aDEPARTMENT OF TRANSPORTATION **4910-9X**

Office of the Secretary

49 CFR Part 40

[Docket OST-2010-0026]

RIN 2105-AD95

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT

ACTION: Final Rule

SUMMARY: The Department of Transportation (the Department or DOT) is amending certain provisions of its drug testing procedures dealing with laboratory testing of urine specimens. Some of the changes will also affect the training of and procedures used by Medical Review Officers. The changes are intended to create consistency with many, but not all, of the new requirements established by the U.S. Department of Health and Human Services.

DATES: This rule is effective October 1, 2010.

FOR FURTHER INFORMATION CONTACT:

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S**UPPLEMENTARY INFORMATION:**

Background and Purpose

On November 25, 2008 (73 FR 7185), the U.S. Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) issued a Final Notice of Revisions to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Mandatory Guidelines) that included changes to the procedures for collection and testing of urine specimens, creation of and requirements for the certification of Instrumented Initial Test Facilities (IITFs), collection site oversight requirements, and changes to the role of and standards for collectors and Medical Review Officers (MROs). The HHS Mandatory Guidelines were to become effective May 1, 2010, but on April 30, 2010 (75 FR 22809), HHS postponed implementation until October 1, 2010.

On February 4, 2010, DOT published a Notice of Proposed Rulemaking (NPRM) (75 FR 5722) seeking comments about changing part 40 to be consistent with certain aspects of the HHS Mandatory Guidelines. The final rule responds to the comments and makes a number of changes to the existing rules governing the Department's drug testing program.

Principal Policy Issues

Requirements of the Omnibus Transportation Employee Testing Act of 1991

Several commenters questioned whether and to what extent the Department must follow the HHS Mandatory Guidelines. Some commenters urged the Department to choose a different approach from the HHS regarding the drugs for which testing occurs, the initial testing of all specimens for 6-Acetylmorphine (6-AM), and the use of IITFs. Although since its passage, the Department has cited the Omnibus Transportation Employee Testing Act of 1991, 49 U.S.C. 31300, *et seq.*, 49 U.S.C. 20100, *et seq.*, 49 U.S.C. 5330, *et seq.*, and 49 U.S.C. 45100, *et seq.* (Omnibus Act), as the definitive authority for our reliance on the HHS Mandatory Guidelines for

scientific testing issues, several of the commenters have challenged this or otherwise asked the Department to clarify what the Omnibus Act requires.

Even before the Omnibus Act, the Department looked to the HHS Mandatory Guidelines for guidance on scientific matters. In a 1988 Interim Final Rule (IFR) the Department relied upon the HHS for testing methodologies to determine the drugs for which testing would be done and which laboratories to use. Specifically, the Department noted that under "the HHS Guidelines, a Federal agency may test a urine sample *only* for certain specified drugs. The Department's Procedures echo this requirement." (53 FR 47002, Nov. 21, 1988; emphasis in the original) In the same IFR, the Department required regulated transportation employers to use only laboratories certified under the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. While deciding to utilize many aspects of the HHS Mandatory Guidelines, the Department acknowledged "that the Guidelines, as written by HHS to apply to testing by Federal agencies, do not fit perfectly the circumstances of employers regulated by DOT . . . . Obviously, the circumstances of industries regulated by DOT are very different from those of Federal agencies." (53 FR 47002) Thus, the Department began to lay the foundation for using the technical expertise of the HHS for the scientific aspects of DOT's testing program while relying upon the Department's own authority and that of DOT agencies to tailor many procedural aspects of DOT testing to fit the transportation industries.

In a 1989 final rule, we discussed the applicability of the Fourth Amendment of the United States Constitution to both the Federal agency programs covered by the HHS Mandatory Guidelines and the testing that transportation employers would conduct in response to the Department's requirements. The Department acknowledged that the HHS Mandatory Guidelines had passed Constitutional scrutiny by the Federal courts, all the way up to the Supreme Court of

the United States. The Federal courts concluded that HHS had met the Fourth Amendment balancing of the Federal need to ensure safety by drug testing versus individuals' strong interests in their right to privacy. The HHS Mandatory Guidelines had set up a testing system with sound methodology that ensured privacy and accuracy. Given these considerations, the Department decided to rely on HHS for the science of DOT's testing program and for the drugs for which we test, the testing methodologies, and the integrity of the HHS certified laboratories. (54 FR 49854, Dec. 1, 1989)

Congress endorsed the Department's decision by explicitly directing, in the Omnibus Act, the Department to incorporate the HHS scientific and technical guidelines for laboratories and testing procedures for controlled substances. The Omnibus Act specifically requires that we incorporate the HHS scientific and technical guidelines that "establish comprehensive standards for all aspects of laboratory controlled substances testing" in order to ensure full reliability and accuracy in testing. [49 U.S.C. 31306(c)(2)(A), 49 U.S.C. 20140(c)(2)(A), 49 U.S.C. 5331(d)(2)(A) and 49 U.S.C. 45104(2)(A)] The legislative history for the Omnibus Act indicates the following intent: "Incorporating the HHS guidelines relating to laboratory standards and procedures for testing controlled substances, as proposed by the reported bill and *as DOT has done in part 40* of title 49 CFR, as it exists at this writing, is an essential component of the procedural safeguard." Senate Report 102-54, Omnibus Transportation Employee Testing Act of 1991, Report of the Senate Committee on Commerce, Science and Transportation on S.676, 102nd Congress, 1st Session, May 2, 1991, page 26 (Senate Report 102-54); (emphasis added). The Omnibus Act also requires the Department and DOT agencies to look to the HHS for laboratory certification, the procedures for reviewing laboratories for certification, and the procedures for the revocation of such certification. In addition, the Department must follow the

HHS Mandatory Guidelines regarding establishing the list of drugs for which we test and the procedures for use of the Federal Drug Testing Custody and Control Form (CCF) to establish the chain of custody of specimens.

The legislative history of the Omnibus Act indicates that Congress wanted the Department and DOT agencies to continue use of the HHS scientific and technical guidelines and the HHS certified laboratories to ensure accuracy, fairness, and the constitutionality of DOT's drug testing program. While the Omnibus Act was being drafted, opponents of drug testing warned that employees were in danger of "false positives" that would result from initial screening of urine that might indicate levels of illegal drugs. The Senate noted that it had addressed this concern: "By incorporating laboratory certification and testing procedures developed by HHS and DOT and by providing for the subdivision of specimens and the opportunity for an independent test of positive samples, the Committee has taken affirmative steps to ensure accuracy." Senate Report 102-54, pages 6-7. The legislative history for the Omnibus Act makes numerous additional references to the understanding that the Department would work with HHS to ensure testing accuracy.

There is also clear indication in the legislative history that Congress recognized that the HHS standards were likely to be modified over time. The Omnibus Act itself explicitly refers to incorporating the HHS "scientific and technical guidelines dated April 11, 1988, and any subsequent amendments thereto…" 49 U.S.C. 31306(c)(2), 49 U.S.C. 20140(c)(2), 49 U.S.C. 5331(d)(2) and 49 U.S.C. 45104(2). Allowing for subsequent amendments, however, did not mean that Congress wanted to lower the standards for testing. "Realizing that these guidelines possibly are subject to future modification, the Committee has acted to specify that the basic elements of certain provisions now in effect are mandated, including the need for comprehensive

standards and procedures for all aspects of laboratory testing of drugs, the establishment of a minimum list of controlled substances for which employees may be tested, the establishment of standards and procedures for the periodic review of laboratories, and the development of criteria for laboratory certification." Senate Report 102-54, pages 21-22, 26 and 32.

When the Omnibus Act requires the Department to follow HHS on specified scientific matters, we adhere to the requirements. When the Omnibus Act allows the Department the option of following HHS, we have always and will continue to weigh the costs and benefits of following HHS in light of our mission. However, when the Omnibus Act specifically requires the Department to take a direction different from that which HHS takes, then the Department is prohibited from following HHS on such matters.

In reviewing the Omnibus Act, its legislative history, and the regulatory history of the Department's testing program, it remains clear that, since the inception of our program, the Department has been tied to HHS for the scientific methodology, for identification of the drugs for which we will require testing; the certified laboratories we are to use; and the technical expertise for certifying and decertifying laboratories. These are the core scientific laboratory functions necessary for the Department's program.

However, it is important to note that the Department has discretion concerning many other aspects of the regulations governing testing in the transportation industries' regulated programs.

As far back as 1988, our regulations established the fundamental roles and concepts for the current DOT regulated industry testing program. Our early regulations established how collections were to be done, who could be an MRO or a Substance Abuse Professional (SAP), and the respective training for and responsibilities of these important gatekeepers. While relying

on HHS for certain scientific efforts, we did not necessarily follow HHS regarding collection issues, laboratory reporting requirements, how MROs handle certain test results, the rehabilitation and the return-to-duty process, and other areas covered by the HHS Mandatory Guidelines. The Department's regulation and the regulations of DOT agencies set their own processes and procedures for all aspects leading up to and through specimen collection and then picking up from what processes and procedures would occur after a laboratory confirmed a drug test result, including the return-to-duty process for individuals who have non-negative test results. In shaping our program to fit the needs of the transportation industries, the Department and DOT agencies have made adaptations to meet the changing needs of the transportation industries. In some cases we have consequently chosen a different path from the one chosen by HHS on the same or similar non-scientific issues.

The Omnibus Act acknowledged that such Departmental and DOT agency regulations were in place with respect to non-scientific issues. Congress explicitly allowed these regulations to continue in effect, with the option for the Department and DOT agencies to amend or further supplement their respective regulations in the future. 49 U.S.C. 31306(i), 49 U.S.C. 20140(f), and 49 U.S.C. 45106(c).

One example of the Department's divergence from HHS on non-scientific matters covered in the HHS Mandatory Guidelines is the issue of how to conduct direct observation collections. On June 25, 2008, the Department issued a final rule (73 FR 35961) that, among other amendments, modified 49 CFR Part 40 at section 40.67(b) and added a new paragraph 40.67(i) to improve direct observation procedures to better address known adulteration and substitution threats. Although HHS addresses direct observation collections in the HHS Mandatory Guidelines, the Department chose to use a different procedure because of evidence

regarding cheating and our experience in regulating the transportation industries. In explaining our rationale, we noted that the use of direct observation collections is "a very significant tool the Department employs to combat attempts by employees to cheat on their tests." (74 FR 37949, July 30, 2009) In addition, we stated in the final rule reinstating the direct observation provisions after the court victory, "the Department remains convinced that conducting all return-to-duty and follow-up tests under direct observation is the most prudent course from the viewpoint of safety." (74 FR 37950, quoting the October 22, 2008 final rule preamble at 73 FR 62918)

The Department's regulations concerning direct observation procedures were affirmed by a unanimous court. (*BNSF Railway Company* v. *Department of Transportation,* 566 F.3d 200 (DC Cir. 2009) In upholding the rule, the U.S. Court of Appeals for the D.C. Circuit noted that the Department had experience, comments, and evidence to support the need to make the improvements to the direct observation procedures. *BNSF Railway Company* v. *Department of Transportation,* 566 F.3d at 204. The Court further found that the improved procedures were constitutional, stating, "[g]iven the combination of the vital importance of transportation safety, the employees' participation in a pervasively regulated industry, their prior violations of the drug regulations, and the ease of obtaining cheating devices capable of defeating standard testing procedures, we find the challenged regulations facially valid under the Fourth Amendment." Id. at 208. Hence, the Department chose a different approach from HHS on direct observation procedures, tailored them to the needs identified, and the Court upheld this approach as constitutional.

Some of the commenters asked the Department to consider deviating from the HHS Mandatory Guidelines regarding the drugs for which testing is required. Some commenters want

the Department to exclude Methylenedioxymethamphetamine (MDMA) from the list of drugs, while others want the Department to include synthetic opiates, and others want alternative testing methodologies to be employed.

It is not unusual for the Department to receive requests from commenters to move away from the illegal drugs for which HHS has set the protocols; however, the Department has remained consistent in our responses and our reliance upon HHS as the scientific experts in these matters. What the Department stated in response to similar requests in the late 1990s to move beyond the HHS minimums still remains true: "This is a long-standing issue in the program, and DOT continues to take the position that we ought not to go beyond the testing that HHS has authorized and for which HHS has certified laboratories." (65 FR 79484, Dec. 19, 2000) In response to those who have urged DOT to go beyond the drugs for which HHS tests, we have consistently stated: "we believe the stability and reliability of the program are well served by limiting testing to the 'HHS five.' HHS has established testing protocols and cutoffs for these drugs, and laboratories are subject to HHS certification for testing of these five drugs. This is not true for other drugs." (65 FR 79491, Dec. 19, 2000) Although the HHS has now expanded its panel to include an additional amphetamine, MDMA, the same reasoning holds true and the Department will continue to follow the HHS testing protocols for the reasons we explained in 2000.

Also in 2000, the Department explained, "With respect to alternative testing technologies such as hair testing, saliva testing, and on-site testing, which commenters recommended in context of several sections of the NPRM, the Department will wait upon the action of HHS before proposing to incorporate additional methods. Approval of these or other methods, and establishment of requirements and procedures for them, are matters primarily within the

expertise of HHS." (65 FR 79489, Dec. 19, 2000) Furthermore, in the preamble to our Specimen Validity Testing final rule in 2008 (SVT Final Rule), we stated that the Omnibus Act "provides only one way to determine that an employee has tested positive for illicit drug use – a drug test confirmed by an HHS-certified laboratory using HHS scientific and testing protocols and verified by an MRO." (73 FR 35966, June 25, 2008)

The Department, as required by the Omnibus Act, has consistently specifically followed HHS on laboratory certification matters, but we have also created responsibilities for laboratories under part 40 that do not impinge upon the scientific and technical aspects of drug testing. As the Department stated in 2000, "laboratories have responsibilities under part 40 independent of their HHS responsibilities (*e.g.,* with respect to relationships with MROs, release of information, and validity testing), and laboratories must be accountable to DOT in those matters." (65 FR 79484, Dec. 19, 2000)

At times, we have had to adapt certain aspects of technical drug testing matters to fit the needs of the transportation industries. For example, in 2003, the Department issued an interim final rule (2003 IFR) concerning laboratory substitution criteria. (68 FR 31624, May 28, 2003) In the 2003 IFR, we did not, and could not, change the HHS-established laboratory testing substitution criteria, but instead addressed how laboratories were to report out their findings to the MROs on the CCF, what subsequent actions would be required of the MROs with respect to the reported result, and whether to tell the employer to send the employee back in for a direct observation collection. In short, we said that specimens reported by laboratories as substituted with creatinine concentration in the 2 - 5 ng/mL range would not be considered by MROs to be refusals to test. Instead, transportation employees with such results would require immediate recollections under direct observation.

In a July 2008 interpretation, which is being incorporated in this final rule at section 40.159, the Department instructed MROs on how to "handle laboratory results reported as invalid because of pH greater than or equal to 9.0 but less than or equal to 9.5." This is another example of how the Department has adapted the HHS scientific requirements established for laboratories to the needs of the transportation industries. In fact, the HHS Mandatory Guidelines have adopted our MRO provisions for invalids due to pH in the 9.0 - 9.5 range.

We read the Omnibus Act to require the Department to follow the HHS on the drugs for which we test and the testing protocols, but the Omnibus Act allows us to, and we have chosen to, diverge from the HHS and the HHS Mandatory Guidelines on collections, MROs, and what laboratories can report. As we said in our 2008 SVT Final Rule preamble, "Since Congress specifically limited the scientific testing methodology upon which DOT can rely in making its drug and alcohol testing regulations; we follow the HHS scientific and technical guidelines, including the amendments to their Mandatory Guidelines." (73 FR 35961, June 25, 2008) In the 2008 SVT Final Rule, we also explained that the "Omnibus Act requires the DOT to incorporate the HHS scientific and technical guidelines, and we do not have the authority to impose additional scientific and technical requirements upon the laboratories." (73 FR 35963, June 25, 2008)

In response to the commenters who would like us to consider alternative specimens such as hair testing and point of collection testing, we reiterate what we said in response to comments on our direct observation final rule in late 2008: "The Department is not opposed to the use of alternative, less intrusive, testing methods as a means of accomplishing the safety purposes of the program while preventing individuals from cheating. Under the Omnibus Transportation Employee Testing Act of 1991, however, the Department is authorized to use only testing

methods that have been approved by the Department of Health and Human Services (HHS). To date, HHS has not approved any specimen testing except urine." (73 FR 62917, Oct. 22, 2008) Therefore, we cannot consider alternative specimens at this particular point in time. In fact, DOT would not desire to do so without the HHS scientific and laboratory certification processes being in place.

Several commenters have asked us to explain how the Omnibus Act affects the Department's determination of whether it will and will not follow HHS. In response, as we explained above, where the Omnibus Act requires the Department to follow the HHS – for the laboratory and testing procedures, the Department will follow the scientific and technical aspects prescribed by the HHS. Where the Omnibus Act limits or otherwise prohibits the Department from following the HHS, the Department must decline to follow the lead of the HHS. For example, when HHS did not embrace a split specimen requirement, the Department departed from the HHS Mandatory Guidelines due to the Omnibus Act's requirements for split specimens. Where the HHS takes a position that we are neither required to follow nor prohibited from following, the Department will continue to view the HHS position as optional. We recognize that the HHS has expertise in the Federal employee testing program for these optional matters, but the Department has its own expertise as the regulator of the largest workplace drug and alcohol testing program in the world. As such, we will consider the optional matters in light of transportation safety, the costs and benefits to our regulated industries, and scientific and forensic considerations.

Use of Instrumented Initial Test Facilities

In our NPRM, we proposed allowing DOT employers to choose between full service laboratories and IITFs. An IITF would be able to provide results to employers only for negative and certain negative dilute specimens, as well as specimens they reject for testing. All other specimens would be forwarded to an HHS certified, full service laboratory. We requested comments as to how this process would impact the industry, specifically employers. The majority of commenters felt that use of IITFs would be detrimental to the turnaround time for reporting of non-negative results and most did not favor use of IITFs. Other commenters believed IITFs would be very useful, accurate, and afford the ability for a rapid turnaround time for their negative results.

DOT Response

The Omnibus Act actually prohibits the Department from following HHS on the issue of IITFs. The Omnibus Act requires "that all laboratories involved in the controlled substances testing of any individual under this section shall have the capability and facility, at such laboratory, of performing screening and confirmation tests." (49 U.S.C. 49 U.S.C. 31306(c)(3), 49 U.S.C. 20140(c)(3), 49 U.S.C. 5331(d)(3) and 49 U.S.C. 45104(3)) An IITF can conduct the initial screening for drugs in a urine specimen, but is not certified to provide a confirmation test.

Since IITFs do not have any confirmation testing capabilities, the Department must not use them in part 40. The Senate Report for S.676, the bill that subsequently became the Omnibus Act, indicates the intent behind this requirement was to ensure that "[a]ny testing program would be required to include procedures to protect individual privacy, incorporate laboratory certification and testing procedures developed by [HHS] . . . require that all

laboratories involved in testing for drugs have the capability of performing screening and confirmation tests at such laboratory." Senate Report 102-54, pages 10-11. Because IITFs do not offer confirmation testing, the Department is prohibited by the Omnibus Act from using laboratory facilities that lack the capability to perform both screening and confirmation tests. Therefore, DOT employers do not have the option of using IITFs. For this reason there are no provisions in this final rule for IITFs, and they will not be authorized for use in DOT's program by our regulated employers.

MDMA Testing

In the NPRM, we proposed to incorporate testing for MDMA into part 40.

Comments

A majority of commenters favored testing for MDMA. A few commenters indicated that their data showed that there would be relatively few positive test results, creating an unnecessary cost burden to employers. One laboratory group opposed the inclusion of MDMA and suggested the Department test instead for "hydromorphone, hydrocodone, oxycodone, and oxymorphone."

Those who favored testing MDMA represented a wide range of interests – MRO groups, third-party administrators, a major employer association, a major service agent association, among them. Most who supported testing for MDMA said that many employers were already testing for MDMA in their non-DOT testing programs. They supported putting MDMA testing into the Federal testing arena.

Some commenters presented information about the use of MDMA, saying that MDMA was no longer a threat; MDMA is strictly a drug for younger persons; MDMA is a "club" drug that is not being used by transportation employees.

Others presented data showing that MDMA use is on the rise and the implication is that the threat of MDMA use will become greater as the current transportation population is replaced via attrition by a younger population.

DOT Response

In this rulemaking, we are adopting the HHS laboratory testing requirements of conducting initial testing for MDMA, conducting confirmatory testing for MDMA, Methylenedioxyamphetamine (MDA), and Methylenedioxyethylamphetamine (MDEA). As we stated in our NPRM, regarding such matters, "past experience has shown that DOT has never deviated from HHS on laboratory testing matters – the drugs for which we test, the specimens we test, specimen validity testing values, initial and confirmatory cutoff values, and laboratory testing processes and procedures, among others. The DOT is required by the Omnibus Transportation Employee Testing Act of 1991 to adhere with the HHS on these important laboratory testing matters." (75 FR 5722-5723, Feb. 4, 2010) We can provide additional guidance to MROs, as appropriate, so that these changes fit the transportation industries. However, we do not read our authority as allowing us to depart from HHS on this subject.

Aside from the fact that the Omnibus Act requires us to test the drugs for which HHS labs are certified to test, we note that, as some commenters said, MDMA is not just a "club drug" any more, it is being marketed to a much larger population in American communities.

The Department of Justice National Drug Intelligence Center's 2010 National Drug Threat Assessment (http://www.justice.gov/ndic/pubs38/38661/38661p.pdf) supports DOT's conclusion with regard to MDMA availability, finding:

> "Asian DTOs [Drug Trafficking Organizations] are responsible for a resurgence in MDMA availability in the United States, particularly since 2005. These groups produce large quantities of the drug in Canada and smuggle it into the United States across the Northern Border. The smuggling of MDMA into the United States from Canada fueled an increase in the availability of the drug that began in 2005, although availability appears to be stabilizing. Data regarding MDMA availability are limited; nonetheless, analysis of National Forensic Laboratory Information System (NFLIS) data shows a 76 percent increase in the number of MDMA submissions from 2005 to 2008, although MDMA submissions make up a much smaller percentage of submissions than other illicit drugs, including cannabis, cocaine, methamphetamine, and heroin. National Drug Threat Survey (NDTS) data also provide an indication of MDMA availability. The percentage of state and local law enforcement agencies that reported moderate or high availability of MDMA in their areas increased from 47.2 percent in 2005 to 51.5 percent in 2009.
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> Seizure data show that the amount of MDMA seized along the U.S. – Canada border increased 156 percent from 2007 to 2008 and that more MDMA was seized at the Northern Border in 2008 than in any year since 2005. MDMA seizure totals declined in 2009 but still exceeded 2007 totals. Although most Northern Border seizures occur at POEs (Points of Entry), the amount of MDMA seized between POEs appears to be increasing, likely because increased scrutiny at POEs has forced smugglers to develop new routes and smuggling methods in an attempt to circumvent law enforcement.

For example, in 2008, more than 243,000 dosage units of MDMA were seized between POEs, compared with none the previous year; seizures between POEs in 2009 exceeded those in 2008.

MDMA seizures along the Southwest Border and through commercial air have also increased, albeit on a much smaller scale. Seizures at or near the Southwest Border show an increase from 114,286 dosage units in 2006 to 387,143 dosage units in 2009. Furthermore, commercial air seizures spiked in 2008, with a 91.4 percent increase from 2007 to 2008 (433,571 dosage units to 829,857 dosage units); MDMA commercial air seizure totals for 2009 decreased, resulting in levels comparable to 2007 levels.

Ready availability of MDMA has enabled distributors to expand their customer base to include new user groups, most notably African American and Hispanic users. Asian DTOs have begun distributing MDMA to African American and Hispanic street gangs, which distribute the drug along with other illicit drugs in markets throughout the United States, most notably in the Southeast, Southwest, and Great Lakes Regions. Moreover, MDMA is no longer exclusively viewed as a "rave" or club drug, which also aids distributors in selling it to nontraditional abusers."

One laboratory group urged DOT to require testing prescription medications and synthetic drugs, rather than MDMA. While DOT shares the group's concern about unauthorized use of the prescription medications and the use of synthetic drugs, testing for prescription medications and synthetic drug and testing for MDMA are separate issues. As part of their non-DOT testing programs, regulated employers can test for prescription medications or synthetic drugs and in many instances it may be appropriate to do so.

Some DOT agencies and the United States Coast Guard (USCG), for instance, have medical qualification standards – for Commercial Drivers License holders, certified pilots and aviation mechanics, and licensed mariners – that focus upon the underlying medical conditions that would require use of prescription medications. Evaluating medical professionals are trained to seek information that would shed light on an individual's use of medicines and their qualification to perform safety sensitive duties.

It is also important to note that employers can expand upon the Department's regulatory requirements, as long as they do not represent the test as being required by DOT. Under their non-DOT testing programs, DOT-regulated companies may test for other drugs of their choosing. Therefore, companies are not prohibited by DOT from testing for additional drugs that may be of concern within their communities and companies.

Lowering Laboratory Cutoff Criteria for Cocaine and Amphetamines

The Department proposed, in the NRPM, to adopt the HHS-lowered laboratory testing cutoffs for cocaine and amphetamines. Initial test cutoffs for cocaine metabolites would go from 300 to 150 ng/mL, while confirmation test cutoffs would go from 150 to 100 ng/mL.

For amphetamines, initial test cutoffs would go from 1000 to 500 ng/mL, while confirmation tests for amphetamines and methamphetamines would go from 500 to 250 ng/mL.

Comments

Most commenters support the Department's conforming to the HHS Mandatory Guidelines in lowering the cutoffs for both cocaine and amphetamines. Most believe doing so

will enhance the safety of the traveling public because more users of illicit drugs and more users of non-prescribed medications will be identified. There was no controversy about the new screening and confirmation test levels for cocaine.

Some commenters believed that there could be "false positive" drug tests stemming from the new cutoffs for amphetamines. Some others believed the amphetamine cutoffs could even cause laboratories to report over-the-counter (OTC) medications as confirmed positive test results. Some others believed that lowering the screening cutoffs for amphetamines will provide little value in the confirmation process, serving only to increase the cost of the program.

Some commenters cited the data from one of the laboratories – Clinical Research Laboratory (CRL) – as reason to support the new cutoffs, while others cited the same data as reason to oppose the new cutoffs.

DOT Response

As stated earlier in this document, the Department must follow the laboratory testing protocols and standards that are established by HHS. Therefore, we must and will adhere to the screening and confirmation drug testing cutoffs that HHS has established for the laboratories and for which the laboratories are certified. In addition, taken with the comment data from Quest Laboratories, we believe the laboratory data sets from both Quest and CRL lead likely to some, but not all, of the same conclusions

Regarding cocaine, based upon data provided by both Quest and CRL, we can expect a marked increase in cocaine users identified using the new screening and confirmation cutoffs

that HHS has established. The Department, like the overwhelming number of commenters, considers this to be a beneficial change.

In 2009, there were nearly 13,000 positive DOT drug test results reported by laboratories as having confirmed positives for cocaine. Quest and CRL data show that we can expect a significant number of confirmed positive test results for cocaine using the new cutoffs. These new lower cutoffs should result in the Department identifying more cocaine users, further assuring the traveling public that the transportation system is the safest it can be. Doing so will also permit us to continue to further deter drug use in the transportation industries and get those identified as using drugs referred for evaluation and treatment.

Regarding amphetamine and methamphetamine, the Quest data report on 68,000 regulated and 132,000 non-regulated specimens and indicate that a 40% increase in screening and a 30% increase in confirmation rates are expected; hence, a large number of currently non-detected users would be identified.

A second submission of amphetamine and methamphetamine test data, this from CRL, includes the reanalysis of a much smaller number of regulated specimens. Several important facts about the CRL study protocols and results were not fully explained or clarified in their data submission. As a result, we are concerned that other commenters may have misinterpreted the CRL data as meaning that there will be "false positive" tests results for amphetamines and that some OTC medications – ephedrine, pseudoephedrine, and phenylpropanolamine – will be confirmed and reported as positives by laboratories.

We want to address these commenters' statements that testing at the new amphetamine screening cutoffs will yield "false positive" test results. Neither CRL nor Quest even alluded to there being a "false positive" testing issue with the new amphetamine cutoffs. Concerns about

the risks of "false positive" test results are not supported by the available data. In fact, no reportable positive test results were identified in the CRL and Quest data on specimens that did not, in fact, screen and confirm positive for a drug for which DOT tests.

In addition, we want to clarify that no OTC medication that CRL chose to test for – ephedrine, pseudoephedrine, and phenylpropanolamine – would confirm positive on a DOT test and would be reported on a DOT test. We are concerned that the CRL confirmation testing on these specimens may have proven misleading to the groups who read the data and believed that our tests for amphetamines would identify these particular OTC medications. It is our opinion that CRL's inclusion of this confirmation test data does not support CRL's conclusion. Laboratories simply will not conduct confirmation testing for or identify these OTC medications in DOT's program.

It is also important to note that only confirmed positive drug tests are reported to the MRO as positive. No results screened positive are reported as positive until and unless they are also positive on a laboratory confirmation test and for the drugs for which we test. And, no test result is reported to the employer until the MRO properly verifies the result by determining if the employee has a legitimate medical explanation for the positive. If the employee has a legitimate medical explanation, the MRO will report the result to the employer as a negative test. These are "due process" steps that have always been an integral part of DOT's testing program.

We realize that laboratories will certainly screen specimens for amphetamines at the new HHS cutoffs and will not realize the same return rate on confirmed positive testing as they observe now, as CRL points out effectively in their data. CRL is concerned that the cost of confirming the increased number of screened positive tests does not warrant the expense for such a small number of confirmed positives, as shown by their data.

It is important to note that the confirmation rates for opiates and amphetamines is now generally less than that for THC, cocaine, and PCP. Therefore, it is not unusual to see a disparity between screening rates and subsequent confirmation rates, especially for opiates and amphetamines.

However, we will urge HHS to closely monitor this screening issue for amphetamines during the first year the new cutoffs are in place. We believe that the issue will be properly evaluated by HHS with DOT, the Center for Substance Abuse Prevention Drug Testing Advisory Board (CSAP DTAB), and laboratories in determining if the screening cutoffs for amphetamine would need to be modified upward if the added cost largely outweighed the benefits. The CSAP DTAB provides advice to the Administrator, SAMHSA, regarding the drug testing laboratory certification program.

Laboratory Testing for 6-Acetylmorphine (6-AM)

In the NPRM, we proposed to incorporate new HHS criteria for initial testing for 6-AM, a marker for heroin. We also asked if there were factual, evidence-based concerns about the need to show morphine with a 6-AM confirmed positive result. Also, if there were evidence-based systematic research and studies showing that morphine must also be present and quantitations reported, we asked for solutions by laboratories and / or MROs to adequately address the issue.

Comments

A slight majority of commenters expressed support for the new HHS screening and confirmation cutoffs for 6-AM. Some who support the tests for 6-AM do so because they believe transportation safety will be enhanced when more heroin users are identified and removed from their safety-sensitive duties. Several who do not support the provision express concern about the new cutoffs no longer requiring a test for morphine – something they say is imperative to ensure that the person is actually a heroin user. At least one commenter believes no additional heroin users will be identified and expresses concern about the cost of having only one supplier of laboratory reagent for 6-AM.

Several laboratory entities and experts weighed in on the issue. RTI International (RTI) agreed with HHS for screening all specimens for 6-AM and for dropping the requirement to ensure a presence of morphine above 2000 ng/mL. RTI indicated that the new testing will increase the positive rate by 8 - 29%, but failed to explain the basis for its concern. They also quote three studies as supporting the HHS decision.

Clinical Research Laboratory (CRL) quoted their own study – for which we have no way to assess the adequacy of the study protocols – and stated that out of 820 tests for opiates and 6-AM, all screened at 3 ng/mL, versus the HHS cutoff of 10 ng/mL, and all except one had opiate positive results above the 2,000ng/mL cutoff. CRL did not attempt to explain why this sample tested positive for 6-AM but did not test for morphine. They concluded that there is no published explanation for the detection of 6-AM without the presence of morphine. Therefore, CRL recommended that the Department provide guidance to MROs and laboratories about conferring with one another if there were ever 6-AM without the presence of morphine.

Quest Laboratories reviewed 1.2 million test results. Of those specimen results, 112 tested positive for 6-AM (heroin). The Quest study data indicated that 7 of those 112 6-AM

positives also tested positive for morphine in the 300-2000 ng/mL range. The remaining 105 6-AM positives had morphine confirmed above 2000 ng/mL. Quest suggested that "only" six tests out of a million would test positive for 6-AM and not have morphine that was present reported to the MRO. Therefore, Quest recommended that DOT provide additional guidance to MROs to speak with laboratories related to morphine that may be present but not reported by the laboratory.

DOT Response

As stated earlier in this document, the Department must follow the laboratory testing protocols and standards that are established by HHS. Therefore, we must adhere to the screening and confirmation drug testing cutoffs that HHS has established for the laboratories and for which the laboratories are certified.

6-AM is a unique metabolite produced when a person uses the illicit drug heroin. 6-AM is both excreted in the urine and further metabolized to morphine. Morphine can also be excreted in the urine as a result of codeine or morphine use. Thus, morphine is a common metabolite of both heroin and codeine.

It is well established that, in some instances, individuals who are positive for 6-AM are atypically low in the coincident morphine concentration found in urine. That is, their morphine concentrations are below the HHS/DOT cutoff of 2000 ng/mL and even below 300 ng/mL. Therefore, testing programs focused on the morphine concentration as the screening discriminator will fail to identify a number of heroin users (estimated by some studies referenced in the docket to be about 10% of the opiate positives).

While morphine positives in the absence of 6-AM require significant MRO intervention to differentiate legitimate morphine or codeine sources for morphine, 6-AM is a definitive marker for heroin use and thus requires no MRO intervention. There are simply no legitimate medical explanations for 6-AM positive tests. Although there has been from time to time some anecdotal suggestion that 6-AM can be produced from morphine, existing scientific evidence does not support such a claim.

The atypical finding of a 6-AM positive in the absence of significant morphine findings by CRL may be the result of recent heroin use close to the time of sampling, a metabolic defect in the metabolism of 6-AM resulting in prolonged excretion, shunting of metabolic pathways away from morphine, or interaction with other substances not identified. Therefore, the 6-AM testing does not require confirmation by the simultaneous detection of a specified quantity of morphine.

Multiple scientific publications have concluded that a portion of the population shows urinary concentrations of 6-AM above 10 ng/mL with morphine concentrations below 300 ng/mL, even though the Quest study showed that none of their 6-AM positive results had morphine below a 300 ng/mL cutoff.

Therefore, the salient facts are:

- 6-AM confirmed positive tests do not need a morphine marker;
- Data show that when one looks for morphine as a marker, it most always exists above the morphine confirmation cutoffs or above Limit of Detection (LOD); and
- If the morphine marker does not exist on a 6-AM positive result, there is ample scientific reason to strongly suggest *recent* heroin use.

Despite these facts and until more information is gathered from DOT's experience with 6-AM testing, when a 6-AM confirmed positive result is reported and morphine for that specimen is not reported at or above the 2000 ng/mL confirmed positive cutoff, the laboratory and MRO must confer to determine if there was confirmed morphine below the 2000 ng/mL, and if not, whether further testing is needed to quantify the amount of morphine present. The laboratory must report the amount of morphine from the test to the MRO.

If a laboratory finds no detectable morphine at its LOD upon further testing, the laboratory must report that fact to DOT's Office of Drug and Alcohol Policy and Compliance (ODAPC) immediately. Based upon the scientific evidence that exists today, we simply do not think that 6-AM with no morphine detected will occur. But we will determine what our first year of 6-AM screening and confirmation testing reveals in this matter. We would work directly with MROs on these cases, if there would be any. We would also work with HHS to determine if additional action is necessary. Ultimately, the MRO, with ODAPC's assistance, would make a verified result determination following these discussions.

Last year, HHS-certified laboratories conducted approximately 5.2 million DOT tests. Quest estimates that there will be 6 tests per one million that would be reported to MROs for 6-AM with morphine concentrations below the established confirmation cutoffs. Extrapolated, this would mean approximately 30 6-AM positive specimen tests a year will be reported to MROs with morphine below 2000 ng/mL. As with other 6-AM positives, the MRO must not accept an assertion that there is a legitimate explanation for the presence of 6-AM in the employee's specimen.

Approval of Medical Review Officer Training and Examination Groups

The HHS Mandatory Guidelines will require that nationally-recognized MRO certification entities or subspecialty boards for medical practitioners in the field of medical review must have their qualifications, training programs, and examinations approved by HHS on an annual basis. The Department requested comments on whether part 40 should require these groups to be approved and if the Department should seek a shared approval process with HHS.

Comments

Commenters were rather evenly divided about whether the Department should require or join the approval process of the nationally-recognized MRO certification and subspecialty boards. Some who support DOT's involvement expressed concern that HHS would be the only approving authority if the Department does not share in that responsibility. Some who did not support the Department's involvement in the approval process also tended not to support HHS approval of these boards, either. Some commenters offered suggestions about basic standards for national certification groups.

DOT Response

While we believe the current MRO training and examination boards have very strong standards, we want to be certain that these groups continue to present well and accurately the Department's part 40 and DOT agency, including the USCG, drug rules. After all, no MRO wants to be in violation of the Department's regulations because of erroneous information presented during training or on a certification examination. Consequently, it makes sense to consider the benefits of additional oversight of MRO certification groups.

Some of the basic standards suggested by one commenter were very similar to our Subpart O requirements for national drug and alcohol counselor certification organizations. Our experience with these counselor certification organizations taught us that having standard requirements rules out up-front substandard counseling organizations. Our SAP experience also taught us that, from the beginning, the major MRO organizations had established highly reputable training and examination modalities. In fact, we used some of the MRO testing standards in laying out the examination requirements that SAP testing organizations now follow.

We liked the idea submitted by one of the commenters for basic standards for the MRO certification organizations and will pass these ideas to HHS. However, we see no pressing need for the Department to use our limited staff time and personnel to participate in or require approval for these established organizations. Again, our experience has been that these national organizations effectively train, test, and certify MROs. As long as they continue to do so, and as long as there are no new MRO certification organizations on the horizon, we see no reason to expend additional resources approving those who have already demonstrated their competence.

We will continue our practice of helping MRO training and examination groups to accurately update DOT's portions of their course materials, manuals, and examination content. We believe our assistance will enable us to make sure that content is DOT-specific and accurate.

We anticipate that HHS approval standards would include all Federal testing programs. However, we do not intend to become involved in this approval process, unless HHS identifies significant deficits with any of the training and examination efforts by any of these boards that affect DOT's program. For now, DOT will not require these MRO training and examination organizations to obtain HHS approval. Furthermore, MROs in the DOT program will not be

required to be trained by an HHS-approved group, as long as the MROs meet DOT's qualification training and requalification training requirements.

Some of the commenters noted that one MRO certification organization reportedly provides an on-line examination. These commenters ask the Department to put a stop to this practice by requiring only proctored testing. One commenter indicated that at least the examination for the initial MRO certification should be proctored. We will defer action on the issue of proctored versus on-line examinations until we know more about the HHS approval process. We would note, however, that the entire issue of proctored versus on-line examinations remains largely unresolved – with supporters in both corners and with studies and literature supporting both camps.[1]

[1] "Proctored Versus Unproctored Online Exams: Studying the Impact of Exam Environment on Student Performance," Kimberly K. Hollister and Mark L. Berenson Decision Sciences Journal of Innovative Education Volume 7 Issue 1, Pages 271 - 294 Published Online: 16 Jan 2009 © 2010 Decision Sciences Institute

"On-line instruction: Are the outcomes the same?" Warren, L., & Holloman, Jr., H. (2005). Journal of Instructional Psychology, 32(2), 148-151.

"Questioning the hybrid model: Student outcomes in different course formats" Reasons, S., Valadares, K., & Slavkin, M., Journal of Asynchronous Learning Networks, (2005) 9(1).

"Comparison of outcomes on like exams administered to in-residence and asynchronous distance-based Pharm. D. students." Ragan, R. & Kleoppel, J. (2004). *Journal of Asynchronous Learning Networks,* 8(4).

"The Relationship Between Performance Levels and Test Delivery Methods," Patricia Royal, Paul Bell; International Journal of Instructional Technology and Distance Learning, July 2008 Vol. 5. No. 7.

"Traditional versus Online Content Delivery and Assessment," Margaret D. Anderson and Mark Connell, International Journal of Instructional Technology and Distance Learning, February 2009, Vol. 6. No. 2.

Medical Review Officer Recurrent Requalification Training and Examination

In our NPRM we sought comments on whether part 40, at 49 CFR Part 40.121(d), should be amended by removing the requirement that MROs must complete 12 Continuing Education Units (CEUs) pertaining to DOT and MRO practices every three years, and instead require MROs to be requalified every five years by an MRO certification board or subspecialty board for medical practitioners.

Comments

Most commenters supported the idea that the Department require MROs to be requalified by being certified on a regular basis. Most also wanted DOT to continue to require MROs to have continuing education (or, Continuing Medical Education) related to their MRO work. Several commenters indicated that they did not see any benefit to changing the requirements, believing that initial qualification training and the continuing education requirement the Department established in 2000 has proven adequate.

DOT Response

Medical review of drug test results is more complex today than when we established the continuing education requirement in 2000. Therefore, we have decided to side with the overwhelming majority of commenters supporting MRO requalification training and reexamination on a regular basis. We will require MRO requalification every five years.

However, to offset the associated costs, we will not maintain the requirement for continuing education.

Over the years, it has been somewhat difficult for us to know whether the 12 CEU hours obtained by many MROs every three years were indeed related to DOT's testing program, as required. However, based on our experience to date, we believe that a requalification requirement every five years will assure DOT agency auditors and inspectors and regulated employers that MRO's are appropriately qualified.

We anticipate that MROs will continue to obtain CEUs by virtue of their MD and DO licensure requirements. In addition, the MRO certification boards provide their members with MRO manuals and periodic newsletters in an effort to keep everyone up-to-date on the Department's program requirements.

The MRO plays a key role in our important Federal safety program and maintains the Constitutionally-mandated balance between the safety and privacy objectives of the program. The MRO's role in gathering and evaluating the medical evidence and providing due process is imperative. These are duties that must be carried out by the MRO and cannot be delegated to anyone.

The MRO is charged with certain important medical and administrative duties. The MRO must have detailed knowledge of the effects of medications and other potential alternative medical explanations for laboratory reported drug test results. He or she is responsible for determining whether legitimate medical explanations are available to explain an employee's drug test result. This medical review process has become far more complex as a result of specimen validity testing and the myriad of medical explanations for adulterated, substituted, and invalid

laboratory test results. These complexities have made MRO knowledge of the effects of drugs and medications even more important than it was in 2000.

Part 40 also requires the MRO to confer with prescribing physicians in making decisions about prescription changes so that alternative medications can be used that will not impact public safety. Similarly, the MRO is required to report to employers the employees' prescription and over-the-counter medication use (or dangerous combinations of use) that the MRO believes will negatively affect duty performance. In addition, the MRO is required to medically assess referral physician examinations and evaluations in certain positive and refusal-to-test situations. These, too, have become more complex over time.

For these reasons, we think qualification training and examination followed by requalification and an examination every five years will be much more effective than the current one-time training and examination requirement with periodic CEUs. To ensure that MROs are well qualified, the requalification process must be very similar to the original qualification training (i.e., a full training program addressing all issues required by part 40) and an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. A mere "up-date" type of training will be considered a violation of part 40.

This regulation text lays out the requirements for when this new requalification training is to take place. MROs must maintain documentation about their qualification training and any subsequent continuing education. MROs would simply be required to complete the new requalification training and examination no later than five years from the date of having last met either their qualification training or continuing education requirements. Following the

completion of the new requalification requirements, MROs will be required to complete requalification training and examination every five years thereafter.

DOT will continue to use the term “qualification training” rather than “certification training” and will use “requalification training” rather than “recertification training” in part 40.

Medical Review Officer Records Maintenance

In the NPRM we asked for discussion related to MRO records; primarily we asked what documentation of consultation and deliberation should be in MRO records. In the NPRM, we stated that our current record keeping requirements for negative and non-negative test results would not change based upon the new HHS MRO record keeping requirements.

Comments

Six commenters addressed the issue of MRO records. All supported the idea that MROs should keep records and that the time frame should be the same as that required for employers.

One association said that DOT inspectors are not qualified to question MRO judgments regarding medical information and its relevance. Another commenter indicated that personal information, which was not defined, should be confidential and not part of the MRO file. This same commenter provided a long list of items that should be part of the record, including various dates and times of MRO contacts and conversations with various Designated Employer Representatives (DERs), collectors, and employers. In addition, this commenter believed that

information should be included related to contacts with other physicians, laboratories, and pharmacies, although without specific detail.

DOT Response

The DOT agrees with commenters that MRO records are very important and integral to the MRO review process. We believe that records and notes generated by the review process need to be maintained. The purpose of any record is to ensure that proper procedures and results were achieved under part 40 requirements. MRO records must show why a particular specimen is negative or non-negative. At times, the test result must withstand legal challenges.

DOT regulations already require MROs to follow the employer's record retention requirements – five years for non-negatives and one year for negatives. Those will not change.

The notes recorded by the MRO are considered by the Department to be part of the record. These notes generally contain all the information that was discussed by the MRO with the employee and any supplemental information the MRO uses to support the various reasons the employee provides as legitimate medical explanation for a non-negative result. The MRO records may include copies of prescriptions, letters from other physicians, and consultations by the MRO with physicians, pharmacy personnel, laboratory personnel, and other appropriate individuals.

However, a listing of these contacts without specific references as to what was discussed would not be effective. There must be a specific comment or rationale to which the MRO can subsequently refer for support and reasoning about the outcome of the verification process. This is especially true if a decision is challenged in a court or an administrative hearing proceeding.

During the verification interview, the employee may share personal information. Unless a specific issue, such as the use of psychotropic medication, is used as a medical explanation for a drug positive, the MRO should not include the other sensitive, unrelated personal information in the record. From a practical point of view, MROs will primarily record information that is specific to the issue at hand or may have an impact upon safety. The Department is comfortable that MROs are trained, both in their role as physicians and as MROs, to maintain a clear balance between recording of pertinent information versus not recording sensitive information which is not relevant to the verification process or transportation safety.

In reference to inspectors' qualifications to question MROs medical decisions, we want to point out that the purpose of an inspection is not to challenge a physician's medical expertise, but rather to ensure that the MRO is abiding by regulations and current requirements. In most cases, the issue would be whether there is adequate documentation for whatever action the MRO took. For example, if the MRO had his or her staff confer with the pharmacist or a prescribing physician – instead of doing so himself or herself, as the regulations require – the MRO's procedures would be contrary to part 40.

When a positive result is downgraded to a negative result, the inspector would look at the reason for this downgrade. If there is a legitimate medical explanation, the inspector would expect to see this clearly spelled out in the record. For example, if a THC positive confirmed laboratory result were downgraded to negative because of an explanation of "medical marijuana" use, the inspector would rightfully view that as a serious matter, because it remains unacceptable for any safety-sensitive employee subject to DOT drug testing rules to use marijuana.

Additional areas of concern by DOT inspectors and auditors focus upon the person(s) who actually talk(s) with the employee following a non-negative result (e.g., the MRO vs. the

MRO staff), how requests for split specimen testing are handled and whether requests are handled in timely manner, and how DERs are notified about non-negative results. The Department also knows that inspectors and auditors are trained to address all of these issues, and they are sensitive to the fact that these MRO records contain medical information and that they must be handled appropriately. We want to reaffirm that inspecting and auditing MRO records has been, and will continue to be, one of the mechanisms that inspectors and auditors use to ensure compliance with DOT regulations.

Section-by-Section Discussion

The following part of the preamble discusses each of the final rule's sections, including responses to comments on each section.

Table of Contents

The Department proposed, in the NPRM, to modify some existing section headings in order to reflect regulation text changes. In all, three section headings have been modified and one has been added. § 40.3, § 40.87, and § 40.139 have been revised, and § 40.140 has been added.

Section 40.3 What do the terms in this part mean?

In order to align more closely the definitions in § 40.3 with definitions contained in the HHS Mandatory Guidelines, in the NPRM, the Department proposed modifying some existing definitions and adding several new ones.

Five commenters supported this proposal and responded by making suggested additions or changes to this section. Several commenters did not support the changes, contending that the Department should not allow DOT-regulated employers to use IITFs. Because the Department is not allowing IITFs, no definitions related to IITFs will be added. A few commenters did not want the Department to change its definition of "cancelled test" because the proposed definition was confusing. After reviewing the comments the Department agrees with the commenters and will keep the current definition of "cancelled test." Other commenters did not want the Department to add definitions that were only applied to the HHS program and not to the DOT program. We have reviewed those definitions and decided that most will be in the regulation. It is necessary to harmonize our terms with HHS definitions, in order that laboratories and others in the drug testing industry have consistent terms with which to operate.

In all, 13 definitions will be modified or added to harmonize with HHS definitions, and one will be removed. The new or modified definitions are "Adulterated specimen," "Confirmatory drug test," "Initial drug test (also known as a Screening drug test)," "Initial specimen validity test," "Invalid drug test," "Laboratory," "Limit of Detection (LOD)," "Limit of Quantitation," "Negative result," "Positive result," "Reconfirmed," "Rejected for testing," and "Split specimen collection." The term "Initial validity test" was removed.

Section 40.87 What are the cutoff concentrations for drug tests?

The Department will require conducting initial and confirmation testing for MDMA, MDA, and MDEA, conducting initial testing for 6-AM, lowering the initial and confirmation cutoff concentrations for amphetamines, and lowering the initial and confirmation cutoff concentrations for cocaine. We include certain instructions for laboratories (and MROs) related

to 6-AM testing. Specific discussions of these issues are included under "Principal Policy Issues" in this preamble.

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

The Department added a paragraph to this section instructing the laboratory to contact ODAPC if it ever confirms 6-AM with no detectable morphine at its LOD, upon further testing. A fuller discussion of this matter is in "Principal Policy Issues."

Section 40.121 Who is qualified to act as an MRO?

Commenters had a number of suggestions related to ongoing training for MROs. The DOT reviewed the comments and, as discussed in the "Principal Policy Issues," will require MRO requalification, including training and examination, every five years.

Section 40.139 On what basis does the MRO verify test results for codeine and morphine?

The Department has revised this section by limiting the section to how MROs are to verify laboratory-confirmed codeine and morphine test results. We removed 6-AM verification from this section and moved it to a new section. We also revised the section's heading.

Section 40.140 On what basis does the MRO verify test results for 6-acetylmorphine (6-AM)?

This new section provides instructions to MROs on how they are to verify confirmed positive 6-AM results from laboratories. Instructions include how MROs are to handle 6-AM confirmed positive results when morphine is above the confirmation cutoff, when morphine is confirmed below the confirmation cutoff, when morphine is confirmed above LOD, and if ever

morphine is not detected at LOD upon further testing. A fuller discussion of this matter is in "Principal Policy Issues."

Section 40.151 What are MROs prohibited from doing as part of the verification process?

The Department has revised this section by adding MDMA, MDA, and MDEA as being among the drugs for the presence of which there exist no legitimate medical explanations. This instruction is consistent with what the Department has said about PCP and 6-AM.

Section 40.159 What does the MRO do when a drug test is invalid?

In response to the commenters' concerns related to pH, this section is based on a July 2008 guidance authorizing MROs to consider time and temperature in making their verification decisions if pH is in the 9.0 - 9.5 range. A fuller discussion of this matter is in "Principal Policy Issues."

Section 40.163 How does the MRO report drug test results?

The majority of the commenters wanted DOT to be clear about the records MROs should keep and how long MROs should keep them. Based upon the comments, we have decided to put more specificity about this issue into the MRO rule text section. MROs keep negative and cancelled drug test reports and records for one year, and all positive and refusal drug test reports and records for five years. A fuller discussion of this matter is in "Principal Policy Issues."

Appendix B to Part 40 - DOT Drug Testing Semi-Annual Laboratory Report to Employers

The Department has modified the requirements for the semi-annual laboratory reports to employers. The changes require laboratories to also report the total number of MDMA, MDA, and MDEA positive drug test results.

Appendix C to Part 40 - DOT Drug Testing Semi-Annual Laboratory Report to DOT

The Department has modified the requirements for the semi-annual laboratory reports to DOT. The changes require laboratories to also delineate the positives for the newly added MDMA, MDA, and MDEA. We are also breaking out the other drugs for which we test in order to make it simpler for laboratories to report and for our staff to tally the reports.

Other Issues

There were several comments that addressed editorial changes and included typographical errors. We appreciate these comments and incorporated a good many of the suggestions and edits.

The Department also received several comments that we consider to be outside of the scope for this rulemaking. However, in order to try to bring closure to these issues, we will provide some explanation and clarification.

One commenter said that section 40.25 stated that the employer was required to obtain consent from the applicant, but the commenter believed that section 40.27 prohibited the employer from obtaining consent for release of the 40.25 information. We would like to point out that section 40.25 requires the employee to sign this written consent in order to perform safety-sensitive duties and is very specific as to the purpose of this consent. Section 40.27 prohibits an employer from requiring the employee to sign a form consenting to participation in

the program, a blanket release form for all drug and alcohol testing information, or any type of waiver of indemnification or liability. There is no contradiction between these two requirements.

Another commenter believed that the HHS employer option for a second collection, if the first test result was "negative dilute," was not adopted by DOT. We would point out that this authorization has already been part of our rule for some time and is clearly spelled out in section 40.197.

One commenter wanted the Department to establish a time limit on how long an employee had to wait at a collection site before providing a urine specimen. This commenter thought that two hours should be the maximum timeframe an employee had to wait to provide a specimen. This same commenter also wanted clarification about what constituted a "drug failure" and that leaving the collection site for a short time should not be considered a refusal, unless the employee left the collection area where the urine sample is actually taken. Additionally, this commenter wanted some grievance procedures to be established should there be problems at a collection site.

Although this commenter was concerned about how long an employee may have to wait to provide a specimen, we would like to emphasize that section 40.61(b) clearly directs the collection site to "begin the testing process without undue delay." The Department's position has always been that testing should start as soon as possible after the employee's arrival at the site. The Department's position has always been that the employee cannot leave the collection site, i.e., the waiting area, even for a short time. Leaving the site provides employees the opportunity to adulterate or substitute their specimens. And finally, collection site problems encountered by employees should be raised to the employer following the collection. The employer is ultimately responsible for the proper operation of its drug testing program.

One association asked for clarification as to what the Department intended by the term "same business day" as it applies under section 40.205. This section directs that if a problem is identified in the testing process, anyone involved in it should make an attempt to correct the problem on the same business day that notification is received about the problem. This commenter provided several scenarios where the employer, the collection site, or the service agent offices are closed, but the information is transmitted to them. The question is how these entities can meet the requirement of responding on the same day that they are notified about a problem.

If an office is closed when information is received, common sense dictates that the next day the office is open is the business day it is received.

Several commenters asked about other HHS Mandatory Guidelines procedures and whether the Department would adopt them. As discussed in the NPRM, the Department identified those HHS Mandatory Guidelines we proposed to adopt and which ones we did not. In this final rule, we have again highlighted those we have adopted.

For example, the Department will not require observers to receive advanced, formalized training to learn about the steps necessary to directly observe a collection. The current process of having a qualified and trained collector provide immediate, precise, and relevant instructions to an observer at the time of a directly observed collection is very appropriate and effective and has been for years. That way, the Department can be assured that the requisite instructions are provided each time that direct observation is required, no matter how many, or few, an observer has already accomplished.

In addition, the costs associated with formally training observers (and the resulting limitation on available observers) does not outweigh any minimal benefits to arguably be

obtained by training observers in advance instead of providing timely and relevant instructions on site at the time direct observation is required. The Department is not aware of any cases where it was not effective to have the qualified and trained collector instruct the observer at the time a direct observation must occur, and to do so each and every time, no matter whether the observer has already been trained and properly informed.

Also, DOT will not change our longstanding regulatory position that a collector need not obtain prior approval from a collection site supervisor before performing a directly observed collection. Requiring collectors to get approval from collection site supervisors would create difficult logistical issues that would complicate the process. There are numerous instances where the collector is alone or does not have immediate access to a collection site supervisor. In fact, the collector may be the site supervisor. Many collections occur off-site or in the middle of the night, where and when supervisors would not be available, and requiring consultation with an unavailable supervisor would prove onerous and serve only to delay the process unnecessarily. We believe qualified collectors should continue to make these direct observation collection decisions and to continue basing those decisions upon the clear requirements set forth in part 40.

Also, we will not change the duration of the paperwork retention requirement for collectors. HHS will require collectors to keep Copy 3 for two years. The Department believes the current 30 days is sufficient in DOT's program. Retention for 30 days has proven a sufficient amount of time in which to ensure that a CCF copy with the employee's signature would be available to the MRO when the MRO's CCF copy was not available. Requiring document retention for two years would greatly increase the paperwork burden without any added safety or efficiency benefit.

Under the revised HHS Mandatory Guidelines, Federal agencies will be required to audit five percent or a maximum of 50 of their collection sites annually. The Department believes that creating a parallel requirement for transportation industry employers would be very expensive to employers in DOT's program in terms of time and resources, with few efficiency and/or safety benefits. The Department would anticipate seeing more effective monitoring by the collection site parent organizations in an effort to ensure for employers that sites under their organization umbrellas, with which employers are contracting, are properly conducting collections. The DOT agencies and the U.S. Coast Guard also provide on-site audits and inspections of collection sites. They have also increased their mock collection inspections and their clandestine inspections. All of these provide added oversight to determine whether collection site personnel are properly performing collections and whether collection sites adhere to DOT's strong security and integrity requirements.

The revised HHS Mandatory Guidelines will require at least three percent blind specimen testing, compared to DOT's current one percent. We believe our current requirements represent a good balance between considerations of reducing burdens and maintaining an effective check upon laboratory performance. We have had few, if any, laboratory accuracy problems over the history of the program, and we believe that we can continue to ensure that this pattern continues while reducing burdens and costs on participants. Coupled with the HHS requirements and the additional proficiency testing required for laboratory certification, the blinds submitted to laboratories for quality control testing purposes via DOT requirements are quite ample.

In the NPRM, the Department estimated the total annual cost of testing for MDMA and 6-AM to be $1,361,063. One commenter believed that estimate to be too low, but did not offer

any recommended cost figure. We believe there will be approximately 5 million DOT tests per year, and an MDMA test will cost on average $ 0.09 per test, and 6-AM will cost on average $.26 per test. MDMA will cost approximately $450 thousand per year, and 6-AM will cost approximately $1.3 million per year, for a total of $1.75 million per year.

REGULATORY ANALYSES AND NOTICES

The statutory authority for this rule derives from the Omnibus Transportation Employee Testing Act of 1991 (49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 *et seq*.) and the Department of Transportation Act (49 U.S.C. 322).

The Department estimates there will be approximately 5 million DOT tests per year. An MDMA test will cost on average $ 0.09 per test, and 6-AM will cost on average $.26 per test. MDMA will cost approximately $450 thousand per year, and 6-AM will cost approximately $1.3 million per year, for a total of $1.75 million per year. Based upon the data discussed in the "Principal Policy Issues," the increased detection of amphetamine, methamphetamine, and cocaine use through drug testing is estimated to be approximately 30% more for amphetamines/methamphetamines, and 30% more for cocaine. In 2009, HHS-certified laboratories reported to DOT that there were 14,195 confirmed DOT positive results for amphetamines/methamphetamines. So, we estimate an increase of over 4,000 confirmed positive amphetamine/methamphetamine test results. Also in 2009, laboratories reported 12,918 DOT cocaine confirmed positive results. Therefore, we estimate an increase of nearly 4,000 confirmed cocaine results. We estimate the cost associated with this increase of 8,000 positive

test results for cocaine and amphetamines/methamphetamines to be $500 thousand. The total program cost of the new regulation will be $2.25 million.

It stands to reason that it will be cost beneficial to identify the illegal drug use of an additional 8,000 safety-sensitive transportation employees annually, across all modes – on roads, rails, water, or in the air, over land and underground. Furthermore, if identifying the illicit drug use by these employees prevents a single serious accident, then the economic benefits of the rule will outweigh its costs. As we have stated throughout this preamble, the Omnibus Act requires us to follow HHS on these specific drug testing matters.

We have concluded that this rule is not significant for purposes of Executive Order 12866 or DOT's regulatory policies and procedures. In addition to its low costs, it modifies our overall part 40 procedures and is intended to further align our laboratory procedures and processes, as well as some collection and MRO procedures, in order to harmonize DOT procedures with requirements that are being directed by HHS Mandatory Guidelines, which were themselves deemed to be non-significant rules. The DOT also certifies, under the Regulatory Flexibility Act, that this rule will not have a significant economic impact on a substantial number of small entities. Given the small net change in regulatory costs compared to the present rule, spread over the many thousands of small entities in the transportation industries, the cost impact per entity is expected to be negligible.

There are no new information collection requirements that would be subject to the Paperwork Reduction Act.

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 ("Federalism"). This rule does not include requirements that (1) have substantial direct effects on the States, the relationship between the national government and the

States, or the distribution of power and responsibilities among the various levels of government, (2) impose substantial direct compliance costs on State and local governments, or (3) preempt State law. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

List of Subjects in 49 CFR Part 40

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

49 CFR subtitle A

Authority and Issuance

Issued August 10 , 2010, at Washington D.C.

Ray LaHood,

Secretary of Transportation

For reasons discussed in the preamble, the Department of Transportation amends Title 49 of the Code of Federal Regulations, Part 40, as follows:

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

1. The authority citation for 49 CFR Part 40 continues to read as follows:

Authority: 40 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq*.

what basis does the MRO verify test results for 6-AM?

* * * * *

2. § 40.3 is amended as follows:

A. Revise the section heading.

B. Revise the definitions of Adulterated specimen, Confirmatory drug test, Initial drug test (also known as a Screening drug test), Invalid drug test, Laboratory, and Limit of detection (LOD).

C. Add in alphabetical order definitions of Initial specimen validity test, Limit of Quantitation, Negative result, Positive result, Reconfirmed, Rejected for testing, and Split specimen collection.

D. Remove the definition of Initial validity test.

The revisions and additions read as follows:

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

* * * * *

Adulterated specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

* * * * *

Confirmatory drug test. A second analytical procedure performed on a different aliquot of

the original specimen to identify and quantify the presence of a specific drug or drug metabolite.

* * * * *

Initial drug test (also known as a "Screening drug test"). The 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 urine specimen is adulterated, diluted, substituted, or invalid.

Invalid drug test. The result reported by an HHS-certified laboratory in accordance with the criteria established by HHS Mandatory Guidelines 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 of Subpart C of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; 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 a measurand can be identified, but (for quantitative assays) the concentration cannot be accurately calculated.

Limit of Quantitation. For quantitative assays, the lowest concentration at which the identity and concentration of the measurand can be accurately established.

* * * * *

Negative result. The result reported by an HHS-certified laboratory to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for the drug or drug class and the specimen is a valid specimen.

* * * * *

Positive result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentrations.

* * * * *

Reconfirmed. The result reported for a split specimen when the second laboratory is able to corroborate the original result reported for the primary specimen.

* * * * *

Rejected for testing. The result reported by an HHS-certified laboratory when no tests are performed for a specimen because of a fatal flaw or a correctable flaw that is not corrected.

* * * * *

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

* * * * *

3. In §40. 87, the section heading and paragraph (a) are revised, and paragraph (e) is added, to read as follows:

§40.87 What are the cutoff concentrations for drug tests?

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

Initial Test Analyte	**Initial Test Cutoff Concentration**	**Confirmatory Test Analyte**	**Confirmatory Test Cutoff Concentration**
Marijuana metabolites	50 ng/mL	THCA[1]	15 ng/mL
Cocaine metabolites	150 ng/mL	Benzoylecgonine	100 ng/mL
Opiate metabolites			
Codeine/Morphine[2]	2000 ng/mL	Codeine	2000 ng/mL
		Morphine	2000 ng/mL
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL

Amphetamines[3]			
AMP/MAMP[4]	500 ng/mL	Amphetamine	250 ng/mL
		Methamphetamine[5]	250 ng/mL
MDMA[6]	500 ng/mL	MDMA	250 ng/mL
		MDA[7]	250 ng/mL
		MDEA[8]	250 ng/mL
[1]Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA)			
[2]Morphine is the target analyte for codeine/morphine testing			
[3]Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff			
[4]Methamphetamine is the target analyte for amphetamine/methamphetamine testing			
[5]To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL			
[6]Methylenedioxymethamphetamine (MDMA)			
[7]Methylenedioxyamphetamine (MDA)			
[8]Methylenedioxyethylamphetamine (MDEA)			

* * * * *

(e) On a 6-AM confirmed positive result:

(1) When a 6-AM confirmed positive result is reported and morphine for that specimen is not reported at or above the 2000 per ng/mL confirmed positive cutoff, you must confer with the MRO to determine if there was confirmed morphine below 2000 ng/mL.

(2) If morphine was not confirmed below 2000 ng/mL, you and the MRO must determine whether further testing is needed to quantify the amount of morphine concentration present.

(3) If you find no detectable morphine at LOD upon further testing, you must report that fact to ODAPC immediately.

4. In § 40.97, paragraph (g) is added to read as follows:

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

* * * * *

(g) If you confirm 6-AM and find no detectable morphine at LOD upon further testing, you must report that fact to ODAPC immediately.

5. In § 40.121, paragraph (d) is revised to read as follows:

§ 40.121 Who is qualified to act as an MRO?

* * * * *

(d) Requalification Training. During each five-year period from the date on which you satisfactorily completed the examination under paragraph (c)(2) of this section or have successfully completed the required continuing education requirements which were mandatory prior to October 1, 2010, you must complete requalification training.

(1) This requalification training must meet the requirements of the qualification training under paragraph (c)(1) of this section.

(2) Following your completion of requalification training, you must satisfactorily complete an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.

* * * * *

6. § 40.139 is revised to read as follows:

§ 40.139 On what basis does the MRO verify test results for codeine and morphine?

As the MRO, you must proceed as follows when you receive a laboratory confirmed positive morphine or codeine test result:

(a) In the absence of 6-AM, if the laboratory detects the presence of either morphine or codeine at 15,000 ng/mL or above, you must verify the test result 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.

(b) For all other opiate positive results, you must verify a confirmed positive test result for opiates only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (i.e., morphine, heroin, or codeine).

(1) As an MRO, it is your responsibility to use your best professional and ethical judgment and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that you may consider in making this judgment include, but are not limited to, the following:

(i) Recent needle tracks;

(ii) Behavioral and psychological signs of acute opiate intoxication or withdrawal;

(iii) Clinical history of unauthorized use recent enough to have produced the laboratory test result;

(iv) Use of a medication from a foreign country. See § 40.137(e) for guidance on how to make this determination.

(2) In order to establish the clinical evidence referenced in paragraphs (b)(1)(i) and (ii) of this section, personal observation of the employee is essential.

(i) Therefore, you, as the MRO, must conduct, or cause another physician to conduct, a face-to-face examination of the employee.

(ii) No face-to-face examination is needed in establishing the clinical evidence referenced in paragraph (b)(1)(iii) or (iv) of this section.

(3) To be the basis of a verified positive result for opiates, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you do not have grounds for verifying the test positive. The admission must be for the substance that was found).

(4) As the MRO, you have the burden of establishing that there is clinical evidence of unauthorized use of opiates referenced in paragraph (b) of this section. If you cannot make this determination (e.g., there is not sufficient clinical evidence or history), you must verify the test as negative. The employee does not need to show you that a legitimate medical explanation exists if no clinical evidence is established.

7. A new § 40.140 is added to read as follows:

§ 40.140 On what basis does the MRO verify test results for 6-acetylmorphine (6-AM)?

As the MRO, you must proceed as follows when you receive a laboratory confirmed 6-AM test result:

(a) If the laboratory confirms the presence of 6-AM in the specimen and there is also any level of quantitation of morphine, you must verify the test result positive.

(b) When a laboratory 6-AM confirmed positive result is reported and morphine for that specimen is not reported at or above the 2000 per ng/mL confirmed positive cutoff, you must confer with the laboratory to determine if there was confirmed morphine below 2000 ng/mL.

(1) If there was confirmed morphine below 2000 ng/mL, you must verify the test result positive.

(2) If morphine was not confirmed below 2000 ng/mL, you and the laboratory must determine whether further testing is needed to quantify the amount of morphine present.

(c) If a laboratory finds detectable morphine at its LOD upon further testing, you must verify the test result positive.

(d) If a laboratory finds no detectable morphine at its LOD upon further testing, you and the laboratory must report that fact to the ODAPC immediately. Following your discussion with ODAPC, you will make a verified result determination.

8. In § 40.151, paragraph (g) is revised to read as follows:

§ 40.151 What are MROs prohibited from doing as part of the verification process?

* * * * *

(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP, 6-AM, MDMA, MDA, or MDEA in a specimen.

* * * * *

9. In § 40.159, paragraph (a)(6) is added to read as follows:

§ 40.159 What does the MRO do when a drug test is invalid?

(a) * * *

(6) When the test result is invalid because pH is greater than or equal to 9.0 but less than or equal to 9.5 and the employee has no other medical explanation for the pH, you should consider whether there is evidence of elapsed time and increased temperature that could account for the pH value.

(i) You are authorized to consider the temperature conditions that were likely to have existed between the time of collection and transportation of the specimen to the laboratory, and the length of time between the specimen collection and arrival at the laboratory.

(ii) You may talk with the collection site and laboratory to discuss time and temperature issues, including any pertinent information regarding specimen storage.

(iii) If you determine that time and temperature account for the pH value, you must cancel the test and take no further action, as provided at paragraph (a)(4) of this section.

(iv) If you determine that time and temperature fail to account for the pH value, you must cancel the test and direct another collection under direct observation, as provided at paragraph (a)(5) of this section.

* * * * *

10. In § 40.163, paragraph (h) is added to read as follows:

§ 40.163 How does the MRO report drug test results?

* * * * *

(h) You must maintain reports and records related to negatives and cancelled results for one year; you must maintain reports and records related to positives and refusals for five years, unless otherwise specified by applicable DOT agency regulations.

11. Appendix B to part 40 is revised to read as follows:

Appendix B 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)

1. 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. Specimens Reported

(a) Negative (number)

(b) Negative and Dilute (number)

3. Specimens Reported as Rejected for Testing (total number)

By Reason

(a) Fatal flaw (number)

(b) Uncorrected Flaw (number)

4. Specimens Reported as Positive (total number) By Drug

(a) Marijuana Metabolite (number)

(b) Cocaine Metabolite (number)

(c) Opiates (number)

(1) Codeine (number)

(2) Morphine (number)

(3) 6-AM (number)

(d) Phencyclidine (number)

(e) Amphetamines (number)

(1) Amphetamine (number)

(2) Methamphetamine (number)

(3) MDMA (number)

(4) MDA (number)

(5) MDEA (number)

5. Adulterated (number)

6. Substituted (number)

7. Invalid Result (number)

12. Appendix C to part 40 is revised to read as follows:

Appendix C to Part 40 - DOT 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

W62-300

1200 New Jersey Avenue, S.E.

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. DOT Specimen Results Reported (total number)

2. Negative Results Reported (total number)

    Negative (number)

    Negative-Dilute (number)

3. Rejected for Testing Results Reported (total number)

    By Reason

    (a) Fatal flaw (number)

(b) Uncorrected Flaw (number)

4. Positive Results Reported (total number)

By Drug

(a) Marijuana Metabolite (number)

(b) Cocaine Metabolite (number)

(c) Opiates (number)

(1) Codeine (number)

(2) Morphine (number)

(3) 6-AM (number)

(d) Phencyclidine (number)

(e) Amphetamines (number)

(1) Amphetamine (number)

(2) Methamphetamine (number)

(3) MDMA (number)

(4) MDA (number)

(5) MDEA (number)

5. Adulterated Results Reported (total number)

By Reason (number)

6. Substituted Results Reported (total number)

7. Invalid Results Reported (total number)

By Reason (number)

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