is not required. The employer may use a C/TPA's address in place of its own, but must continue to include its name, telephone and fax numbers, and any other appropriate contact information.

(3) As an employer you may preprint the box in Step 1–D of the CCF for the DOT agency under whose authority the test will occur.

(4) As a collector, you may use a CCF with your name, address, telephone number, and fax number preprinted, but under no circumstances may you sign the form before the collection event. If a collection takes place at a clinic, the actual address of the clinic should be used, not a corporate address of the collection company. If the collection takes place onsite at the employer, the employer's address must be noted as the collection site address. If the collection takes place in a ''mobile unit'' or at an accident site, the collector must enter the actual location address of the collection or as near an approximation as possible. The collector must ensure that the required collector telephone number is the number that the laboratory, MRO, or employer may use to directly contact the individual collector and/or the collector's supervisor during the collection site's business hours. The collector must not provide a number for a call center.

* * * * *

§ 40.47 [Redesignated as § 40.41]

■ 25. Redesignate § 40.47 as § 40.41.

§ 40.41 [Amended]

■ 26. Amend newly redesignated § 40.41 in paragraph (a) by removing the word ''urine'' wherever it appears.

■ 27. Amend § 40.43 by revising the section heading to read as follows:

§ 40.43 What steps must operators of collection sites and collectors take to protect the security and integrity of urine collections?

* * * * *

§ 40.49 [Redesignated as § 40.44]

■ 28. Redesignate § 40.49 as § 40.44.

§ 40.51 [Redesignated as § 40.45]

■ 29. Redesignate § 40.51 as § 40.45.

■ 30. Add §§ 40.47, 40.48, 40.49, and 40.51 to subpart D to read as follows:

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§ 40.47 Where does an oral fluid collection for a DOT drug test take place?

(a) An oral fluid collection for a DOT drug test must take place in a collection site meeting the requirements of this section.

(b) If you are operating an oral fluid collection site:

(1) You must ensure that it meets the security requirements of § 40.48;

(2) The site may be a permanent or temporary facility located either at the work site or at a remote site;

(3) The site may be in a medical facility, a mobile facility (*e.g.,* a van), a dedicated collection facility, or any other location meeting the requirements of this section; and

(4) You must have all necessary personnel, materials, equipment, and facilities that include privacy and supervision to provide for the collection, temporary storage, and shipping of specimens to a laboratory, and a suitable clean surface for writing.

(c) If a collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident investigation), another site may be used for the collection, if the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with this part and the manufacturer's procedures for the collection device.

§ 40.48 What steps must operators of collection sites and collectors take to protect the security and integrity of oral fluid collections?

(a) Collectors and operators of collection sites must take the steps listed in this section to prevent unauthorized access that could compromise the integrity of collections.

(b) As a collector, you must do the following before each collection to deter tampering with specimens:

(1) Ensure that access to collection materials and specimens is effectively restricted;

(2) Ensure that undetected access (*e.g.,* through a door not in your view) is not possible; and

(3) Ensure the security of the facility during the collection process to maintain privacy to the employee and prevent distraction of the collector. Limited-access signs must be posted.

(c) As a collector, you must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only one employee at a time. However, during the time one employee is in the period for drinking fluids in a ''dry mouth'' situation (*see* § 40.72(b)(1)), you may conduct a collection for another employee as long as the employee with ''dry mouth'' remains supervised.

(2) To the greatest extent practicable, keep an employee's collection container within view of both you and the employee between the time the employee has provided the oral fluid specimen and the specimen is sealed.

(3) Ensure you are the only person in addition to the employee who handles the specimen before it is sealed with tamper-evident seals.

(4) In the time between when the employee gives you the specimen and when you seal the specimen, remain within the collection site.

(5) Maintain personal control over each specimen and CCF throughout the collection process.

(d) If you are operating a collection site, you must implement a policy and procedures to prevent unauthorized personnel from entering any part of the site in which oral fluid specimens are collected or stored.

(1) Only employees being tested, collectors and other collection site workers, DERs, employee and employer representatives authorized by the employer (*e.g.,* employer policy, collective bargaining agreement), and DOT agency representatives are authorized persons for purposes of this paragraph (d).

(2) You must ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(3) You or the collector may remove any person who obstructs, interferes with, or causes a delay in the collection process.

(e) If you are operating a collection site, you must minimize the number of persons handling specimens.

§ 40.49 What materials are used to collect oral fluid specimens?

For each DOT drug test, you must use a collection device meeting the requirements of appendix B of this part.

§ 40.51 What materials are used to send oral fluid specimens to the laboratory?

(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from damage in the transport of specimens from the collection site to the laboratory.

(b) You are not required to use a shipping container if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

■ 31. Revise the heading for subpart E to read as follows:

Subpart E—Specimen Collections

■ 32. Amend § 40.61 by revising the section heading and paragraphs (a), (b)(1) introductory text, (b)(3) and (4), (e), and (f)(5)(i) to read as follows:

§ 40.61 What are the preliminary steps in the drug testing collection process?

* * * * *

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's work site, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing, the DER must determine whether the employee has refused to test (*see* §§ 40.191(a)(1) and 40.355(i)). In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing (other than for a pre-employment test) and the employee does not appear, the C/TPA must determine whether the employee has refused to test (*see* §§ 40.191(a)(1) and 40.355(j)).

(b) * * *

(1) If the employee is also going to take a DOT alcohol test, you must ensure, to the greatest extent practicable, that the alcohol test is completed before the drug testing collection process begins.

* * * * *

(3) You must not collect a specimen from an unconscious employee to conduct a drug test under this part.

(4) You must not catheterize a conscious employee for purposes of a urine test. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner. If an employee normally voids through self-catheterization, but

declines to do so for the urine test, the collector should notify the DER of the circumstances, so that the actual employer can determine whether the situation constitutes a refusal to test by the employee.

* * * * *

(e) Explain the basic collection procedure to the employee, and notify the employee that instructions for completing the CCF can be found at the HHS (*https://www.samhsa.gov/workplace*) and DOT (*https://www.transportation.gov/odapc*) websites.

(f) * * *

(5) * * *

(i) Determine if the material appears to be brought to the collection site with the intent to alter the specimen, and, if it is, either conduct a directly observed urine collection using direct observation procedures (*see* § 40.67) or an oral fluid specimen collection, make a note on the CCF and continue with collection process; or

* * * * *

■ 33. Amend § 40.63 by revising paragraph (a) to read as follows:

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

* * * * *

(a) Ensure all items under Step 1 of the CCF are complete and accurate (*e.g.,* if Step 1.D is not checked, put a check mark for the ''Specify DOT Agency'' under the authority of which the test will take place; if the address where the collection is actually taking place is not in Step 1.G, update that.)

* * * * *

■ 34. Amend § 40.65 by revising the section heading and paragraphs (b)(5) and (6), and (c)(1) to read as follows:

§ 40.65 What does the collector check for when the employee presents a urine specimen?

* * * * *

(b) * * *

(5) If the specimen temperature is outside the acceptable range, you must immediately conduct a new urine collection using direct observation procedures (*see* § 40.67) or an oral fluid collection.

(6) In a case where a specimen is collected under direct observation because of the temperature being out of range, you must process both the original specimen and the specimen collected using direct observation (including oral fluid) and send the two sets of specimens to their respective laboratories. This is true even in a case in which the original specimen has insufficient volume and the temperature is out of range. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

* * * * *

(c) * * *

(1) If it is apparent from this inspection that the employee has tampered with the specimen (*e.g.,* blue dye in the specimen, excessive foaming when shaken, or smell of bleach), you must immediately conduct a new urine collection using direct observation procedures (*see* § 40.67) or an oral fluid collection.

* * * * *

■ 35. Amend § 40.67 by:

■ a. Revising the section heading and paragraph (a) introductory text;

■ b. Adding paragraph (a)(4);

■ c. Removing ''paragraphs (a) and (b)'' and adding ''paragraph (a)'' in its place in paragraph (c)(1);

■ d. Revising paragraphs (c)(3) and (4);

■ e. Adding paragraph (c)(5);

■ f. Revising paragraph (d)(2);

■ f. Removing ''§ 40.67(b)'' and adding in its place ''paragraphs (c)(2) through (4) of this section'' in paragraph (e)(2); and

■ g. Revising paragraph (g).

The revisions and additions read as follows:

§ 40.67 When and how is a directly observed urine collection conducted?

(a) As an employer, you must direct an immediate collection under direct observation with no advance notice to the employee, if:

* * * * *

(4) You realize a collection under direct observation was required but was not conducted or the service agent informs you that a direct observation should have been collected but was not (*see* paragraph (n) of this section).

(c) * * *

(3) The temperature on the original specimen was out of range (*see* § 40.65(b)(5));

(4) The original specimen appeared to have been tampered with (*see* § 40.65(c)(1)); or

(5) The test reason is return-to-duty or follow-up.

(d) * * *

(2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed collection.

* * * * *

(g) As the collector, you must ensure that the observer is the same gender as the employee.

(1) You must never permit an opposite gender person to act as the observer.

(2) The observer can be a different person from the collector and need not be a qualified collector.

(3) If a same gender collector cannot be found or in circumstances of nonbinary or transgender employees:

(i) If the employer has a standing order to allow oral fluid testing in such situations, the collector will follow that order;

(ii) If there is no standing order from the employer, the collector must contact the DER and either conduct an oral fluid test if the collection site is able to do so, or send the employee to a collection site acceptable to the employer for the oral fluid test.

* * * * *

■ 36. Amend § 40.69 by:

■ a. Revising the section heading;

■ b. Redesignating paragraphs (a) through (g) as paragraphs (b) through (h);

■ c. Adding new paragraph (a); and

■ d. Revising newly redesignated paragraph (e).

The revisions and addition read as follows:

§ 40.69 How is a monitored urine collection conducted?

(a) As stated in § 40.42(f)(2), if you are conducting a urine collection in a multi-stall restroom and you cannot secure all sources of water and other substances that could be used for adulteration and substitution, you must conduct a monitored collection. This is the only circumstance in which you must conduct a monitored collection.

* * * * *

(e) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation. *See* §§ 40.63(e), 40.65(c), and 40.67(c)(2)(3)).

* * * * *

■ 37. Amend § 40.71 by revising the section heading and paragraph (b)(1) to read as follows:

§ 40.71 How does the collector prepare the urine specimen?

* * * * *

(b) * * *

(1) After the collection, check the box on the CCF (Step 2) indicating that this was a ''Urine'' and ''Split'' specimen collection.

* * * * *

§ 40.73 [Redesignated as § 40.79]

■ 38. Redesignate § 40.73 as § 40.79.

■ 39. Add new §§ 40.72 through 40.74 to read as follows:

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§ 40.72 What steps does the collector take in the collection process before the employee provides an oral fluid specimen?

(a) The collector requests that the employee open the employee's mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (*e.g.,* candy, gum, food, or tobacco) or could be used to adulterate, substitute, or alter the specimen.

(1) If the collector finds indication(s) of anything identified above, the collector will ask the employee to lift their tongue and/or separate their cheek from their gum to permit full inspection. If this occurs, the employee may cleanse his or her hands, but must not decline the collector's request for further inspection.

(2) If the employee claims that he or she has a medical condition that prevents opening his or her mouth for inspection, the collector follows the procedure described in § 40.193(a).

(3) If the collector observes materials brought to the collection site or the employee's conduct clearly indicates an attempt to adulterate, substitute, or alter the specimen, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the circumstances to the DER, so that the employer can decide whether to deem the situation a refusal in accordance with § 40.191(a).

(b) If an item is present that might impede or interfere with the collection of an oral fluid specimen, the collector must request the employee remove the item.

(1) If the employee removes any item that could impede or interfere with the collection of an oral fluid specimen, the employee has abnormally colored saliva, or the employee claims to have ''dry mouth,'' then the collector must give the employee water, up to 8 ounces, to rinse their mouth. The employee may drink the water. The collector must then wait 10 minutes before beginning the specimen collection.

(2) If the employee refuses to remove the item or rinse, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the information to the DER to test as described in § 40.191(a)(8) (failure to cooperate), so that the employer can decide whether to deem the situation a refusal.

(c) If there is nothing of concern in the oral cavity and no ''dry mouth'' condition, the collector starts a 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in § 40.73.

(d) During the 10-minute wait period:

(1) Review with the employee the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(2) Complete all items under Step 1 of the CCF, and for clarification:

(i) In Step 1.D of the CCF, the collector must put a check mark for the ''Specify DOT Agency'' under whose authority the test will take place.

(ii) In Step 1.G of the CCF for the ''Collection Site Address'', the collector must provide the address where the collection took place.

(3) The collector will provide, or the employee may select, a specimen collection device that is clean, unused, and wrapped/sealed in original packaging.

(i) The collector will check the expiration date on the device or the package containing the device and show it to the employee.

(ii) The collector must not use the device after its expiration date.

(iii) The collector must open the specimen collection device in view of the employee.

(4) The collector will complete Step 2 of the CCF.

(i) Check ''Oral Fluid'',

(ii) For ''Oral Fluid: Split Type'' check ''Subdivided'', and

(iii) Check ''Each Device Within Expiration Date?'' after ensuring the device is within its expiration date.

(5) The collector will enter the Split Specimen Device Expiration Date in Step 4 of the CCF. Since the collector will use one oral fluid device that will collect a single specimen, which is then subdivided in the presence of the donor, only one entry in Step 4 is to be made for the device expiration date.

(6) The collector must instruct the employee to use hand sanitizer or wash and dry his or her hands.

(e) To the greatest extent practicable, the collector must keep the employee's unwrapped collection device within view of both the collector and the employee, between the time the employee has provided a specimen and the specimen is sealed.

§ 40.73 How is an oral fluid specimen collected?

(a) The collector must be present and maintain visual contact with the employee during the procedures outlined in this section.

(b) The collector must note any unusual behavior or appearance of the employee on the CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must terminate the collection and report the information to the DER so that the employer can decide whether to deem the situation a refusal.

(c) The employee and collector must complete the specimen collection in accordance with the manufacturer's instructions for the collection device.

(1) Under the observation of the collector, the employee is responsible for positioning the specimen collection device for collection.

(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.

(3) If the employee states that he or she is unable to provide an oral fluid specimen or provides an insufficient specimen during the collection process, the collector must continue to make one attempt to collect, after an insufficient specimen, the collector follows the procedure in § 40.193.

(4) The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering. If it is apparent from this inspection that the employee has tampered with the specimen, the collector must conduct a new collection.

(i) Document any unusual characteristics referenced above in the Remarks section of the CCF.

(ii) Proceed with obtaining the new oral fluid specimen from the donor. Note on the new CCF that this is another collection for the same testing event (*i.e.,* Document in the remarks section that this is Specimen 2 of 2 and include the Specimen ID number of the other specimen). Make the same notation on the CCF of the suspect specimen.

§ 40.74 How does the collector prepare the oral fluid specimens?

(a) The collector follows the manufacturer's instructions to package the split specimen collections.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Bottle

A'', and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Bottle B'', or an otherwise sufficient amount of oral fluid is collected to permit an HHS-certified laboratory to analyze the specimen(s).

(c) In the presence of the employee, the collector places a tamper-evident seal from the CCF over the cap of each specimen container, taking care not to obstruct the expiration date on the collection containers. The collector must record the date of the collection on the tamper-evident seals, after they are affixed to the specimen containers.

(d) The collector instructs the employee to initial the tamper-evident seals on each specimen container. If the employee declines to do so, the collector must note this in the ''Remarks'' line of the CCF (Step 2) and complete the collection process.

§§ 40.75–40.78 [Reserved]

■ 40. Add reserved §§ 40.75 through 40.78 to subpart E.

■ 41. Amend newly redesignated § 40.79 by revising paragraph (a)(1) to read as follows:

§ 40.79 How is the collection process completed?

(a) * * *

(1) Direct the employee to read and sign the certification statement on Copy 2 of the CCF and provide all information required in Step 5. If the employee declines to sign the CCF or to provide any of the required information, you must note this in the ''Remarks'' line (Step 2) of the CCF and complete the collection. If the employee declines to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

* * * * *

§ 40.81 [Amended]

■ 42. Amend § 40.81 in paragraph (a) by removing the words ''all testing'' and adding in their place the words ''each specimen testing methodology performed''.

■ 43. Amend § 40.83 by:

■ a. Removing the word ''urine'' in paragraph (b);

■ b. Removing the word ''urine'' and adding in its place the word ''specimen'' in paragraph (c)(7);

■ c. Adding paragraphs (c)(8) and (9);

■ d. Adding the word ''urine'' before the word ''specimen'' in paragraph (f) introductory text;

■ e. Removing ''40.45(a)'' and adding in its place ''40.40(a)'' in paragraph (g) introductory text;

■ f. Removing the word ''urine'' and adding in its place the word ''specimen'' in paragraphs (h)(1)(i), (iii), and (iv); and

■ g. Removing ''(g)(1)'' and adding in its place ''(h)(1)'' in paragraph (h)(2).

§ 40.83 How do laboratories process incoming specimens?

* * * * *

(c) * * *

(8) For an oral fluid collection, the collector used an expired device at the time of collection.

(9) For an oral fluid collection, if the collector failed to enter the expiration date in Step 4 of the CCF and the laboratory is unable to determine the expiration date by inspecting Bottles A and B.

* * * * *

§ 40.85 [Redesignated as § 40.82]

■ 44. Redesignate § 40.85 as § 40.82.

§ 40.99 [Redesignated as § 40.84]

■ 45. Redesignate § 40.99 as § 40.84.

§ 40.87 [Redesignated as § 40.85]

■ 46. Redesignate § 40.87 as § 40.85.

■ 47. Amend newly redesignated § 40.85 by revising the section heading and footnote 2 to read as follows:

§ 40.85 What are the cutoff concentrations for urine drug tests?

* * * * *

[2] An immunoassay must be calibrated with a target analyte.

* * * * *

§ 40.89 [Redesignated as § 40.86]

■ 48. Redesignate § 40.89 as § 40.86.

■ 49. Amend newly redesignated § 40.86 by revising the section heading to read as follows:

§ 40.86 What is urine validity testing, and are laboratories required to conduct it?

* * * * *

§ 40.91 [Redesignated as § 40.87]

■ 50. Redesignate § 40.91 as § 40.87.

■ 51. Amend newly redesignated § 40.87 by revising the section heading, and in the introductory text, removing ''§ 40.89'' and adding in its place ''§ 40.86''.

The revision reads as follows:

§ 40.87 What validity tests must laboratories conduct on primary urine specimens?

* * * * *

§ 40.93 [Redesignated as § 40.88]

■ 52. Redesignate § 40.93 as § 40.88.

■ 53. Amend newly redesignated § 40.88 by revising the section heading to read as follows:

§ 40.88 What criteria do laboratories use to establish that a urine specimen is dilute or substituted?

* * * * *

§ 40.95 [Redesignated § 40.89]

■ 54. Redesignate § 40.95 as § 40.89.

■ 55. Amend newly redesignated § 40.89 by revising the section heading to read as follows:

§ 40.89 What are the adulterant cutoff concentrations for initial and confirmation urine tests?

* * * * *

§ 40.96 [Redesignated as § 40.90]

■ 56. Redesignate existing § 40.96 as § 40.90.

■ 57. Amend newly redesignated § 40.90 by revising the section heading to read as follows:

§ 40.90 What criteria do laboratories use to establish that a urine specimen is invalid?

* * * * *

■ 58. Add new §§ 40.91 through 40.93 to read as follows:

* * * * *

Sec.

* * * * *

§ 40.91 What are the cutoff concentrations for oral fluid drug tests?

As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests for oral fluid specimens. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

TABLE 1 TO § 40.91—ORAL FLUID TESTING CUTOFF CONCENTRATIONS

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana (THC) [2]	4 ng/mL [3]	THC	2 ng/mL.
Cocaine/Benzoylecgonine	15 ng/mL	Cocaine	8 ng/mL.
		Benzoylecgonine	8 ng/mL.
Codeine/Morphine	30 ng/mL	Codeine	15 ng/mL.
		Morphine	15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL	Hydrocodone	15 ng/mL.
		Hydromorphone	15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL	Oxycodone	15 ng/mL.
		Oxymorphone	15 ng/mL.
6-Acetylmorphine	4 ng/mL [3]	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL	Amphetamine	25 ng/mL.
		Methamphetamine	25 ng/mL.
MDMA [4]/MDA [5]	50 ng/mL	MDMA	25 ng/mL.
		MDA	25 ng/mL.

[1] For grouped analytes (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.,* with concentrations equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte.
[3] *Alternate technology (THC and 6-AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.,* 2 ng/mL for THC, 2 ng/mL for 6-AM).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

§ 40.92 What is oral fluid validity testing, and are laboratories required to conduct it?

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human oral fluid. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the oral fluid, if the oral fluid was altered.

(b) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then you may conduct validity testing.

(c) If you determine that the specimen is invalid and HHS guidelines direct you to contact the MRO, you must contact the MRO and together decide if testing the primary specimen by another HHS-certified laboratory would be useful in being able to report a positive or adulterated test result.

§ 40.93 What validity tests must laboratories conduct on primary oral fluid specimens?

As a laboratory, if you conduct validity testing under § 40.92, you must conduct it in accordance with the requirements of this section.

(a) You may test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant.

(b) You must follow the applicable HHS requirements for any additional validity testing.

■ 59. Revise § 40.97 to read as follows:

§ 40.97 What do laboratories report and how do they report it?

(a) As a laboratory, when reporting a result of any kind, you must report the specimen type.

(b) You must also report the results for each primary specimen, which will fall into one of the following three categories. As a laboratory, you must report the actual results (and not the categories):

(1) *Category 1: Negative results.* As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as applicable:

(i) Negative, or

(ii) For urine only, negative-dilute, with numerical values for creatinine and specific gravity.

(2) *Category 2: Non-negative results.* As a laboratory, when you find a specimen to be non-negative, you must report the test result as being one or more of the following, as applicable:

(i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s).

(ii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remarks(s);

(iii) For urine only, positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s) and with numerical values for creatinine and specific gravity;

(iv) For urine only, substituted, with confirmatory test values for creatinine and specific gravity; or

(v) For urine only, invalid result, with remark(s). Laboratories will report actual values for pH results.

(vi) For oral fluid only, invalid result, with remark(s). Laboratories must report numerical values of the specimen validity test results that support a specimen reported as invalid.

(3) *Category 3: Rejected for testing.* As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).

(c) As a laboratory, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (*e.g.,* a C/TPA).

(1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF which has been signed by the certifying scientist, or you may provide the laboratory

results report electronically (*i.e.,* computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;

(B) Employer's name (you may include I.D. or account number);

(C) Medical review officer's name;

(D) Specimen I.D. number;

(E) SSN or Employee ID from Step 1C of the CCF, if provided;

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) For oral fluid only, collection device expiration date;

(J) Date received at the laboratory;

(K) Date certifying scientist released the results;

(L) Certifying scientist's name;

(M) Results (*e.g.,* positive, adulterated) as listed in paragraph (a) of this section; and

(N) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report must not contain information that does not appear on the CCF.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage (*e.g., see* § 40.351).

(2) Non-negative and Rejected for Testing results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.

(d) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax or other electronic means, the electronic communication must be accessible only to authorized individuals.

(e) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(f)(1) You must provide quantitative values for confirmed positive drug test results to the MRO.

(2) You must provide numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO.

(3) You must also provide the MRO numerical values for creatinine and specific gravity for the negative-dilute urine test result, without a request from the MRO.

(g) You must provide quantitative values for confirmed positive morphine and/or codeine urine results at or below 15,000 ng/mL, and for confirmed positive morphine or codeine oral fluid results at or below 150 ng/mL.

■ 60. Amend § 40.111 by revising paragraphs (a) introductory text and (d) to read as follows:

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in appendix D of this part with respect to each specimen type for which you conduct tests to the employer on a semi-annual basis.

* * * * *

(d) As a laboratory, you must transmit an aggregate statistical summary listed in appendix E of this part for each specimen type for which you conduct testing to DOT on a semi-annual basis. The summary must be sent by January 31 of each year for July 1 through December 31 of the prior year. It must be sent by July 31 of each year for January 1 through June 30 of the current year. If you withdraw or are removed from NLCP's laboratory certification during a reporting period, you must provide the aggregate statistical summary to the DOT-regulated employers and to ODAPC for the last reporting period in which you conducted DOT-regulated testing.

§ 40.121 [Amended]

■ 61. Amend § 40.121 in paragraph (c)(1)(i) by removing the word ''urine''.

§ 40.123 [Amended]

■ 62. Amend § 40.123 in paragraph (c) by removing the words ''invalid drug tests results'' and adding in their place ''invalid results''.

§ 40.127 [Amended]

■ 63. Amend § 40.127 in the second sentence of paragraph (g)(2) by adding the words ''of all specimen types combined'' before the words ''in any quarter''.

§ 40.129 [Amended]

■ 64. Amend § 40.129 in paragraph (a) introductory text by removing the words ''invalid drug tests'' and adding in their place ''invalid results'', in paragraph (b) by removing the words ''text cancelled'', and in paragraph (d) by removing ''drug test report'' and adding ''result'' in its place.

§ 40.135 [Amended]

■ 65. Amend § 40.135 in paragraph (d) introductory text by removing the word ''test'' after the word ''invalid'' and adding in its place the word ''result''.

■ 66. Amend § 40.139 by revising paragraph (b) and in paragraph (c) introductory text by removing the word ''urine''.

The revision reads as follows:

§ 40. 139 On what basis does the MRO verify text results involving 6-acetylmorphine, codeine, and morphine?

* * * * *

(b) In the absence of 6–AM, if the laboratory confirms the presence of either morphine or codeine equal to or above 15,000 ng/mL (in urine) or equal to or above 150 ng/mL (in oral fluid), you must verify the test result as positive, unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see § 40.137). Consumption of food products (*e.g.,* poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine at these concentrations.

* * * * *

■ 67. Amend § 40.141 by revising paragraph (b) to read as follows:

§ 40.141 How does the MRO obtain information for the verification decision?

* * * * *

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication (*i.e.,* a legally valid prescription consistent with the Controlled Substances Act), you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides.

(1) You may contact the employee's physician or other relevant medical personnel for further information.

(i) If you decide to contact the employee's pharmacy to authenticate whether the prescription offered by the employee was filled by the pharmacy,

you or staff under your operational control can contact the pharmacy.

(ii) If you utilize staff to perform the inquiry in paragraph (b)(1)(i) of this section, you must ensure operational control over the hiring, firing, evaluation of the staff and you must oversee the performance of the function of contacting a pharmacy to authenticate specific prescription(s) (*e.g.,* outline or script what the staff will ask the pharmacy; occasionally monitor calls to assure quality control; or other methods to ensure the staff are properly conducting the calls with the pharmacies).

(2) You may request an HHS-certified laboratory with validated protocols (*see* § 40.81(c)) to conduct testing for D,L stereoisomers of amphetamine and methamphetamine or testing for tetrahydrocannabivarin (THC–V) when verifying lab results, as you determine necessary.

§ 40.145 [Amended]

■ 68. Amend § 40.145 in the last sentence of paragraph (g)(3) by removing the word ''urine'' and adding the word ''drug'' in its place and in paragraph (h) introductory text by adding the word ''urine'' before the word ''result''

■ 69. Amend § 40.151 by revising paragraphs (a), (b), (g), and (i) to read as follows:

§ 40.151 What are MROs prohibited from doing as part of the verification process?

* * * * *

(a) You must not consider any evidence (verbal or written information) from any drug tests that are not collected or tested in accordance with this part. For example, if an employee tells you he went to his own physician, provided a urine specimen, sent it to a laboratory, and received a negative test result, you are required to ignore this test result.

(b) It is not your function to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF (*e.g.,* concerning allegations that the collector left the area or left open collection containers where other people could access them.)

* * * * *

(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP, 6–AM, MDMA, or MDA in a specimen.

* * * * *

(i) You must not accept, as a legitimate medical explanation for a substituted specimen, an assertion that an employee can produce a urine specimen for which the creatinine level is below the laboratory's limit of detection. There are no physiological means through which a person can produce a urine specimen having this characteristic.

■ 70. Amend § 40.159 by revising paragraphs (a)(1) and (a)(5)(ii) to read as follows:

§ 40.159 What does the MRO do when a drug test result is invalid?

(a) * * *

(1) Discuss the laboratory results with a certifying scientist to determine if the primary specimen should be tested at another HHS-certified laboratory. If the laboratory did not contact you as required by §§ 40.91(e) and 40.96(b), you must contact the laboratory.

* * * * *

(5) * * *

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take place immediately under direct observation. Recommend to the employer that an alternate specimen should be collected if practicable (*e.g.,* oral fluid, if the specimen was urine).

* * * * *

■ 71. Amend § 40.161 by revising paragraphs (a) and (c) to read as follows:

§ 40.161 What does the MRO do when a drug test specimen is rejected for testing?

* * * * *

(a) Place a check mark in the ''Test Cancelled'' box (Step 6) on Copy 2 (or a legible copy of Copy 3–5) of the CCF and enter the reason on the ''Remarks'' line. If you do not have Copy 2 (or a legible copy of Copy 3–5), then enter ''Test Cancelled'' and the reason for the cancellation on a report in the format required under § 40.163(c).

* * * * *

(c) You may only report a test cancelled because of a ''rejected for testing'' laboratory result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature. If you do not have Copy 2 (or a legible copy of Copy 3–5), then enter ''Test Cancelled'' and the reason for the cancellation on a report in the format required under § 40.163(c).

■ 72. Amend § 40.163 in paragraph (c)(2) by removing the words ''donor SSN or employee ID number'' and adding in their place the words ''SSN or employee ID No.'' and by revising paragraph (e).

The revision reads as follows:

§ 40.163 How does the MRO report drug test results?

* * * * *

(e) If you use a written report as provided in paragraph (c) of this section to report results, you must retain a copy of the written report. If you use the electronic data file to report negatives, as provided in paragraph (d) of this section, you must retain a retrievable copy of that report in a format suitable for inspection and audit by a DOT representative. In either case, you must keep the completed Copy 2 of the CCF. When completing Copy 2, either the MRO must sign and date it (for both negatives and non-negatives) or MRO staff must stamp and date it (for negatives only).

* * * * *

■ 73. Amend § 40.177 by revising paragraphs (a) through (c) to read as follows:

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) confirmed in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.85 or § 40.91, as applicable.

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.87 or § 40.93, as applicable.

* * * * *

§ 40.179 [Amended]

■ 74. Amend § 40.179 in paragraph (a) by removing ''§ 40.95'' and adding in its place ''§ 40.89 or § 40.93, as applicable''.

■ 75. Revise § 40.181 to read as follows:

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing a urine split specimen, you must test the split specimen using the confirmatory tests for creatinine and specific gravity, using the criteria set forth in § 40.88.

§ 40.187 [Amended]

■ 76. Amend § 40.187 in paragraphs (b)(1), (c)(1)(iii), and (c)(2)(iii) by removing ''Appendix D'' and adding in

its place ''appendix F'' and in paragraph (e)(3) by removing ''appendix D'' and adding in its place ''appendix F''.

■ 77. Amend § 40.191 by revising paragraphs(a)(2) through (11), (c), and (d)(1) to read as follows:

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

(a) * * *

(2) Fail to remain at the testing site until the testing process is complete. Provided that an employee who leaves the collection site before the testing process commences (*see* § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test. The collector is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

(3) Fail to provide a specimen for any drug test required by this part or DOT agency regulations. Provided that an employee who does not provide a specimen because he or she has left the testing site before the testing process commences (*see* § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test. The collector is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

(4) In the case of a directly observed or monitored urine collection in a drug test, fail to permit the observation or monitoring of an employee's provision of a specimen (*see* §§ 40.67(m) and 40.69(g));

(5) Fail to provide a sufficient amount of specimen when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (*see* § 40.193(d)(2));

(6) Fail or decline to take an additional drug test the employer or collector has directed you to take (*see,* for instance, § 40.197(b) as applicable);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under § 40.193(c). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(8) Fail to cooperate with any part of the testing process (*e.g.,* refuse to empty pockets when directed by the collector, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector, fail to remove objects from mouth, fail to permit inspection of the oral cavity, or fail to complete a rinse when requested);

(9) For an observed urine collection, fail to follow the observer's instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process;

(10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process; or

(11) Admit to the collector or MRO that you adulterated or substituted the specimen.

* * * * *

(c) As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations. The consequences specified under DOT agency regulations for a refusal cannot be overturned or set aside by an arbitration, grievance, State court or other non-Federal forum that adjudicates the personnel decisions the employer has taken against the employee.

(d) * * *

(1) As the collector, you must note the actions that may constitute a refusal in the ''Remarks'' line (Step 2), and sign and date the CCF. The collector does not make the final decision about whether the employee's conduct constitutes a refusal to test; the employer has the sole responsibility to decide whether a refusal occurred, as stated in § 40.355(i), the employer has a non-delegable duty to make the decision about whether the employee has refused to test.

* * * * *

■ 78. Revise § 40.193 to read as follows:

§ 40.193 What happens when an employee does not provide a sufficient amount of specimen for a drug test?

(a) If an employee does not provide a sufficient amount of specimen to permit a drug test (*i.e.,* 45 mL of urine in a single void, or 2mL oral fluid in a single sampling, as applicable) you, as the collector, must provide another opportunity to the employee to do so. In accordance with the employer's instructions, this can be done using the same specimen type as the original collection or this can be done by a collector qualified to use an alternate specimen collection for this purpose.

(1) If you change to an alternate specimen collection at this point (*i.e.,* from urine to oral fluid; or from oral fluid to urine), the next collection begins under § 40.61(e) for urine or § 40.72 for oral fluid collection.

(i) If you proceed with an alternate specimen collection, discard the insufficient specimen and proceed with the next specimen collection.

(ii) If you proceed with an alternate specimen collection, discard the CCF for the insufficient specimen and begin a new CCF for the next specimen collection with a notation in the remarks section of the new CCF.

(b)(1) As the collector, you must do the following when continuing with a urine specimen collection under this section:

(i) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (*see* § 40.65(b) and (c)).

(ii) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. Document on the Remarks line of the CCF (Step 2), and inform the employee of the time at which the three-hour period begins and ends.

(iii) If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note that fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER of the conduct as provided in § 40.191(e)(1); the employer decides whether the situation is deemed to be a refusal.

(iv) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER. You must also discard any specimen the employee previously provided, including any specimen that is ''out of temperature range'' or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, note the fact that the employee provided an ''out of temperature range specimen'' or ''specimen that shows signs of tampering'' and that it was discarded

because the employee did not provide a second sufficient specimen.

(2) As the collector, you must do the following when continuing with an oral fluid specimen collection under this section:

(i) If the employee demonstrates an inability to provide a specimen after 15 minutes of using the collection device, and if the donor states that he or she could provide a specimen after drinking some fluids, urge the employee to drink (up to 8 ounces) and wait an additional 10 minutes before beginning the next specimen collection (a period of up to one hour must be provided, or until the donor has provided a sufficient oral fluid specimen, whichever occurs first). If the employee simply needs more time before attempting to provide an oral fluid specimen, the employee is not required to drink any fluids during the one-hour wait time. It is not a refusal to test if the employee declines to drink. The employee must remain at the collection site, in a monitored area designated by the collector, during the wait period.

(ii) If the employee has not provided a sufficient specimen within one hour of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER.

(3) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.

(c) As the DER, if the collector informs you that the employee has not provided a sufficient amount of specimen (*see* paragraph (b) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's failure to provide a urine (*see* paragraph (b)(1) of this section) or oral fluid (*see* paragraph (b)(2) of this section) sufficient specimen, but not both. The evaluation and MRO determination required by this section only applies to the oral fluid or the urine insufficient specimen that was the final methodology at the collection site. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the employee was required to take a DOT drug test, but was unable to provide a sufficient amount of specimen to complete the test;

(ii) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.

(2) [Reserved]

(d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. As the MRO, if you accept this recommendation, you must:

(i) Check ''Test Cancelled'' (Step 6) on the CCF; and

(ii) Sign and date the CCF.

(2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. As the MRO, if you accept this recommendation, you must:

(i) Check the ''Refusal to Test'' box and ''Other'' box in Step 6 on Copy 2 of the CCF and note the reason next to the ''Other'' box and on the ''Remarks'' lines, as needed.

(ii) Sign and date the CCF.

(e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (*e.g.,* a urinary system dysfunction in the case of a urine test or autoimmune disorder in the case of an oral fluid test), or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or dehydration.

(f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(g) If, as the referral physician making this evaluation in the case of a pre-employment, return-to-duty, or follow-up test, you determine that the employee's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of specimen for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of § 40.195, where applicable.

(h) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. You must report your determination to the DER in writing as soon as you make it.

(i) As the employer, when you receive a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. If the test reason was 'random', the employee remains in the random testing pool.

■ 79. Amend § 40.195 by revising the section heading to read as follows:

§ 40.195 What happens when an individual is unable to provide a sufficient amount of specimen for a pre-employment, follow-up, or return-to-duty test because of a permanent or long-term medical condition?

* * * * *

■ 80. Amend § 40.197 by revising the section heading to read as follows:

§ 40.197 What happens when an employer receives a report of a dilute urine specimen?

* * * * *

■ 81. Amend § 40.199 by revising paragraph (b)(7) and adding paragraphs (b)(8) and (9) to read as follows:

§ 40.199 What problems always cause a drug test to be cancelled?

* * * * *

(b) * * *

(7) Because of leakage or other causes, there is an insufficient amount of specimen in the primary specimen bottle for analysis and the specimens cannot be re-designated (*see* § 40.83(h)).

(8) For an oral fluid collection, the collector used an expired device at the time of collection.

(9) For an oral fluid collection, the collector failed to enter the expiration date in Step 4 of the CCF and the laboratory confirmed that the device was expired.

* * * * *

§ 40.201 [Amended]

■ 82. Amend § 40.201 in the first sentence of paragraph (f) by removing the word ''urine'' and adding in its place the word ''specimen''.

■ 83. Amend § 40.207 by adding paragraph (d) to read as follows:

§ 40.207 What is the effect of a cancelled drug test?

* * * * *

(d) If a test is cancelled for a correctible flaw (*i.e.,* § 40.203 or § 40.205), only the MRO who cancelled the test can reverse the cancellation and must do so within 60 days of the cancellation. After 60 days, the MRO who cancelled the test cannot reverse the cancellation without the permission of ODAPC. For example, if an MRO cancels a test because the MRO did not receive a copy of the CCF, but later receives a copy of the CCF, the MRO may reverse the decision to cancel the test within 60 days. After 60 days, the MRO must contact ODAPC for permission to reverse the cancellation. An MRO must not reverse the cancellation of a test that the laboratory has reported as rejected for testing, as described in § 40.83(g). A laboratory is not authorized to reverse a cancellation due to a fatal flaw, as described in § 40.199.

■ 84. Revise § 40.208 to read as follows:

§ 40.208 What problems require corrective action but do not result in the cancellation of a test?

(a) If, as a laboratory, collector, employer, or other person implementing the DOT drug testing program, you become aware that any of the following omissions listed in paragraphs (a)(1) through (3) of this section occurred, you must take corrective action, including securing a memorandum for the record explaining the problem and taking appropriate action to ensure the problem does not recur:

(1) For a urine collection, the specimen temperature on the CCF was not checked and the ''Remarks'' line did not contain an entry regarding the temperature being out of range; or

(2) For an oral fluid collection, the collector failed to check the box in Step 2 of the CCF that indicates ''Each Device was Within Expiration Date'' but the collector entered the ''Split Specimen Device Expiration Date'' in Step 4 of the CCF.

(3) For an oral fluid collection, the collector erred by entering the expiration date as the ''Primary/Single Specimen Device Expiration Date'' instead of entering the date as the ''Split Specimen Device Expiration Date'' in Step 4 of the CCF.

(b) The errors listed in paragraph (a) of this section do not result in the cancellation of the test.

(c) As an employer or service agent, the errors listed in paragraph (a) of this section, even though not sufficient to cancel a drug test result, may subject you to enforcement action under DOT agency regulations or subpart R of this part.

■ 85. Amend § 40.209 in paragraph (b)(1) by removing ''social security number'' and adding in its place ''SSN or Employee ID No.'', in paragraph (b)(3) by removing ''(see § 40.33)'' and adding in its place ''(*see* §§ 40.33 or 40.35)'', in paragraph (b)(7) by removing ''§ 40.41'' and adding in its place ''§ 40.42'', and by adding paragraph (b)(11).

The addition reads as follows:

§ 40.209 What procedural problems do not result in cancellation of a test and do not require correction?

* * * * *

(b) * * *

(11) The failure to use a new CCF for a second collection after an insufficient specimen was conducted under a different methodology (*e.g.,* failing to use a new CCF for an oral fluid test after an insufficient quantity of urine was produced on a urine test.)

* * * * *

■ 86. Revise § 40.210 to read as follows:

§ 40.210 What kinds of drug tests are permitted under the regulations?

Both urine and oral fluid specimens are authorized for collection and testing under this part. An employer can use one or the other, but not both at the beginning of the testing event. For example, if an employee is sent for a test, either a urine or oral fluid specimen can be collected, but not both simultaneously. However, if there is a problem in the collection that necessitates a second collection (*e.g.,* insufficient quantity of urine, temperature out of range, or insufficient saliva), then a different specimen type could be chosen by the employer (*i.e.,* through a standing order or a discussion with the collector) or its service agent (*i.e.,* if there is no standing order and the service agent cannot contact the DER) to complete the collection process for the testing event. Only urine and oral fluid specimens screened and confirmed at HHS-certified laboratories (*see* § 40.81) are allowed for drug testing under this part. Point-of-collection (POC) urine, POC oral fluid drug testing, hair testing, or instant tests are not authorized.

§ 40.225 [Amended]

■ 87. Amend § 40.225 in paragraph (a) by removing ''Appendix G'' and adding in its place ''appendix I''.

■ 88. Amend § 40.261 by revising paragraphs (a)(2) and (3) and (b), redesignating paragraph (c) as paragraph (c)(1), and adding paragraph (c)(2)

The revisions and addition read as follows.

§ 40.261 What is a refusal to take an alcohol test?

* * * * *

(a) * * *

(2) Fail to remain at the testing site until the testing process is complete. Provided that an employee who leaves the collection site before the testing process commences (*see* § 40.243(a)) for a pre-employment test is not deemed to have refused to test. The BAT or STT is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

(3) Fail to provide an adequate amount of saliva or breath for any alcohol test required by this part or DOT agency regulations; *Provided* that an employee who does not provide an adequate amount of breath or saliva because he or she has left the testing site before the testing process commences (*see* § 40.243(a)) for a pre-employment test is not deemed to have refused to test. The BAT or STT is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

* * * * *

(b) As an employee, if you refuse to take an alcohol test, you incur the same consequences specified under DOT agency regulations for a violation of those DOT agency regulations. The consequences specified under DOT agency regulations for a refusal cannot be overturned or set aside by an arbitration, grievance, State court or other non-Federal forum that adjudicates the personnel decisions the employer has taken against the employee.

(c) * * *

(2) As the BAT or STT, you must note the actions that may constitute a refusal in the ''Remarks'' line (Step 3), and sign and date the ATF. The BAT or STT does not make the final decision about whether the employee's conduct constitutes a refusal to test; the employer has the sole responsibility to decide whether a refusal occurred, as stated in § 40.355(i), the employer has a non-delegable duty to make the decision about whether the employee has refused to test.

* * * * *

■ 89. Amend § 40.281 by adding paragraph (f) to read as follows:

§ 40.281 Who is qualified to act as a SAP?

* * * * *

(f) *Limitation.* If you are an otherwise qualified SAP under this part, you must abide by the geographic limitations applicable to your credential when performing remote evaluations. You must not conduct an evaluation that exceeds your geographic limitations.

§ 40.283 [Amended]

■ 90. Amend § 40.283 in paragraph (c) by removing ''Appendix E'' and adding in its place ''appendix G''.

§ 40.285 [Amended]

■ 91. Amend § 40.285 in paragraph (b) by removing the word ''urine''.

■ 92. Amend § 40.291 by revising paragraphs (a)(1) and (3) to read as follows:

§ 40.291 What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has violated DOT Agency drug and alcohol testing regulations?

(a) * * *

(1) Making a clinical assessment and evaluation to determine what assistance is needed by the employee to resolve problems associated with alcohol and/or drug use. At the SAP's discretion, this assessment or evaluation may be performed face-to-face in-person or remotely. If a SAP is not prohibited from using technology within the parameters of the SAP's State-issued license or other credential(s), a remote evaluation must be must be conducted in accordance with the following criteria:

(i) The technology must permit real-time audio and visual interaction between the SAP and the employee; and

(ii) The quality of the technology (*e.g.,* speed of the internet connection and clarity of the video display) must be sufficient to allow the SAP to gather all the visual and audible information the SAP would otherwise gather in an in-person face-to-face interaction, while providing security to protect the confidentiality of the communications at the level expected by industry standards for remote substance abuse evaluations.

* * * * *

(3) Conducting a follow-up evaluation to determine if the employee has actively participated in the education and/or treatment program and has demonstrated successful compliance with the initial assessment and evaluation recommendations. This assessment or evaluation may be performed face-to-face in-person or remotely. A face-to-face remote evaluation must meet the criteria in paragraphs (a)(1)(i) and (ii) of this section.

* * * * *

■ 93. Amend § 40.293 by:

■ a. Removing the words ''face-to-face'', and after the words ''clinical evaluation,'' adding the words ''meeting the requirements of § 40.291(a)(1)'' in paragraph (a);

■ b. Redesignating paragraphs (e) through (g) as paragraphs (f) through (h); and

■ c. Adding new paragraph (e).

The addition reads as follows:

§ 40.293 What is the SAP's function in conducting the initial evaluation of an employee?

* * * * *

(e) You must assess and clinically evaluate each employee on an individual basis and use your professional judgment to determine education and/or treatment, as well as a follow-up testing plan unique to the needs of the individual employee. For example, do not require the same and/or substantially similar education, treatment, and/or follow-up testing plan for most of the employees you assess.

* * * * *

■ 94. Amend § 40.297 by adding paragraph (c) to read as follows:

§ 40.297 Does anyone have the authority to change an SAP's initial evaluation?

* * * * *

(c) The SAP, who is otherwise fully qualified under this subpart, must not perform evaluations outside the geographic jurisdiction for their credential(s). If the SAP who made the evaluation exceeds their geographic jurisdiction, the employee will not be required to seek the evaluation of a second SAP.

§ 40.301 [Amended]

■ 95. Amend § 40.301 in paragraph (b)(2) by removing the words ''face-to-face'', and after the words ''clinical interview'', adding the words ''meeting the requirements of § 40.291(a)(1)''.

■ 96. Amend § 40.305 by adding paragraph (d) to read as follows:

§ 40.305 How does the return-to-duty process conclude?

* * * * *

(d) As the employer, if a SAP who is otherwise fully qualified under this subpart performed a remote evaluation of the employee outside the geographic jurisdiction for their credential(s), the employee who they evaluated will not be required to seek the evaluation of a second SAP. If you decide that you want to permit the employee to return to the performance of safety-sensitive functions, you will proceed with the requirements of paragraph (a) of this section.

■ 97. Amend § 40.307 by adding paragraph (g) to read as follows:

§ 40.307 What is the SAP's function in prescribing the employee's follow-up tests?

* * * * *

(g) As the employer, SAP, or other service agent, you must not provide to the employee a copy of their drug and/or alcohol follow-up testing schedule prescribed by the SAP. No employer, SAP, or other service agent will indicate to the employee what the frequency or duration of the employee's follow-up testing schedule will be. The SAP can require follow-up testing for either or both drugs and alcohol for a drug-related or an alcohol-related violation.

§ 40.311 [Amended]

■ 98. Amend § 40.311 in paragraphs (c)(4), (d)(4), and (e)(4) after the word ''Date(s)'' by adding the words ''and format (*i.e.,* face-to-face or remote)'' and in paragraphs (c)(1), (d)(1), and (e)(1) by removing ''SSN'' and adding in its place ''SSN or employee ID No.''.

■ 99. Amend § 40.327 by:

■ a. Removing the reference ''paragraph (c)'' and adding in its place ''paragraph (d)'' in paragraph (a) introductory text;

■ b. Redesignating paragraph (c) as paragraph (d); and

■ c. Adding a new paragraph (c).

The addition reads as follows:

§ 40.327 When must the MRO report medical information gathered in the verification process?

* * * * *

(c) The MRO must not report such medical information using the CCF. Instead, the MRO must provide the information in a separate written communication (*e.g.,* letter, secure email). The information must state the specific nature of the MRO's safety concern (*e.g.,* the effects of a medication the employee is taking, the employee's underlying medical condition that the employee disclosed to the MRO).

* * * * *

§ 40.345 [Amended]

■ 100. Amend § 40.345 in paragraph (b) by removing ''Appendix F'' and adding in its place ''appendix H''.

§ 40.355 [Amended]

■ 101. Amend § 40.355 in Example 3 to paragraph (n) by removing the word ''urine''.

§ 40.365 [Amended]

■ 102. Amend § 40.365 in paragraph (b)(8) by removing the words ''face-to-

face interviews'' and adding in their place the words ''without interviews meeting the requirements of § 40.291(a)(1)''.

Appendices E Through H to Part 40 [Redesignated as Appendices G Through J to Part 40]

■ 103. Redesignate appendices E through H to part 40 as appendices G through J to part 40.

Appendix C to Part 40 [Redesignated as Appendix E to Part 40]

■ 104. Redesignate appendix C to part 40 as appendix E to part 40.

Appendix C to Part 40 [Reserved]

■ 105. Add reserved appendix C to part 40.

Appendix D to Part 40 [Redesignated as Appendix F to Part 40]

■ 106. Redesignate appendix D to part 40 as appendix F to part 40.

Appendix B to Part 40 [Redesignated as Appendix D to Part 40]

■ 107. Redesignate appendix B to part 40 as appendix D to part 40.

■ 108. Add new appendix B to part 40 to read as follows:

Appendix B to Part 40—Oral Fluid Collection Kit Contents

1. Oral Fluid Collection Device

a. A single device, which can be subdivided in the employee's presence into an ''A'' specimen and a ''B'' split specimen bottle sufficient for laboratory testing, that is either of the following:

(1) An oral fluid collection device made to collect a sufficient amount of oral fluid to permit an HHS-certified laboratory to analyze the specimen(s). For example, a device that directs the oral fluid into two separate collection bottles.

(2) A device that uses buffering solution that collects a specimen using a single pad or dual pads joined for insertion together into the same region of the mouth, which can be subdivided into two separate collection bottles. Such a buffered device may use a diluent (or other component, process, or method that modifies the volume of the testable specimen). The volume specifications for the device must be consistent with those set by HHS.

b. Must have unit markings or other indicators that demonstrate the adequacy of the volume of oral fluid specimen collected.

c. Must be sufficiently transparent to permit a visual assessment of the contents without opening the specimen bottle.

d. Must be individually packaged in an easily visible tamper-evident system.

e. Must have the device's expiration date on the specimen bottles sent to the laboratory (*i.e.,* the shortest expiration date of any component).

f. Must not have components that substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen and/or interfere with an accurate analysis of the specimen.

g. Must maintain the integrity of the specimen during storage and transport so the specimen can be tested in an HHS-certified laboratory.

h. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit without concealing the expiration date on the bottles, without damage to the seal when the collector dates and the employee initials it.

i. Must be approved by HHS for use by the specific HHS-certified laboratory that will test the specimen gathered by this device.

2. Instructions

Must include the manufacturer's instructions within the device's packaging. The instructions must provide sufficient detail to allow for an error-free collection when the instructions are followed.

3. Leak-Resistant Plastic Bag

a. Must have two sealable compartments or pouches that are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork, as applicable.

b. The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident.

4. Absorbent Material

Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. Shipping Container

a. Must be designed to adequately protect the specimen bottles from damage during shipment of the specimens from the collection site to the laboratory (*e.g.,* standard courier box, small cardboard box, plastic container).

b. May be made available separately at collection sites rather than being part of an actual collection device sent to collection sites.

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimen bottles in the leak-resistant plastic bags from the collection site to the laboratory.

■ 109. Revise the newly redesignated appendix D to read as follows:

Appendix D to Part 40—DOT Drug Testing Semi-Annual Laboratory Report to Employers

The following items are required on each laboratory report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
Employer Identification: (name; may include Billing Code or ID code)
C/TPA Identification: (where applicable; name and address)

A. Urine Specimens

1. Urine Specimen Results Reported (Total Number) By Test Reason

(a) Pre-employment (number)
(b) Post-Accident (number)
(c) Random (number)
(d) Reasonable Suspicion/Cause (number)
(e) Return-to-Duty (number)
(f) Follow-up (number)
(g) Type of Test Not Noted on CCF (number)

2. Urine Specimens Reported

(a) Negative (number)
(b) Negative and Dilute (number)

3. Urine Specimens Reported as Rejected for Testing (Total Number) by Reason

(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)

4. Urine Specimens Reported as Positive (Total Number) by Drug

(a) Marijuana Metabolite (number)
(b) Cocaine Metabolite (number)
(c) Opioids (number)
  (1) Codeine (number)
  (2) Morphine (number)
  (3) 6–AM (number)
  (4) Hydrocodone (number)
  (5) Hydromorphone (number)
  (6) Oxycodone (number)
  (7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
  (1) Amphetamine (number)
  (2) Methamphetamine (number)
  (3) MDMA (number)
  (4) MDA (number)

5. Urine Adulterated (Number)

6. Urine Substituted (Number)

7. Urine Invalid Result (Number)

B. Oral Fluid Specimens

1. Oral Fluid Specimen Results Reported (Total Number) by Test Reason

(a) Pre-employment (number)
(b) Post-Accident (number)
(c) Random (number)
(d) Reasonable Suspicion/Cause (number)
(e) Return-to-Duty (number)
(f) Follow-up (number)
(g) Type of Test Not Noted on CCF (number)

2. Oral Fluid Specimens Reported

(a) Negative (number)
(b) Negative and Dilute (number)

3. Oral Fluid Specimens Reported as Rejected for Testing (Total Number) by Reason

(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)

4. Oral Fluid Specimens Reported as Positive (Total Number) by Drug

(a) Marijuana (number)
(b) Cocaine and/or Cocaine Metabolite (number)
(c) Opioids (number)
  (1) Codeine (number)
  (2) Morphine (number)
  (3) 6–AM (number)
  (4) Hydrocodone (number)
  (5) Hydromorphone (number)
  (6) Oxycodone (number)

(7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
(3) MDMA (number)
(4) MDA (number)

5. Oral Fluid Adulterated (Number)

6. Oral Fluid Substituted (Number)

7. Oral Fluid Invalid Result (Number)

■ 110. Revise newly redesignated appendix E to part 40 to read as follows:

Appendix E to Part 40—Drug Testing Semi-Annual Laboratory Report to DOT

Mail, fax or email to: U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE, Washington, DC 20590.
Fax: (202) 366–3897.
Email: ODAPCWebMail@dot.gov.
The following items are required on each report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
1. Specimen Type:
—oral fluid or urine
2. DOT agency
—FMCSA, FAA, FRA, FTA, PHMSA, or USCG
3. Test Reason
—Pre-Employment, Random, Reasonable Suspicion/Cause, Post-Accident, Return-to-Duty, Other, and Follow-up
A. DOT Specimen Results Reported (total number)
B. Negative Results Reported (total number)
1. Negative (number)
2. Negative-Dilute (number)
C. Rejected for Testing Results Reported (total number) By Reason
1. Fatal flaw (number)
2. Uncorrected Flaw (number)
D. Positive Results Reported (total number) By Drug
1. Marijuana or Marijuana Metabolite (number)
2. Cocaine and/or Cocaine Metabolite (number)
3. Opioids (number)
a. Codeine (number)
b. Morphine (number)
c. 6–AM (number)
d. Hydrocodone (number)
e. Hydromorphone (number)
f. Oxycodone (number)
g. Oxymorphone (number)
4. Phencyclidine (number)
5. Amphetamines (number)
a. Amphetamine (number)
b. Methamphetamine (number)
c. MDMA (number)
d. MDA (number)
E. Adulterated Results Reported (total number) By Reason (number)
F. Substituted Results Reported (total number)
G. Invalid Results Reported (total number) By Reason (number)

■ 111. Revise newly redesignated appendix F to part 40 to read as follows:

Appendix F to Part 40—Report Format: Split Specimen Failure To Reconfirm

Mail, fax, or submit electronically to: U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE, Washington, DC 20590.
Fax: (202) 366–3897.
Submit Electronically: https://www.transportation.gov/odapc/mro-split-specimen-cancellation-notification.
The following items are required on each report:
1. MRO name, address, phone number, and fax number.
2. Collection site name, address, and phone number.
3. Date of collection.
4. Specimen I.D. number.
5. Specimen type.
6. Laboratory accession number.
7. Primary specimen laboratory name, address, and phone number.
8. Date result reported or certified by primary laboratory.
9. Split specimen laboratory name, address, and phone number.
10. Date split specimen result reported or certified by split specimen laboratory.
11. Primary specimen results (*e.g.,* name of drug, adulterant) in the primary specimen.
12. Reason for split specimen failure-to-reconfirm result (*e.g.,* drug or adulterant not present, specimen invalid, split not collected, insufficient volume).
13. Actions taken by the MRO (*e.g.,* notified employer of failure to reconfirm and requirement for re-collection).
14. Additional information explaining the reason for cancellation.
15. Name of individual submitting the report (if not the MRO).

Appendix H to Part 40 [Amended]

■ 112. Amend newly redesignated appendix H under ''Drug Testing Information'' by removing the reference ''§ 40.129(d)'' and adding in its place the reference ''§ 40.129(e)''.

PART 219—CONTROL OF ALCOHOL AND DRUG USE

■ 113. The authority citation for part 219 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20140, 21301, 21304, 21311; 28 U.S.C. 2461 note; Div. A, Sec. 412, Public Law 110–432, 122 Stat. 4889 (49 U.S.C. 20140 note); Sec. 8102, Public Law 115–271, 132 Stat. 3894; and 49 CFR 1.89.

§ 219.4 [Amended]

■ 114. Amend § 219.4 in paragraphs (a) introductory text and (b)(1) and (2) by removing the term ''return-to-service'' and adding in its place the term ''return-to-duty'' and in paragraph (b)(2) by removing ''paragraph (d) of this section'' and adding ''§ 219.104(d)''.

§ 219.11 [Amended]

■ 115. Amend § 219.11 in paragraph (a)(2) by removing the word ''urine'' and adding in its place ''body fluid'' and in paragraph (h) by removing the words ''urine or blood'' and adding in their place the words ''body fluid'' and by adding ''or oral fluid from a sampling'' after the word ''void''.

§ 219.617 [Amended]

■ 116. Amend § 219.617 in paragraph (b)(2) by removing the word ''urine'' and adding in its place ''body fluid''.

§ 219.619 [Amended]

■ 117. Amend § 219.619 by removing the word ''urine'' and adding in its place ''body fluid'' in two places.

§ 219.621 [Amended]

■ 118. Amend § 219.621 in paragraph (a) by removing the word ''urine'' and adding in its place ''body fluid''.

§ 219.903 [Amended]

■ 119. Amend § 219.903 in paragraph (a) by removing the word ''urine'' and adding in its place ''body fluid''.

PART 240—QUALIFICATION AND CERTIFICATION OF LOCOMOTIVE ENGINEERS

■ 120. The authority citation for part 240 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20135, 21301, 21304, 21311; 28 U.S.C. 2461 note; and 49 CFR 1.89.

§ 240.119 [Amended]

■ 121. Amend § 240.119 in paragraphs (e)(4)(iv)(A) and (f)(1)(iii) by removing the word ''urine'' and adding in its place ''body fluid''.

PART 242—QUALIFICATION AND CERTIFICATION OF CONDUCTORS

■ 122. The authority citation for part 242 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20135, 20138, 20162, 20163, 21301, 21304, 21311; 28 U.S.C. 2461 note; and 49 CFR 1.89.

§ 242.115 [Amended]

■ 123. Amend § 242.115 in paragraphs (e)(4)(iv)(A) and (f)(1)(iii) by removing the word ''urine'' and adding in its place ''body fluid''.

PART 382—CONTROLLED SUBSTANCES AND ACOHOL USE AND TESTING

■ 124. The authority citation for part 382 continues to read as follows:

Authority: 49 U.S.C. 31133, 31136, 31301 *et seq.,* 31502; sec. 32934 of Public Law 112–141, 126 Stat. 405, 830; and 49 CFR 1.87.

§ 382.107 [Amended]

■ 128. Amend § 382.107:

■ a. In the definitions of ''Confirmation (or confirmatory) drug test'' and ''Confirmation (or confirmatory) validity'' by adding ''or oral fluid'' after the word ''urine'';

■ b. In the definition of ''Controlled substances'' by removing ''§ 40.85'' and adding in its place ''§ 40.82'';

■ c. In paragraphs (3) and (5) to the definition of ''Refuse to submit (to an alcohol or controlled substances test'' by adding ''or oral fluid'' after the word ''urine'' each place it appears; and

■ d. In paragraph (1) to the definition of ''Screening test (or initial test)'' by adding ''or oral fluid'' after the word ''urine''.

§ 382.401 [Amended]

■ 129. Amend § 382.401 in paragraph (b)(3) by adding the words ''and MRO reversal of canceled controlled substances test results'' after the words ''canceled controlled substances test results'' and in paragraph (c)(1)(vii) by adding ''or oral fluid'' after the word ''urine''.

§ 382.403 [Amended]

■ 130. Amend § 382.403 in the third sentence of paragraph (b) by removing ''appendix H'' and adding in its place ''appendix J''.

§ 382.409 [Amended]

■ 131. Amend § 382.409 in paragraph (b) by adding the words ''and MRO reversal of cancelled controlled substances test results'' after the words ''test results''.

§ 382.705 [Amended]

■ 132. Amend § 382.705 in paragraph (a)(2)(vii)(D) by adding ''or oral fluid'' after the word ''urine''.

PART 655—PREVENTION OF ALCOHOL MISUSE AND PROHIBITED DRUG USE IN TRANSIT OPERATIONS

■ 133. The authority citation for part 655 continues to read as follows:

Authority: 49 U.S.C. 5331; 49 CFR 1.91.

§ 655.5 [Amended]

■ 134. Amend § 655.5 in paragraph (c) by removing ''400 Seventh Street SW'' and adding in its place ''1200 New Jersey Ave. SE''.

§ 655.15 [Amended]

■ 135. Amend § 655.15 in paragraph (e) by removing the word ''illegal'' and adding in its place the word ''prohibited''.

§ 655.44 [Amended]

■ 136. Amend § 655.44 in paragraph (a)(1)(i) by removing ''389.303(a)(1) or (b)(1)'' and adding in its place ''§ 382.303''.

§ 655.47 [Amended]

■ 137. Amend § 655.47 by adding the word ''covered'' before the word ''employee''.

§ 655.53 [Amended]

■ 138. Amend § 655.53 by removing the words ''collection person'' and by adding ''or oral fluid collector'' after the word ''urine''.

§ 655.61 [Amended]

■ 139. Amend § 655.61 in paragraph (a)(3) by removing the words ''an employee'' and adding in their place the words ''a covered employee''.

§ 655.71 [Amended]

■ 140. Amend § 655.71 in paragraph (c)(1)(v) by adding the words ''or oral fluid'' after the word ''urine'' and removing the word ''breathe'' and adding in its place ''breath''.

Signed in Washington, DC, on or around April 7, 2023.

Peter Paul Montgomery Buttigieg,

Secretary of Transportation.

Signed in Washington, DC, on or around April 7, 2023.

Billy Nolen,

Acting Administrator, Federal Aviation Administration.

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