14-4101-cv

To Be Argued By:
CYNTHIA S. ARATO

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

DOCTOR FRED L. PASTERNACK,

Plaintiff-Appellant,

—against—

LABORATORY CORPORATION OF AMERICA HOLDINGS,
a/k/a LABCORP, CHOICEPOINT, INC.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR PLAINTIFF-APPELLANT

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PRELIMINARY STATEMENT

For over forty years, Fred Pasternack had a successful career as a part-time pilot and a senior medical examiner for the Federal Aviation Administration ("FAA"). In 2007, Pasternack was randomly selected for a drug test. He appeared, cooperated with the test, and tested negative for any controlled substances. Nonetheless, the companies who collected his urine specimen and administered the test made a series of blunders and missteps along the way, causing the FAA to revoke Pasternack's pilot certificate and examiner designation on the erroneous basis that he had refused to take his test. This appeal concerns Pasternack's right to pursue tort claims against those companies to remedy the harms they caused him.

ChoicePoint, Inc., an entity hired by Pasternack's employer, administered the overall testing process; another company, Laboratory Corporation of America ("LabCorp") collected and tested the urine sample. After Pasternack had completed his test and had tested negative for drugs, ChoicePoint erroneously reported him to the FAA as a "refusal to test" because he had temporarily left the specimen-collection facility before the test had ended. But Pasternack did not refuse anything. He cooperated with the test, left the facility with permission, completed his test three hours later with the employer's blessing, and ultimately tested negative for drugs. ChoicePoint knew all of that. But without even

conducting any investigation, ChoicePoint reported to the FAA that Pasternack had "refused" to take the test. ChoicePoint had no authority to make that determination, and the determination it made was wrong. ChoicePoint's carelessness had devastating consequences for Pasternack because "refusing" to take a test is treated the same as, or worse than, testing positive for drugs.

LabCorp's improper conduct also launched the damage to Pasternack. Before he left the facility, Pasternack attempted to provide a specimen but was unable to produce enough urine. LabCorp's personnel failed to inform Pasternack, as required by federal law, that he was required to remain at the facility to attempt certain "shy bladder" procedures. Instead, Pasternack was simply told to sit in the waiting room. Then, when he raised the possibility of leaving the facility temporarily to attend to a work matter, he was not informed that leaving could or would be deemed a refusal to test under federal regulations. Quite the contrary, LabCorp suggested that there would no negative consequences. LabCorp allowed Pasternack to leave the facility and unwittingly expose himself to FAA sanctions.

Pasternack fought the FAA to restore his licenses through two rounds of administrative proceedings, and after five years and two appeals, he ultimately prevailed in the D.C. Circuit. He filed this lawsuit to recover for the harms he suffered as a result of ChoicePoint's and LabCorp's negligence in wrongfully administering and reporting the results of his drug test. The district court,

however, dismissed Pasternack's negligence claims on the pleadings. It held that neither ChoicePoint nor LabCorp owed Pasternack a duty to act with reasonable care in administering his drug test. In the court's view, the only duty the administrator of a drug test owes to a test subject is the limited duty to avoid "mishandling" or "improper testing" of a specimen. The court thought Pasternack's claims required an unwarranted extension of existing precedent.

That ruling was wrong. At the time of the decision, numerous cases in New York and elsewhere had recognized that the administrator of a drug test owes a duty to the test subject to perform the drug test reasonably. Although many of the cases involved "mishandling" or "improper testing" of a specimen, no case expressly limited the duty to those particular facts, or justifies such a limitation.

More importantly, following the decision but while this case was still pending below, the New York Court of Appeals made clear that the scope of an administrator's duty to a test subject, whose livelihood and reputation hangs in the balance, is quite broad. In *Landon v. Kroll Laboratory Specialists, Inc.*, 22 N.Y.3d 1 (2013), the Court held that drug test administrators owe their test subjects a broad duty of care throughout the testing and reporting process. Pasternack moved for reconsideration of the original dismissal in light of *Landon*, but the district court refused to reinstate his negligence claims, based on an overly narrow and erroneous interpretation of *Landon*, other New York negligence law, and a

misreading of this Court's precedent on the interplay between the Federal Aviation Act and state tort law.

The district court also erroneously concluded that Pasternack had not properly alleged causation simply because the FAA was the most immediate cause of his injuries. But black-letter law established that more than one negligent actor may contribute to a plaintiff's injury.

Finally, the district court wrongfully dismissed Pasternack's fraud claim against LabCorp. The New York Court of Appeals has long held that a plaintiff may state a claim for fraud under New York law when the defendant knowingly makes false statements to a third party and the plaintiff is harmed by the third party's reliance. In accord with that precedent, Pasternack alleged that LabCorp is liable in fraud for intentionally making false statements to FAA investigators, which led to the revocation of Pasternack's pilot's licenses and AME designation. Yet the district court again rejected the controlling New York authority and held that Pasternack failed to state a claim. This, too, was error.

For these reasons and others, the district court's decisions should be reversed, and its judgment vacated.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1332(a). The court entered a final judgment on September 30, 2014 that disposed of all parties'

claims. (A-288).[1] Pasternack filed a timely notice of appeal on October 29, 2014. (A-290). This Court has jurisdiction under 28 U.S.C. § 1291.

ISSUES PRESENTED

1. Whether the district court erred when it held, contrary to the New York Court of Appeals' 2013 decision in *Landon*, that drug test administrators owe test subjects no duty of care under New York law to follow federal regulations and guidelines or for making and reporting a false, unreasonable, and unauthorized "refusal to test" determination leading to profound and life-altering consequences for the test subject.

2. Whether the district court erred when it held, contrary to black-letter tort law, that a plaintiff cannot state a claim for negligence unless the defendant's negligence is the sole cause of the plaintiff's injury.

3. Whether the district court's ruling that a fraud claim cannot be based on a misrepresentation made to and relied upon by a third party must be reversed because it contravenes controlling authority of the New York Court of Appeals.

STATEMENT OF THE CASE

Plaintiff-Appellant Pasternack filed this action in the United States District Court for the Southern District of New York on June 3, 2010, asserting, as relevant here, claims for negligence, gross negligence, negligent misrepresentation and

[1] "A" refers to the Joint Appendix. "ADD" refers to the Addendum attached to this brief.

fraud against Defendant-Appellants LabCorp and ChoicePoint. (A-14).[2] The district court (Gardephe, J.) issued three Orders at issue on this appeal, all of which concern the sufficiency of Pasternack's actual or proposed pleadings.

Initially, LabCorp answered Pasternack's pleading and ChoicePoint moved to dismiss it. On August 1, 2011, the district court granted ChoicePoint's motion to dismiss all of the claims asserted against it. *Pasternack v. Lab. Corp. of Am.*, No. 10 Civ. 4426 (PGG), 2011 WL 3478732 (S.D.N.Y. Aug. 1, 2011) (A-89). Pasternack then obtained permission to, and did, move for leave to amend his pleading to assert, again as relevant here, claims for negligence and gross negligence against ChoicePoint and claims for negligence, gross negligence, negligent misrepresentation and fraud against LabCorp. (A-115). ChoicePoint alone opposed the motion and, on September 6, 2012, the district court denied Pasternack leave to amend as to ChoicePoint. *Pasternack v. Lab. Corp. of Am.*, 892 F. Supp. 2d 540 (S.D.N.Y. 2012) (A-139).

Pasternack filed his Second Amended Complaint against LabCorp on September 12, 2012 (A-164), and LabCorp moved to dismiss that pleading. The New York Court of Appeals issued its decision in *Landon* while LabCorp's motion was pending. Pasternack provided *Landon* to the district court as new authority supporting his opposition to LabCorp's motion to dismiss Pasternack's negligence

[2] Pasternack filed an Amended Complaint on August 13, 2010, as of right, before either ChoicePoint or LabCorp had responded to his initial pleading. (A-50).

claims and also moved for reconsideration of the district court's prior Orders regarding ChoicePoint in light of that same decision. On September 29, 2014, the district court denied Pasternack's motion for reconsideration and granted LabCorp's motion to dismiss. *Pasternack v. Lab. Corp. of Am.*, No. 10 Civ. 4426 (PGG), 2014 WL 4832299 (S.D.N.Y. Sept. 29, 2014) (A-251). The District Court entered judgment on September 30, 2014 closing the case. (A-288).

STATEMENT OF FACTS

A. Pasternack's Medical and Aviation Careers

Pasternack is an accomplished physician and civilian pilot who served this country with honor for over three decades as a flight surgeon in both the United States Air Force and the Air National Guard. (A-166 ¶ 8).

Pasternack has been an attending physician at Lenox Hill Hospital in New York City since 1979, and he also maintains a private practice as both an internist and a cardiologist. (*Id.* ¶ 7). In addition, from 1978 until the events giving rise to this appeal, Pasternack served as a Senior Aviation Medical Examiner ("AME") for the FAA. (*Id.* ¶ 9). In that capacity, Pasternack performed medical examinations of pilots and prospective pilots. (*Id.*).

Pasternack had also been a licensed pilot since 1965, and had flown commercial flights for a variety of aviation companies for decades. (A-167 ¶ 10). At the time of his drug test in 2007, Pasternack flew charter flights for

Northeastern Aviation Corporation ("Northeastern") and piloted airplanes for an aerial advertising business. (*Id.*).

B. The Drug Testing Regime and the Defendants' Role

The FAA is authorized by Congress to adopt regulations as "necessary for safety in air commerce and national security." 49 U.S.C. § 44701(a)(5). By these regulations, the FAA mandates that aviation employees be subjected to random drug testing. 14 C.F.R. § 120.103 (ADD-1). The FAA regulations incorporate by reference the Department of Transportation's drug-testing regulations ("DOT Regulations"), which are codified at 49 C.F.R. Part 40. *Id.* These regulations provide detailed protocols and procedures that test administrators must know and follow when conducting and administering drug tests. 49 C.F.R. §§ 40.1, 40.33(a), 40.121(b)(3) (ADD-3; ADD-10; ADD-13). The tests are also governed by DOT's Urine Specimen Collection Guidelines (the "Guidelines"), which are similarly mandatory.[3]

[3] Guidelines at 3 (ADD-33) ("The procedures for collection of urine under these rules are very specific and *must be followed* whenever a DOT-required urine specimen collection is performed. . . . It is imperative that collectors fully understand and follow these procedures. These guidelines, together with 49 CFR Part 40 and the DOT operating administrations' rules, will provide collectors with the information needed in the performance of their collection duties." (emphasis added)); *see* 49 C.F.R. § 40.33(a) (ADD-10) (requiring that collectors know and keep current on the Guidelines). We have attached a complete set of the then-pending Guidelines in the Addendum.

DOT Regulations permit employers to use third-parties to perform certain drug testing functions, including collecting specimens from employees, testing specimens for the presence of drugs and acting as a "Medical Review Officer" ("MRO").[4] 49 C.F.R. § 40.15(a) (ADD-9). Northeastern hired ChoicePoint to administer Northeastern's drug testing, and ChoicePoint became the MRO for those tests. (A-168 ¶ 14). ChoicePoint, in turn, subcontracted with LabCorp for LabCorp to do the actual collection and testing of specimens. (*Id.* ¶ 15).

C. Defendants' Faulty Administration of Pasternack's Drug Test

1. LabCorp Failed to Follow the "Shy Bladder" Procedures or to Tell Pasternack about the Consequences of Leaving the Facility.

On June 1, 2007, Northeastern notified Pasternack that he had been randomly selected for a drug test. (A-168 ¶ 16). Pasternack reported to LabCorp's collection site on June 5 at 1:10 pm with a pre-printed chain-of-custody form ("CCF") provided to him by Northeastern, as the DOT Regulations require. (A-168-69 ¶¶ 16 - 17). Once there, Pasternack followed the instructions of LabCorp's collector, Theresa Montalvo, and attempted to provide a urine specimen for his drug test. (A-169 ¶ 18). In what is commonly referred to as a "shy bladder" scenario, Pasternack was unable to produce a sufficient volume of urine. (*Id.* ¶

[4] MROs provide a range of medical related functions, including "medical reviews of employees' test results" and determining "whether there is a legitimate medical explanation for a confirmed positive, adulterated, substituted, and invalid drug test results from the laboratory." 49 C.F.R. §§ 40.3, 40.123(b)-(d) (ADD-7; ADD-16).

18). Although Montalvo knew that Pasternack had not produced enough urine—she told him as much at the time (*id.*)—she ignored mandatory DOT procedures on how to handle the situation.

Specifically, when a test subject fails to produce a sufficient specimen, the DOT Guidelines require test administrators to explain the so-called "shy bladder process" to the subject. (ADD-48-50). Both the Regulations and the Guidelines prescribe what the administrator is to say: the test administrator must "[u]rge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first." 49 C.F.R. § 40.193(b)(2) (ADD-23); (ADD-49). Montalvo did not tell Pasternack any of this. Instead, she merely directed Pasternack to return to the waiting area, with no instruction about what to do or what would happen next. (A-169).

Pasternack complied with Montalvo's instruction and returned to the waiting area. (*Id.* ¶ 21). However, he was scheduled to examine a pilot that afternoon in his AME role and became concerned that he would not produce a sufficient specimen before that appointment. (*Id.*). As a result, Pasternack told Montalvo that he would need to leave the facility and return later to complete the test. (A-170 ¶ 22). He and Montalvo discussed the details of his departure—whether he should take his CCF form with him or leave it at the facility, and when he would

return—and Montalvo concluded by telling him only that she would need to notify his employer of his departure. (*Id.*).

In this interaction, Montalvo once again failed to follow the DOT Regulations and Guidelines or the standard of care that any reasonable person in her situation would follow if, as was later contended, Pasternack was leaving the facility without permission: She did not inform him, as required by these federal rules, of the serious consequences of his leaving the facility without completing the test—that he would or could be deemed a "refusal to test," or that the test would immediately terminate. (*See* ADD-50 ("The collector must specifically tell the employee that he or she is not permitted to leave the collection site and if they do so, that it will be considered a refusal to test."). *See also* 49 C.F.R. § 40.191(d) (ADD-20) (requiring collector to terminate test and notify employer immediately if subject refuses to test by leaving the facility before the completion of the test)).

Relying on Montalvo's incomplete and misleading information, and without knowing of the shy bladder procedures or the potential negative consequences he could face, Pasternack left the collection site to attend to his AME appointment. (A-170 ¶ 25). Pasternack returned to the LabCorp facility approximately three hours later and completed his test without incident and with Montalvo's cooperation. (A-170-71 ¶¶ 26-27). After greeting Pasternack, Montalvo again explained that she would need to contact Northeastern before accepting a second

specimen and she then phoned Northeastern, whose General Manager approved taking a second urine specimen. (A-170-71 ¶ 26). After obtaining employer approval, Montalvo proceeded with normal collection procedures to obtain Pasternack's specimen. (A-171 ¶¶ 26-28). Montalvo used the same CCF form to complete the collection that she had initiated before Pasternack left the facility. (A-171 ¶ 28).

This time, Pasternack produced a sufficient specimen for LabCorp to test, and his specimen tested negative for any prohibited drug. (A-171 ¶¶ 27, 29). LabCorp forwarded the negative test result to ChoicePoint, along with the completed CCF form, on which Montalvo had noted Pasternack's temporary departure and Northeastern's approval of the second collection. (A-171 ¶¶ 26, 29).

2. ChoicePoint Erroneously and Unreasonably Reported a Failure to Test.

As the MRO, ChoicePoint was responsible for verifying Pasternack's negative test result. ChoicePoint, however, disregarded that result and reported Pasternack to both Northeastern and the FAA as a "Refusal to Test." (A-172 ¶¶ 30-31; A-124-25 ¶¶ 35-36, 40). The consequences of a refusal are generally the same, or more severe, than testing positive for prohibited drugs. *See* Procedures for Transportation Workplace Drug and Alcohol Testing Programs, 65 Fed. Reg. 79462-01, 79500-01 (Dec. 19, 2000) ("For the most part, the consequences of a refusal are the same or more severe as for any other violation of DOT agency drug

and alcohol regulations."); Procedures for Transportation Workplace Drug and Alcohol Testing Programs, 64 Fed. Reg. 69076-01, 69081 (Dec. 9, 1999) ("[A] refusal is a violation of DOT agency regulations, with consequences similar to those of a positive test. . . . Under some DOT agency regulations . . . the consequences of a refusal to test can be more stringent than those of a positive test.").

An employee can be deemed a "Refusal to Test" for a variety of reasons, but the MRO's duties vary greatly depending on the reason. In particular, the DOT Regulations explicitly *forbid* an MRO from determining that an employee has refused a drug test except where the MRO determines that an employee adulterated or substituted his specimen. 49 C.F.R. § 40.355(i) (ADD-28). In all other circumstances, the Regulations direct that:

> [Y]ou [the MRO] *must not make a determination that an employee has refused a drug or alcohol test. This is a non-delegable duty of the actual employer.* You may, however, provide advice and information to employers regarding refusal-to-test issues.

Id. (emphasis added). *See also* 49 C.F.R. § 40.151 (ADD-18) (an MRO should not make factual determinations that do not depend on its medical knowledge and training).

As a result, federal law prohibited ChoicePoint from making and reporting its erroneous determination that Pasternack had refused his test as a result of his

temporary departure. ChoicePoint, moreover, issued its unauthorized report classifying Pasternack as a "refusal" even though the CCF form that LabCorp sent expressly noted that Northeastern had approved the taking of Pasternack's second specimen after he had left and returned to LabCorp's facility. (A-170-71 ¶¶ 26, 29).

ChoicePoint also issued its prohibited report without conducting any investigation, as the Regulations also direct and which was reasonable under the circumstances. (A-172 ¶ 30; A-124-25 ¶ 36, 38); *see* 49 C.F.R. § 40.123(e) (ADD-16) (MROs "must act *to investigate* and correct problems where possible and notify appropriate parties (e.g., HHS, DOT, employers, service agents) where assistance is needed, (e.g., cancelled or problematic tests, incorrect results, problems with blind specimens)").

Finally, ChoicePoint failed to disclose any of the relevant information in its erroneous report to the FAA and to Northeastern. (A-125 ¶ 38). ChoicePoint failed to disclose that it was reporting Pasternack as a refusal to test based on his having left the facility (an incident it was *not* allowed to report on) as opposed to adulterating or substituting a specimen (incidents it could report on); that, upon his return, Northeastern had approved Pasternack's continuation of his test; or that Pasternack had actually tested negative. (*Id.*).

D. The FAA's Actions and Pasternack's Successful Administrative Challenge

Upon receiving ChoicePoint's erroneous report, the FAA revoked Pasternack's airman certificates and terminated his AME designation after a brief investigation. (A-173 ¶ 36). During the FAA's investigation, Montalvo falsely represented that Pasternack had been uncooperative during the collection and prevented her from explaining the shy bladder process and the consequences of his leaving the facility. (A-172-73 ¶¶ 33-35).[5] Montalvo also concealed from the FAA that Pasternack told her during the initial collection that he planned to return to complete his collection. (A-173 ¶ 35).

On the basis of ChoicePoint's false report and LabCorp's false statements, the FAA revoked Pasternack's airman certificates and terminated his AME designation. (A-173 ¶ 36; A-126-27 ¶ 45). As a result, Pasternack was unable to pilot flights or perform AME duties and lost substantial income from his inactivity. (A-174 ¶ 39).

Pasternack challenged the FAA's actions through two rounds of administrative proceedings. (A-173-74 ¶ 37). *See Pasternack v. Huerta*, 513 F. App'x 1 (D.C. Cir. 2013); *Pasternack v. NTSB*, 596 F.3d 836 (D.C. Cir. 2010). The administrative law judge ("ALJ") found in favor of the FAA, and the National

[5] Among other misrepresentations, Montalvo stated that Pasternack was on his cell phone during the initial attempted collection. But Pasternack's cell phone records establish that he did not use his cell phone during the collection. (A-172-73 ¶ 33).

Transportation Board ("NTSB") affirmed these findings, primarily on the basis of Montalvo's false testimony that Pasternack "rushed" out of the facility and did not give her enough time to tell him what the DOT Regulations and Guidelines required. (A-205).

The D.C. Circuit reversed and remanded, holding that the ALJ failed to properly assess Montalvo's credibility, and rejecting the claim that Pasternack prevented her from telling him about the consequences of leaving the LabCorp facility. *Pasternack*, 596 F.3d at 838-39. As the D.C. Circuit explained: even crediting Montalvo's version of events, "it is utterly implausible that Montalvo had no opportunity to tell Pasternack that his leaving would be deemed a refusal" given that "it would have taken no more than a few seconds for Montalvo to convey that crucial piece of information," and Montalvo admitted that she and Pasternack spoke about his departure. *Id.* at 839. Although the Court remanded for "further proceedings consistent with [its] opinion," *id.* at 839, the NTSB and ALJ charted a new course. The ALJ openly "note[d] [his] disagreement" with the D.C. Circuit, made findings of fact on issues not raised in the Court's opinion, and again held that Pasternack had refused his test. (A-241-48). The NTSB again affirmed, and Pasternack again appealed.

On March 22, 2013, just 11 days after oral argument, the D.C. Circuit vacated the administrative rulings a second time and entered judgment for

Pasternack. *Pasternack*, 513 F. App'x at 2. In its final ruling, the Court criticized the administrative rulings for ignoring that Montalvo never treated Pasternack as a refusal during the contemporaneous testing process, and noted that even the FAA conceded that "leaving with permission does not constitute a refusal" under the DOT Regulations. *Pasternack*, 513 F. App'x at 2.[6] And it held that "substantial evidence does not support the NTSB's determination that [LabCorp] did not impliedly give Dr. Pasternack permission to leave" after his first collection attempt. *Id.*

The FAA has since reinstated Pasternack airman's certificates and AME designation and expunged his record of any reference to a drug test refusal.

E. The District Court's Orders

The district court ruled three times that Pasternack's actual or proposed pleadings failed to allege a duty of care because the duty owed by test administrators to test subjects is limited to specimen handling or evaluation. Its opinions use a variety of shifting and confusing formulations to support the same erroneous conclusion, including that any duty should be restricted to the "direct mishandling" of a specimen (A-109); to both "a mishandling of plaintiff's urine

[6] *See Babbitt v. Rojas*, NTSB Order No. EA-5496, 2009 WL 5213712, at *5 (N.T.S.B. Dec. 30, 2009) (affirming reversal of the FAA revocation order where the collector had excused the subject from the test). *See also Babbitt v. O'Doherty*, Docket No. SE-18981, 2011 WL 1086073, at *6 (N.T.S.B. Jan. 27, 2011) (reversing an FAA revocation order because the test administrator failed to inform the subject that leaving could be deemed a refusal).

sample" as well as "improper testing" (A-158); to "classic" negligence (*id.*; A-271); or to "a violation of industry-wide standards for specimen evaluation" (A-271). The court also held that negligence claims under New York law cannot be premised solely on an alleged violation of federal regulations or guidelines. (A-271).

In one of its earlier Orders, the court also held that Pasternack could not properly allege causation because his injury was caused "by the legal determination of the FAA and the ALJ." (A-162).[7] After Pasternack argued in his motion for reconsideration that the court's analysis ignored fundamental principles of New York law (*see* Mem. of Law, Oct. 24, 2013, at 14-16; Reply Mem. of Law, Dec. 20, 2013, at 3-4), the court apparently abandoned that erroneous conclusion, as it did not mention its prior causation analysis in its final 2014 Order.

Finally, the district court dismissed Pasternack's fraud claims on the basis that his complaint alleged "that only the FAA—and not Pasternack—relied on LabCorp's alleged misrepresentations." (A-283). The court expressly rejected binding New York Court of Appeals' precedents holding that "it matters not whether the false representations be made to the party injured or to a third party,

[7] Notably, ChoicePoint never advocated this position; the district court raised it *sua sponte*.

whose conduct is thus influenced to produce the injury, or whether it be direct or indirect in its consequences." *Rice v. Manley*, 66 N.Y. 82, 87 (1876).[8]

This appeal followed.

SUMMARY OF ARGUMENT

Under settled New York law, laboratories and other drug test administrators owe their test subjects a broad duty of care throughout the testing process. The New York Court of Appeals expressly recognized this duty in *Landon*, where it held that test subjects can sue for negligence when they are harmed by a false report resulting from a test administrator's lack of reasonable care. The Court permits negligence claims in this context because false test reports can have devastating consequences for test subjects, the test administrators are in the best position to prevent harm, and test subjects have no statutory remedy to redress their injuries.

[8] The opinions were also rife with comments exposing the court's hostility to Pasternack. The court ridiculed Pasternack's initial pleading as "gibberish." (A-100). It volunteered its disbelief—based on facts outside the pleadings and arising from a since-vacated ALJ proceeding—that, as Pasternack alleged, he did not know that leaving the collection facility could be deemed a refusal to test. (A-258 (relying on FAA testimony before the ALJ); A-145 (relying on since-vacated ALJ findings regarding Pasternack's prior experience). Finally, the court implicitly criticized the D.C. Circuit's legal conclusions, and even appeared to express disdain for Pasternack's vindication of his rights in the administrative process. (A-261 ("In a March 22, 2013 summary order, however, the D.C. Circuit reversed, finding – despite the ALJ's credibility determinations and findings concerning Pasternack's knowledge of the DOT regulations . . . ."); A-272 (seemingly chastising Pasternack for "[t]he endless administrative proceedings and appeals in Washington reviewing the FAA's actions")).

Under *Landon*, therefore, ChoicePoint and LabCorp each owed Pasternack a duty to administer his drug test with care, as Pasternack alleged, and he stated negligence claims against them. Nonetheless, the district court dismissed Pasternack's claims for failing to allege a legally cognizable duty. The district court misread *Landon* as somehow requiring a violation of "industry-wide" standards, as opposed to standards established by federal law, and as being limited to the physical handling and testing of drug specimens. The district court also erred by *sua sponte* concluding that Pasternack could not allege causation because Defendants' negligence was not the sole cause of his injuries. The court overlooked that, under New York law, causation is satisfied when a defendant's negligence leads to injuries from the foreseeable intervening acts of others, even if the defendant did not directly cause the plaintiff's harm.

The district court also improperly dismissed Pasternack's fraud claim. Under New York law, a plaintiff may state a claim for fraud based on a third party's reliance on fraudulent misstatements or omissions, and not only where the plaintiff himself relied on the defendant's false statements. Pasternack stated a valid fraud claim against LabCorp under controlling New York Court of Appeals precedents, and the district court erred by rejecting those authorities and dismissing his claim on the pleadings.

STANDARD OF REVIEW

This Court reviews each of the district court's Orders *de novo*. *See Walker v. Schult*, 717 F.3d 119, 124 (2d Cir. 2013) (*de novo* review of order dismissing claims under Rule 12(b)(6)); *Hutchison v. Deutsche Bank Sec. Inc.*, 647 F.3d 479, 490 (2d Cir. 2011) (same for denial of leave to amend on ground of futility); *Freidus v. Barclays Bank PLC*, 734 F.3d 132, 138 (2d Cir. 2013) (same for denial of motion to reconsider order denying leave to amend on ground of futility); *Bayerische Landesbank, New York Branch v. Aladdin Capital Mgmt. LLC*, 692 F.3d 42, 52 n.3 (2d Cir. 2012) (same for denial of motion to reconsider order dismissing claims under Rule 12(b)(6)). In so doing, this Court "owe[s] no deference to the district court's interpretation of New York law." *Reddington v. Staten Island Univ. Hosp.*, 511 F.3d 126, 133 (2d Cir. 2007) (citing *Elliott Assocs., L.P. v. Banco de la Naciòn*, 194 F.3d 363, 370 (2d Cir. 1999)).

When reviewing the motions to dismiss under Rule 12(b)(6), this Court "must 'accept as true all of the factual allegations set out in plaintiff's complaint, draw inferences from those allegations in the light most favorable to plaintiff, and construe the complaint liberally.'" *Rescuecom Corp. v. Google Inc.*, 562 F.3d 123, 127 (2d Cir. 2009) (quoting *Gregory v. Daly*, 243 F.3d 687, 691 (2d Cir. 2001)). This Court reviews Pasternack's proposed amended complaint under the same liberal standards. *See Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d

114, 119 (2d Cir. 2012). A motion for reconsideration should be granted when there has been "an intervening change of controlling law." *Virgin Atl. Airways, Ltd. v. Nat'l Mediation Bd.*, 956 F.2d 1245, 1255 (2d. Cir. 1992) (internal quotation marks omitted).

ARGUMENT

I. PASTERNACK ALLEGED A DUTY OF CARE UNDER CONTROLLING NEW YORK LAW

Under New York law, a plaintiff must allege three elements to state a negligence claim: "(i) a duty owed to the plaintiff by the defendant; (ii) breach of that duty; and (iii) injury substantially caused by that breach." *Lombard v. Booz-Allen & Hamilton, Inc.*, 280 F.3d 209, 215 (2d Cir. 2002).[9] Pasternack's actual and proposed pleadings alleged facts supporting each of these elements.

The district incorrectly ruled, however, that Pasternack failed to allege a cognizable legal duty on the part of either defendant because his claims extended beyond specimen handling and evaluation and/or were grounded solely in violations of federal regulations and guidelines. These rulings were erroneous under controlling precedents and should be reversed.

[9] Because the district court dismissed Pasternack's gross negligence and negligent misrepresentation claims for the same reasons it dismissed his ordinary negligence claims, the differences between the claims are immaterial for purposes of this appeal. We refer to all three claims collectively as "negligence" claims.

A. *Landon* Establishes That the Duty of Care Extends Throughout the Testing Process

In *Landon* the New York Court of Appeals held that drug test administrators owe their test subjects a duty of care, and that the scope of that duty necessarily extends throughout the testing process. The Court held that drug test administrators owe a broad duty to "the test subject to perform his drug test in keeping with relevant professional standards." N.Y.3d at 6-7.

While serving a term of probation, the plaintiff, Eric Landon, was directed by his probation officer to submit to a drug test. His probation officer collected an oral sample and transmitted it to the defendant, Kroll Laboratory Specialists, Inc. ("Kroll"), for testing. Kroll determined that Landon tested positive for cannabinoids and reported that result to the probation department, which commenced proceedings to revoke Landon's probation and have him incarcerated. Landon sued Kroll, contending that Kroll was negligent not only in how it tested his specimen but also in its failure to confirm the test results and in issuing an incomplete report. Specifically, Landon claimed that "the screen test cutoff level employed by Kroll was substantially lower than that recommended by [the company that manufactured the collection device] or by federal standards and that Kroll failed to disclose those differences in its report." *Id.* at 4-5. Landon also claimed that New York State Department of Health Laboratory Standards "requir[e] samples to be subject to confirmatory testing through the use of gas

chromatography-mass spectronomy, [but] Landon's sample was not subject to any type of confirmation test before defendant reported a positive result." *Id.* at 5. Finally, Landon claimed that Kroll negligently failed to disclose in its report that its testing of an oral fluid sample alone, rather than with a contemporaneous urine sample as proposed federal guidelines would require, heightened the potential for false positive readings. *Id.*

The Court of Appeals held that Kroll owed Landon a duty of reasonable care with respect to these alleged acts and omissions. *Id.* at 6-7. The Court identified five reasons why drug test administrators should be held to such a duty:

1. A laboratory "'launche[s] a force or instrument of harm'" against the test subject when it releases a false test report. *Id.* at 6 (quoting *Espinal v. Melville Snow Contractors, Inc.*, 98 N.Y.2d 136, 140 (2002)).

2. The harm to a test subject is "not remote or attenuated. Indeed, [in *Landon*], it was his own biological specimen that was the sole subject of this testing and he was directly harmed by the positive test result . . . ." *Id.* at 6.

3. A false test report "will have profound, potentially life-altering, consequences for a test subject." *Id.* at 6.

4. Those conducting drug tests are in the "best position" to prevent the release of damaging test results. *Id.*

5. There is "no apparent statutory remedy" for a victim of negligent drug testing. *Id.* at 7.

Although *Landon* has been recognized as a landmark decision,[10] its holding is premised on bedrock principles of New York negligence law. *See*, *e.g.*, *Tenuto v. Lederle Labs.*, 90 N.Y.2d 606, 612 (1997) (New York courts "resolve legal duty questions by resort to common concepts of morality, logic and consideration of the social consequences of imposing the duty."); *Stanford v. Kuwait Airways Corp.*, 89 F.3d 117, 123 (2d Cir. 1996) ("[T]he duty of vigilance to prevent injury has its source in the law applicable to human relations rather than in a narrow conception of privity." (internal quotation marks omitted)). Indeed, under New York law,

> [w]henever one person is by circumstances placed in such a position with regard to another that every one of ordinary sense who did think would at once recognize that if he did not use ordinary care and skill in his own conduct with regard to the circumstances he would cause danger of injury to the person or property of the other, a duty arises to use ordinary care and skill to avoid such danger.

[10] *See* Thomas A. Moore & Matthew Gaier, "Court of Appeals Addresses Duties of Care and Limits of Liability," *New York Law Journal* (Dec. 3, 2013) ("The duty of care and concomitant cause of action recognized in *Landon* has potentially significant impact."); Evan B. Citron, "New York Court of Appeals Creates Negligent Drug Testing Claim" (Nov. 1, 2013) (*Landon* created "a new cause of action" that is "likely to significantly alter the landscape of employee drug testing in New York State"), available at http://www.martindale.com/appellate-practice-law/article_Ogletree-Deakins-Nash-Smoak-Stewart-PC_2021286.htm; Jeff Overley, "NY's Top Court Opens Door To Drug-Test Negligence Suits," *Law360* (Oct. 10, 2013) (as a result of *Landon*, "drug testing companies in [New York] may revisit their policies to ensure they are not vulnerable to being viewed by courts as substandard").

Id. (internal quotation marks omitted); *see also Palka v. Servicemaster Mgmt. Servs. Corp.*, 83 N.Y.2d 579, 587 (1994) (defendant owed duty of care because its conduct "placed [plaintiff] in an unreasonably risky setting greater than" if defendant had not acted at all).

Landon's holding is also consistent with the many courts throughout this country that have held that drug and alcohol test administrators owe their test subjects a common law duty of care in conducting drug tests. *See*, *e.g.*, *Drake v. Lab. Corp. of Am. Holdings*, No. 02-CV-1924 (FB)(RML), 2007 WL 776818, at *2-3 (E.D.N.Y. Mar. 13, 2007) (negligence claim against LabCorp for violating FAA regulations adequately pled); *Coleman v. Town of Hempstead*, 30 F. Supp. 2d 356, 365 (E.D.N.Y. 1999) (denying LabCorp's motion to dismiss a negligence action); *Santiago v. Greyhound Lines, Inc.*, 956 F. Supp. 144, 152-53 (N.D.N.Y. 1997) (holding that a physician had a duty to collect a urine specimen with due care).[11]

[11] *See also*, *e.g.*, *Phillips v. Quality Terminal Servs., LLC*, 855 F. Supp. 2d 764, 780 (N.D. Ill. 2012); *Warshaw v. Concentra Health Servs.*, 719 F. Supp. 2d 484, 505-06 (E.D. Pa. 2010); *Balistrieri v. Express Drug Screening, LLC*, No. 04-C-0989, 2008 WL 906236, at *13-16 (E.D. Wis. 2008); *Quisenberry v. Compass Vision, Inc.*, 618 F. Supp. 2d 1223, 1228-31 (S.D. Cal. 2007); *Chapman v. LabOne*, 460 F. Supp. 2d 989, 1001 (S.D. Iowa 2006); *Baker v. Abo*, No. Civ. 01-1248 JRTJSM, 2003 WL 21639151, at *2 n.7 (D. Minn. July 2, 2003); *Williams v. Nat'l R.R. Passenger Corp.*, 16 F. Supp. 2d 178, 181-82 (D. Conn. 1998); *Webster v. Psychemedics Corp.*, No. 2010-01087-COA-R3-CV, 2011 WL 2520157, at *6 (Tenn. Ct. App. June 24, 2011); *Berry v. Nat'l Med. Servs.*, 205 P.3d 745, 749-51 (Kan. Ct. App. 2009); *Sharpe v. St. Luke's Hosp.*, 821 A.2d 1215, 1219-21 (Pa.

Landon constitutes the law of New York and bound the district court, just as it binds this Court. *See Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 739 F.3d 45, 48 (2d Cir. 2013) ("We are bound, of course, by the law of New York as interpreted by the New York Court of Appeals.").

B. ChoicePoint and LabCorp Owed Pasternack a Duty of Care Under *Landon*

After *Landon*, it is settled law in New York that ChoicePoint and LabCorp owed Pasternack a broad duty of care to act reasonably in administering his drug test. Indeed, each of the reasons that drove the Court of Appeals to recognize a duty of care in *Landon* applies equally (if not more so) here.

First, ChoicePoint and LabCorp "launche[d] a force or instrument of harm" against Pasternack because, due to their carelessness in administering his drug test, the test report erroneously labeled him a "refusal to test." *See Landon*, 22 N.Y.3d at 6 (Kroll "launche[d] a force or instrument of harm . . . when it failed to adhere to professionally accepted testing standards and, consequently, released a report finding that plaintiff had tested positive"). LabCorp created the situation that led to the harmful report and revocation because it failed to inform Pasternack of the

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2003); *Ragsdale v. Mount Sinai Med. Ctr. of Miami*, 770 So. 2d 167, 168-69 (Fla. Dist. Ct. App. 2000); *Duncan v. Afton, Inc.*, 991 P.2d 739, 744-46 (Wyo. 1999); *Stinson v. Physicians Immediate Care, Ltd.*, 269 Ill. App. 3d 659, 662-65 (2d Dist. 1995); *Nehrenz v. Dunn*, 593 So. 2d 915, 917-18 (La. Ct. App. 1992); *see also King v. Garfield County Pub. Hosp. Dist. No. 1*, 17 F. Supp. 3d 1060, 1072-73 (E.D. Wash. 2014).

"shy bladder" procedures, or that leaving the collection facility could result in a "refusal to test" determination. (A-169-70). And ChoicePoint actually released the false report that Pasternack had "refused" his drug test —without any authority to do so, without conducting a prior investigation, and without reporting any other information. (A-123-25).[12]

Second, the harm to Pasternack was "not remote or attenuated." *Landon*, 22 N.Y.3d at 6. Because LabCorp knew that leaving a collection site could or would be deemed a refusal under the DOT Regulations, and because ChoicePoint knew that labeling Pasternack a refusal was the equivalent of reporting him as positive for prohibited drugs, or worse, ChoicePoint and LabCorp should have foreseen that their actions might lead the FAA to revoke Pasternack's licenses. *See Stanford*, 89 F.3d at 125 ("[T]he risk reasonably to be perceived defines the duty to be obeyed, and risk imports relation . . . ." (quoting *Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 344 (1928))). In *Landon*, moreover, the Court held that the harm was sufficiently proximate, even though "Kroll did not know that plaintiff was the person whose sample was being tested." 22 N.Y.3d at 9 (dissent). Here,

[12] The applicable regulations acknowledge the direct connection between ChoicePoint's misconduct and the harm to test subjects. For example, the DOT enacted a procedure whereby an MRO's noncompliance with the DOT Regulations could disqualify it from being an MRO in the future because "if an MRO . . . disregards DOT rules and guidance for making verification decisions," then, among other things, "individuals can be unfairly identified as drug users." 64 Fed. Reg. 69076-01, 69086.

ChoicePoint and LabCorp both knew Pasternack by name: ChoicePoint's report identified Pasternack as the test subject and LabCorp dealt with Pasternack directly. *See Palka*, 83 N.Y.2d at 589 (defendant owed duty of care because conduct was "not directed to a faceless or unlimited universe of persons" but to "a known and identifiable group"). In other words, the "possibilit[y] of danger" to Pasternack was so "apparent as to entitle him to be protected." *Palsgraf*, 248 N.Y. at 345.

Third, just like a false report that a subject tested positive, a false report of a refusal "will have profound, potentially life-altering, consequences for a test subject." *Landon*, 22 N.Y.3d at 6. In fact, under the DOT Regulations, refusing a test is tantamount to a positive test result or worse. *See* 49 C.F.R. § 40.191(c) (ADD-20) ("As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations."); 49 C.F.R. § 40.285(b) (ADD-26) (defining both "a verified positive DOT drug test result" and "a refusal to test" as "a DOT drug and alcohol regulation violation"); *see supra* 12-13. And the FAA stripped Pasternack of his pilot's certificate and AME designation because of the purported "refusal"—which is exactly what would have happened if ChoicePoint had falsely reported that he tested positive.

Fourth, ChoicePoint and LabCorp were in the "best position" to prevent the harm to Pasternack. *Landon*, 22 N.Y.3d at 6; *see also Hamilton v. Beretta U.S.A. Corp.*, 96 N.Y.2d 222, 233 (2001) (a "key" factor favoring recognition of a duty is "that the defendant's relationship with either the tortfeasor or the plaintiff places the defendant in the best position to protect against the risk of harm"). The DOT Regulations forbade ChoicePoint from reporting Pasternack as a refusal in the first place, because that determination must be made by the employer and is not delegable to the MRO, where, as here, it is based on a departure from the testing facility. 49 C.F.R. § 40.355(i) (ADD-28). Thus, ChoicePoint could have prevented all of this harm if it had acted reasonably and left the determination of a refusal and reporting of such to Pasternack's employer—the entity that, along with LabCorp, had given him permission to conclude his test. At a minimum, as the MRO, ChoicePoint was to act "as an independent and impartial 'gatekeeper' and advocate for the accuracy and integrity of the drug testing process." 49 C.F.R. § 40.123(a) (ADD-16). In that role, ChoicePoint could, and should, have conducted an investigation about Pasternack's early departure before reaching any conclusion about his actions.

For its part, LabCorp, as a collector, was supposed to "instruct[] and assist[] employees at a collection site." 49 C.F.R. § 40.3 (ADD-5). "The collector has a major role in the success of the DOT's drug testing program [because] . . . [t]he

collector is the one individual in the testing process with whom all employees have direct, face-to-face contact." Guidelines at 3 (ADD-33). To instruct and assist Pasternack, LabCorp should have informed him about the "shy bladder" procedures which, if successfully followed, would have averted the entire "refusal to test" incident. It also should have informed him that he would or could be deemed a refusal to test by leaving LabCorp's facility without completing the test. Had LabCorp done either of these things, Pasternack would never have left the facility in the first place and risked being falsely reported as a failure to test. (A-170 ¶ 24).

And, fifth, just as in *Landon*, Pasternack should be able to pursue negligence claims against ChoicePoint and LabCorp because he has no statutory remedy for the lost income, legal expenses and other damages he suffered as a result of their misconduct. *See Landon*, 22 N.Y.3d at 7.

The district court erred, therefore, by dismissing Pasternack's negligence claims in spite of *Landon*. *See Hegger v. Green*, 646 F.2d 22, 26 (2d Cir. 1981) ("[W]e must abide by intervening decisions handed down by New York's highest court.") (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)).

Separately, LabCorp also owed Pasternack a duty of care because it gave him a false sense of safety that "foreseeably led plaintiff to change his own conduct." *Heard v. City of New York*, 82 N.Y.2d 66, 72-73 (1993); *see Nallan v.*

Helmsley-Spear, Inc., 50 N.Y.2d 507, 522 (1980) (defendant owes duty if plaintiff "was lulled into a false sense of security and, as a consequence, neglected to take the precautions he might otherwise have taken"); *Giglio v. Saratoga Care, Inc.*, 117 A.D.3d 1143, 1145, 985 N.Y.S.2d 314, 316 (3d Dep't 2014) (security guard indicated to plaintiff that it was safe to walk); *Kievman v. Philip*, 84 A.D.3d 1031, 1033, 924 N.Y.S.2d 112, 114 (2d Dep't 2011) (driver waved pedestrians across the road). *See also McKinney v. Bellevue Hosp.*, 183 A.D.2d 563, 565-66, 584 N.Y.S.2d 538, 540 (1st Dep't 1992) (failure to tell plaintiff that pre-employment physical had detected a serious medical condition negligently "induced reliance by plaintiff on his general good health and resulted in the failure to seek treatment").

C. The District Court's Reasoning Cannot Be Reconciled with *Landon*

The district court initially decided that ChoicePoint owed Pasternack no duty of care because the case law recognizing such a duty was purportedly limited to "mishandling" a specimen or "improper testing." After *Landon* was decided, the court refused to reconsider that holding. *Landon*, in its view, was a case involving the "violation of industry-wide standards for specimen evaluation," whereas Pasternack's claim was purportedly "premised solely on violations of the DOT Regulations and Guidelines." (A-158; A-271; A-273). Neither of these reasons can withstand scrutiny under *Landon.* Indeed, both the New York courts and this Court have recognized that once the applicable duty of care has been well-

established, fact specific limitations of that duty are to be avoided. *See, e.g., Stagl v. Delta Airlines, Inc.*, 52 F.3d 463, 469 (2d Cir. 1995) (fact specific limitations are to be imposed only in the exceptional case and not on an ad hoc basis); *Palka*, 83 N.Y.2d at 585 ("duty is not something derived or discerned from an algebraic formula"); *Espinal*, 98 N.Y.2d at 139 ("[T]he 'policy-laden' nature of the existence and scope of a duty generally precludes any bright-line rules.").

1. A Test Administrator Owes a Broad Duty of Care to a Test Subject, Not Simply the Duty to Avoid "Mishandling" or "Improper Testing."

From the outset, the district court sought to artificially cabin the duty of reasonable care that test administrators owe to test subjects. In its first and second opinions, the court sought to limit the existing precedent to cases involving "mishandling" of a specimen or something called "improper testing"—a term that court did not even attempt to define, but which it presumably meant to refer to laboratory work (as opposed to the administering or reporting of test and test results).

Even before the New York Court of Appeals decided *Landon*, this reasoning was unconvincing. While it is true that many of the pre-*Landon* cases involved conduct involving specimen collection, handling or testing, Pasternack cited cases recognizing a duty of care that extended beyond that. *See, e.g., Drake v. Lab. Corp. of Am. Holdings*, 290 F. Supp. 2d 352, 357 (E.D.N.Y. 2003) (MRO

approved unlawful re-test and reported results to employer) (duty recognized in *Drake*, 2007 WL 776818, at *3); *Warshaw*, 719 F. Supp. 2d at 505 (claims "relate[d] to the processing or reporting of a drug test, and not its collection or handling"); *Balistieri*, 2008 WL 906236, at *14-16 (denying defendant's motion for summary judgment insofar as plaintiff alleged that, in violation of the DOT Regulations and Guidelines (and other requirements), a female collector was physically present and talking to him while he was attempting, unsuccessfully, to provide a specimen, which resulted in a "refusal to test" determination; *Duncan*, 991 P.2d at 741 (claims involving document falsification).

In any case, *Landon* put an end to any effort to artificially limit the applicable duty to avoiding "mishandling" or "improper testing" of specimens. As explained, the Court in *Landon* held that the plaintiff stated a claim for negligence not only with respect to how Kroll conducted the laboratory testing itself ("improper testing" in the lower court's terminology), but also its test design, its interpretation of Landon's test results, its failure to verify the test results, and its report to the probation department (which allegedly omitted critical information).

In fact, the dissent made the same argument that the district court made here—that the duty of care should be limited to cases involving "specific, narrow allegations of active negligence by the testing laboratory, such as mishandling, misidentifying or improperly collecting the specimen." *Landon*, 22 N.Y.3d at 10.

But the majority rejected that view, endorsed a broad duty that requires test administrators to exercise reasonable care throughout the testing process, and expressly recognized a cause of action for "negligent testing" broadly defined.

Moreover, drawing the line at "mishandling" and "improper testing" (narrowly defined) would lead to arbitrary and absurd results. For example, a false "positive" report is as likely to occur from a laboratory mis-testing a specimen as from an MRO mis-reporting a negative test as positive. And as noted, an MRO's false report of a refusal to test has the same consequences to the test subject as a false positive. Moreover, avoiding harm to the test subject—and the integrity of the testing process generally—depends on the due care of the test administrators at *each* stage of the testing process: by the collectors to guide and instruct the test subject at the collection phase (whether those instructions relate to the proper handling of the specimen, the procedures to be used to complete the test in the event of a "shy bladder," or the consequences of failing to complete the test and leaving early); by the laboratory to test his specimen using reliable methods; and by the MRO to verify the test results, investigate any abnormalities, and report the test results accurately and in accordance with the federal rules.

2. ChoicePoint and LabCorp's Violation of DOT Regulations and Guidelines Support a Duty of Care.

The district court also attempted to distinguish *Landon* because it involved the violation of "industry-wide standards" whereas Pasternack's claims are

"premised solely" on violations of the DOT Regulations and Guidelines.[13] This effort to sidestep *Landon* is wrong.

First, Pasternack's claims remain rooted in New York common law, even if the relevant standard of care stems from the DOT Regulations and Guidelines.[14] He alleged that ChoicePoint and LabCorp each owed him a basic common-law duty to conduct his drug test with reasonable care. (*See* A-132 ¶ 76 (ChoicePoint owed duty to "review and evaluate" his test with reasonable care); A-175 ¶ 44 (LabCorp owed duty to "administer the collection" of his specimen with reasonable care)). This duty is cognizable directly under *Landon* and the Court of Appeals precedents on which it builds, even if that standard is measured by DOT Regulations and Guidelines.

Second, Pasternack may properly premise his claims on those federal regulations and guidelines. Indeed, "[w]hen a statute designed to protect a particular class of persons against a particular type of harm is invoked by a

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[13] In two footnotes, the district court suggested that Pasternack had overstated the DOT Regulations' requirements. (*See* A-267; A-272). Pasternack's pleadings, however, plainly distinguished which requirements are imposed by the DOT Regulations and which are imposed by the Guidelines. (*See*, *e.g.*, A-169 ¶ 19).

[14] The district court also repeatedly mischaracterized Pasternack's claims as asserting a duty "to properly interpret" the DOT Regulations and Guidelines. (A-109; A-267; A-270; A-272; A-273; A-275). Pasternack never alleged such a duty, and it is not the basis of his claims. Rather, Pasternack alleges that ChoicePoint and LabCorp had a duty to administer his test with reasonable care, and they breached that duty through conduct that also violated the DOT Regulations and Guidelines.

member of the protected class, a court may, in furtherance of the statutory purpose, interpret the statute as creating an additional standard of care." *Dance v. Town of Southampton*, 95 A.D.2d 442, 445, 467 N.Y.S.2d 203, 206 (2d Dep't 1983); *see also Drake v. Lab. Corp. of Am. Holdings*, 458 F.3d 48, 63-64 (2d Cir. 2006) (allowing plaintiff's negligence claims based on "duties established by the federal regulations"); *Lopes v. Rostad*, 45 N.Y.2d 617, 623 (1978) (in negligence action, discussing a duty that had its source both in common law and statute); *McSweeney v. Rogan*, 209 A.D.2d 386, 387, 618 N.Y.S.2d 430, 431 (2d Dep't 1994) (town ordinance gave rise to duty even when common law did not).

The FAA adopted the DOT Regulations and Guidelines specifically to protect test subjects from harm to their careers and reputations. *See* Omnibus Transportation Employee Testing Act of 1991, Pub. L. No. 102–143, § 2(6), 105 Stat. 953 (1991) (directing the FAA to regulate a drug test program with "adequate safeguards . . . [to] ensure[] that no individual's reputation or career development is unduly threatened or harmed"); *see* Anti-Drug Program for Personnel Engaged in Specified Aviation Activities, 53 Fed. Reg. 47024-01, 47043 (Nov. 21, 1988) ("The FAA believes that the review and evaluation functions of an MRO provide critical and necessary safeguards for an employee who is subject to drug testing under the comprehensive anti-drug program."). And that purpose is self-evident in the particular provisions at issue here. These Regulations and Guidelines require

collectors to guide test subjects so that they do not unwittingly refuse a test, and prevent MROs from making critical determinations about test subjects that are beyond MROs' medical expertise. The specific regulations and guidelines at issue are undoubtedly designed to protect test subjects from harm, and thus give rise to a duty enforceable by the subject of laboratory tests through state-law tort remedies. Indeed, in *Drake*, 458 F.3d at 63-64, this Court expressly endorsed "state-law remedies for violation of the FAA regulations."

The district court, moreover, misconstrued *Drake* when it reasoned that Pasternack's negligence claims could not be premised *solely* on an alleged violation of federal regulations or guidelines, because such violations are merely "some" evidence of negligence. (A-160; A-271). As explained, *Drake* makes clear that a violation of DOT Regulations, standing alone, *is* sufficient to support a negligence claim. This Court held in *Drake* that victims of FAA regulation violations could find redress under state negligence law even though the Federal Aviation Act itself creates no federal private right of action. 458 F.3d at 63-65. Indeed, *Drake* suggested that state law negligence claims cannot extend *beyond* a violation of DOT Regulations, because, if they did, they would be preempted. *Id.* Accordingly, under Drake, a state-law based negligence claim grounded solely upon a violation of a DOT Regulation is not only proper; it may be the only way a negligence claim can proceed. *Id.* at 52 ("Drake's claims [were] not preempted . . .

insofar as his state-law causes of action do no more than provide remedies for violations of the federal regulations."). In other words, in *Drake*, this Court allowed the plaintiff's state law negligence claim to proceed precisely because it was based solely on a violation of a DOT Regulation.[15]

Third, the district court's distinction between standards established by federal regulations and guidelines and so-called "industry-wide" standards has no basis in *Landon*. The DOT Regulations and Guidelines are standards that the federal government imposes on the drug testing industry as a whole. Accordingly, they do represent industry-wide standards, albeit ones imposed from the government and not developed organically from within. There is no principled reason to draw a distinction between these standards, and "industry-wide standards" that develop from other sources. If anything, federal government guidelines set a more reliable and meaningful standard of care than industry-wide norms, since test administrators are required by law to understand the guidelines and know that they can be subject to regulatory enforcement for violations. *See* 49 C.F.R. §§ 40.33(a), 40.363(a) (ADD-10; ADD-30) (providing that the DOT can exclude a collector or MRO from performing those services if it determines that

[15] And New York courts recognize, even on summary judgment, that evidence that the defendant's conduct violated a regulation or an industry guideline ordinarily is sufficient to send a negligence claim to the jury. *See*, *e.g.*, *Madry v. Heritage Holding Corp.*, 96 A.D.3d 1022, 1023-24, 947 N.Y.S.2d 588, 590 (2d Dep't 2012); *Scotto v. Marra*, 23 A.D.3d 543, 544, 806 N.Y.S.2d 603, 604 (2d Dep't 2005).

the administrator "[has] failed or refused to provide drug or alcohol testing services consistent with the requirements of [the DOT Regulations]"); *cf. Braverman v. Bendiner & Schlesinger, Inc.*, 121 A.D.3d 353, 359, 990 N.Y.S.2d 605, 611 (2d Dep't 2014) (finding no duty of care to disclaim that accurate positive drug result was to be used only for clinical and not forensic purposes where plaintiff's contention that disclaimer was needed was "unsupported by reference to statutory, regulatory or professional standards.").

Finally, the district court rejected Pasternack's allegations that ChoicePoint owed a duty under the DOT Regulations, 49 C.F.R. § 40.123(e), to investigate Pasternack's test. In the court's view, Section 40.123(e) is "too vague" to support a negligence claim. (A-158). New York law, however, requires only that the regulation "prohibits the doing of acts or imposes a specific duty." *Monroe v. City of New York*, 67 A.D.2d 89, 99, 414 N.Y.S.2d 718, 724 (2d Dep't 1979). In clear terms, Section 40.123(e) commands MROs that they "must act to investigate" problem tests. (ADD-16). This is more than sufficient to support Pasternack's negligence claims, and New York courts have held far less specific provisions sufficient. *See*, *e.g.*, *Guzman v. Haven Plaza Hous. Dev. Fund Co.*, 69 N.Y.2d 559, 566 (1987) (provisions requiring that property be kept "in good repair" and "safe" gave rise to duty).

II. THE DISTRICT COURT APPLIED AN ERRONEOUS STANDARD OF PROXIMATE CAUSATION

When it denied Pasternack leave to amend, the district court held that the proposed amendment would be futile because, *inter alia*, Pasternack's injury "was caused by the legal determination of the FAA and the ALJ"—not ChoicePoint. (A-162). The district court raised the issue *sua sponte* and cited only one case, a district court decision that merely stated the elements of a negligence cause of action and did not otherwise address causation.

The court erred. It took no account of the principles that a plaintiff's injury may have "more than one proximate cause," *Kalland v. Hungry Harbor Associates, LLC*, 84 A.D.3d 889, 889, 922 N.Y.S.2d 550, 551 (2d Dep't 2011), and that "an intervenor's actions will not break the necessary chain of causation where they are 'a normal or foreseeable consequence of the situation created by the defendant's negligence,'" *Stagl*, 52 F.3d at 473 (quoting *Derdiarian v. Felix Contracting Corp.*, 51 N.Y.2d 308, 315 (1980)); *accord Stanford*, 89 F.3d at 127.

Here, when ChoicePoint reported to the FAA that Pasternack had "refused" his drug test, it set in motion a process that foreseeably would lead to the FAA relying on its report to revoke Pasternack's pilot certifications and AME designation. *See Lapidus v. State*, 57 A.D.3d 83, 95-96, 866 N.Y.S.2d 711, 720-21 (2d Dep't 2008) (to "sever the causal connection," intervening act "must be a new and independent force, which was not set in motion by the defendant's own

wrongful acts" (internal quotation marks omitted)). In fact, the risk that the FAA and an ALJ would accept ChoicePoint's report that Pasternack refused his drug test was "the very same risk" that rendered ChoicePoint's conduct negligent. *See Derdiarian*, 51 N.Y.2d at 315. The district court erred, therefore, by holding that the FAA and ALJ actions displaced ChoicePoint's liability.

III. PASTERNACK'S PLEADINGS STATED A VIABLE FRAUD CLAIM AGAINST LABCORP

The district court erred when it rejected controlling case law and dismissed Pasternack's fraud claim based on an interpretation of New York law that the New York Court of Appeals has rejected.

For well over a century, it has been the law in New York that a plaintiff may establish a fraud claim where a false representation is made to a third party whose reliance causes injury to the plaintiff. The rule traces to *Rice v. Manley*, 66 N.Y. 82 (1876), and other decisions of the New York Court of Appeals.

In *Rice*, the plaintiff had an agreement to buy "a large quantity of cheese" from a third party, and the defendant—pretending to be plaintiff—sent a false telegraph to the third party saying that the plaintiff no longer wanted to buy the cheese. 66 N.Y. at 83-84. The Court held that the plaintiff could sue for fraud even though the false statement was not made to him and he did not rely on it; in fact, the plaintiff would have known that the statement was false. The Court held: "*[I]t matters not whether the false representations be made to the party injured or*

to a third party, whose conduct is thus influenced to produce the injury, or whether it be direct or indirect in its consequences. Schemes of fraud may be so cunningly devised as to elude the eye of justice, but they must not escape condemnation and reparation when discovered." *Id.* at 87 (emphasis added).

Similarly, in *Piper v. Hoard*, 107 N.Y. 73 (1887), the defendant allegedly induced the plaintiff's mother to marry a landowner by falsely promising that the land would transfer to any child born to the couple. The landowner had already transferred the land to the defendant, and the transfer would have been invalidated under the terms of a governing will had the landowner died without having a child. The defendant thus had to ensure that the landowner had a child in order to keep the property, and so he lied to the plaintiff's mother to induce her to marry. *Id.* at 75-76. The defendant ultimately kept the land for himself, and the plaintiff sued on the ground that the defendant had made false statements to the plaintiff's mother, on which the plaintiff's mother relied, and which resulted in plaintiff being "the very person injured by the fraud." *Id.* at 79. The Court of Appeals held that the plaintiff could recover for the fraud even though she did not rely upon it. *Id.*

Following these cases, courts in New York's Appellate Division have repeatedly reaffirmed and applied the rule that a plaintiff may state a claim in fraud for misrepresentations that are made to a third party. *See Ruffing v. Union Carbide Corp.*, 308 A.D.2d 526, 528, 764 N.Y.S.2d 462, 465 (2d Dep't 2003) ("'[F]raud

. . . may . . . exist where a false representation is made to a third party, resulting in injury to the plaintiff'" (quoting *Eaton, Cole & Burnham Co. v. Avery*, 83 N.Y. 31 (1880)); *Buxton Mfg. Co. v. Valiant Moving & Storage, Inc.*, 239 A.D.2d 452, 454, 657 N.Y.S.2d 450, 451 (2d Dep't 1997) ("Fraud . . . may also exist where a false representation is made to a third party, resulting in injury to the plaintiff."); *Desser v. Schatz*, 182 A.D.2d 478, 479-80, 581 N.Y.S.2d 796, 797 (1st Dep't 1992) ("[I]t is of no moment, in this context, that the false representation was not made directly to plaintiff."); *Cooper v. Weissblatt*, 154 Misc. 522, 526, 277 N.Y.S. 709, 714 (2d Dep't 1935) ("[I]t is not necessary that the deceit should have been practiced directly upon the plaintiff. It is sufficient if the initial fraud intended to injure the plaintiff caused him damage through intermediate agencies thereby set in motion.").[16]

Nonetheless, in two decisions, this Court held that "a plaintiff does not establish the reliance element of fraud for purposes of . . . New York law by showing only that a third party relied on a defendant's false statements." *Cement & Concrete Workers Dist. Council Welfare Fund, Pension Fund, Legal Servs. Fund & Annuity Fund v. Lollo*, 148 F.3d 194, 196 (2d Cir. 1998); *City of New York v. Smokes-Spirits.com, Inc.*, 541 F.3d 425, 454 (2d Cir. 2008), *rev'd and remanded*

[16] Although some Appellate Division cases have held that the "third-party reliance" theory is not viable, *see*, *e.g.*, *Briarpatch Ltd., L.P. v. Frankfurt Garbus Klein & Selz, P.C.*, 13 A.D.3d 296, 297-98, 787 N.Y.S.2d 267, 268 (1st Dep't 2004), the Court of Appeals has never so held.

sub nom. Hemi Grp., LLC v. City of New York, N.Y., 559 U.S. 1 (2010). Neither of these cases cited or attempted to reconcile their holdings with the New York Court of Appeals decisions discussed above. Pasternack respectfully submits that the Court's prior statements of New York law are inaccurate, and that the Court is bound by the New York Court of Appeals' prior holdings on this issue.

Indeed, given the bedrock rules of federalism, which mandate that the New York Court of Appeals has the final word on New York state law and is controlling on the federal courts, many district courts in this Circuit have declined to follow *Lollo* and *Smokes-Spirits.com*, as even the district court here acknowledged. (*See* A-277). *See*, *e.g.*, *Good Luck Prod. Co. v. Crystal Cove Seafood Corp.*, ---F. Supp. 3d---, No. 14-CV-1727 JS SIL, 2014 WL 6390310, at *8-9 (E.D.N.Y. Nov. 17, 2014); *Chevron Corp. v. Donziger*, 871 F. Supp. 2d 229, 256-57 (S.D.N.Y. 2012); *My First Shades v. Baby Blanket Suncare*, 914 F. Supp. 2d 339, 352 (E.D.N.Y. 2012); *Prestige Builder & Mgmt. LLC v. Safeco Ins. Co. of Am.*, 896 F. Supp. 2d 198, 203-05 (E.D.N.Y. 2012); *Liberty Life Assur. Co. of Boston v. Bahan*, No. 09 Civ. 4715 (JSR), 2010 WL 3431147, at *2 n.4 (S.D.N.Y. Aug. 23, 2010); *O'Brien v. Argo Partners, Inc.*, 736 F. Supp. 2d 528, 537 (E.D.N.Y. 2010); *N.B. Garments*

(PVT), Ltd. v. Kids Int'l Corp., No. 03 Civ. 8041(HB), 2004 WL 444555, at *3 (S.D.N.Y. Mar. 10, 2004).[17]

The district court attempted to reason around the New York Court of Appeals' decision in *Rice* and the long line of cases that have followed it. The court acknowledged the Court of Appeals' sweeping language but decided that, although the decision indisputably concerns a claim for "fraud," the Court must have meant to describe a different tort—that of "tortious interference with business relations." (A-281-82). It is not proper for the federal courts to rewrite the plain language of the Court of Appeals. Absent "persuasive evidence" that the Court of Appeals would not adhere to its own prior precedent— and the district court's speculation about what the Court of Appeals supposedly intended to convey was not "persuasive evidence"—*Rice* should be followed. *See Blue Cross & Blue Shield of New Jersey, Inc. v. Philip Morris USA Inc.*, 344 F.3d 211, 221 (2d Cir. 2003). By its plain language, the Court of Appeals allows a plaintiff to state a claim for fraud based on a third party's reliance, and this Court should follow the New York Court of Appeals' holding on this point.

We recognize that one panel of this Court ordinarily "is bound by prior decisions of this [C]ourt unless and until the precedents established therein are

[17] A few district courts, on the other hand, have followed *Lollo* and *Smokes-Spirits.com*. *See*, *e.g.*, *City of New York v. Cyco.Net, Inc.*, 383 F. Supp. 2d 526, 559 (S.D.N.Y. 2005); *Barnhart v. Federated Dep't Stores, Inc.*, No. 04 Civ. 3668 (JGK), 2005 WL 549712, at *8 (S.D.N.Y. Mar. 8, 2005).

reversed *en banc* or by the Supreme Court." *United States v. Jass*, 569 F.3d 47, 58 (2d Cir. 2009). However, this Court has revisited its prior decisions through a so-called "mini-*en banc*" process when those decisions erroneously relied on other precedent, have significant effects on the federal courts, or are otherwise wrong. *See*, *e.g.*, *Shipping Corp. of India v. Jaldhi Overseas Pte Ltd.*, 585 F.3d 58, 67 & n.9 (2d Cir. 2009); *United States v. Brutus*, 505 F.3d 80, 87 & n.5 (2d Cir. 2007).[18] Here, the Court's prior precedents are contrary to controlling New York law and are creating controversy in the district courts and the federal judicial system. This Court should, accordingly, revisit its prior decisions through the mini-*en banc* process and correct them.

Pasternack stated a valid fraud claim against LabCorp under controlling New York law, and the district court's dismissal should be reversed.

[18] Under this process, this panel would circulate its opinion to all active members of this Court before filing. *Brutus*, 505 F.3d at 87 n.5.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's judgment and vacate the three district court Orders that are at issue in this appeal.

Dated: New York, New York
December 22, 2014

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENT, AND TYPE STYLE REQUIREMENT

1. The undersigned counsel of record for Plaintiff-Appellant Fred L. Pasternack certifies pursuant to Fed. R. App. P. 32(a)(7)(C) that the foregoing brief contains 11,569 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii), according to the Word Count feature of Microsoft Word 2010.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Time New Roman.

Dated: December 22, 2014

/s/ Cynthia S. Arato
Cynthia S. Arato

ADDENDUM

TABLE OF CONTENTS

ADD-1

Code of Federal Regulations
Title 14. Aeronautics and Space
Chapter I. Federal Aviation Administration, Department of Transportation
Subchapter G. Air Carriers and Operators for Compensation or Hire: Certification and Operations
Part 120. Drug and Alcohol Testing Program (Refs & Annos)
Subpart E. Drug Testing Program Requirements

14 C.F.R. § 120.103

§ 120.103 General.

Effective: January 20, 2010
Currentness

(a) Purpose. The purpose of this subpart is to establish a program designed to help prevent accidents and injuries resulting from the use of prohibited drugs by employees who perform safety-sensitive functions.

(b) DOT procedures.

(1) Each employer shall ensure that drug testing programs conducted pursuant to 14 CFR parts 65, 91, 121, and 135 comply with the requirements of this subpart and the "Procedures for Transportation Workplace Drug Testing Programs" published by the Department of Transportation (DOT) (49 CFR part 40).

(2) An employer may not use or contract with any drug testing laboratory that is not certified by the Department of Health and Human Services (HHS) under the National Laboratory Certification Program.

(c) Employer responsibility. As an employer, you are responsible for all actions of your officials, representatives, and service agents in carrying out the requirements of this subpart and 49 CFR part 40.

(d) Applicable Federal Regulations. The following applicable regulations appear in 49 CFR or 14 CFR:

(1) 49 CFR Part 40--Procedures for Transportation Workplace Drug Testing Programs

(2) 14 CFR:

(i) § 67.107--First–Class Airman Medical Certificate, Mental.

(ii) § 67.207--Second–Class Airman Medical Certificate, Mental.

(iii) § 67.307--Third–Class Airman Medical Certificate, Mental.

(iv) § 91.147--Passenger carrying flight for compensation or hire.

(v) § 135.1--Applicability

(e) Falsification. No individual may make, or cause to be made, any of the following:

(1) Any fraudulent or intentionally false statement in any application of a drug testing program.

(2) Any fraudulent or intentionally false entry in any record or report that is made, kept, or used to show compliance with this part.

(3) Any reproduction or alteration, for fraudulent purposes, of any report or record required to be kept by this part.

Credits
[Amdt. 120–0A, 75 FR 3153, Jan. 20, 2010]

SOURCE: Amdt. 120–0, 74 FR 22653, May 14, 2009; Amdt. 120–1, 78 FR 42003, July 15, 2013, unless otherwise noted.

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

Current through December. 4, 2014; 79 FR 72103.

ADD-3

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart A. Administrative Provisions

49 C.F.R. § 40.1

§ 40.1 Who does this regulation cover?

Currentness

(a) This part tells all parties who conduct drug and alcohol tests required by Department of Transportation (DOT) agency regulations how to conduct these tests and what procedures to use.

(b) This part concerns the activities of transportation employers, safety-sensitive transportation employees (including self-employed individuals, contractors and volunteers as covered by DOT agency regulations), and service agents.

(c) Nothing in this part is intended to supersede or conflict with the implementation of the Federal Railroad Administration's post-accident testing program (see 49 CFR 219.200).

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (49)

Current through Dec. 11, 2014; 79 FR 73796.

End of Document

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart A. Administrative Provisions

49 C.F.R. § 40.3

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

Effective: September 27, 2011
Currentness

In this part, the terms listed in this section have the following meanings:

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.

Affiliate. Persons are affiliates of one another if, directly or indirectly, one controls or has the power to control the other, or a third party controls or has the power to control both. Indicators of control include, but are not limited to: interlocking management or ownership; shared interest among family members; shared facilities or equipment; or common use of employees. Following the issuance of a public interest exclusion, an organization having the same or similar management, ownership, or principal employees as the service agent concerning whom a public interest exclusion is in effect is regarded as an affiliate. This definition is used in connection with the public interest exclusion procedures of Subpart R of this part.

Air blank. In evidential breath testing devices (EBTs) using gas chromatography technology, a reading of the device's internal standard. In all other EBTs, a reading of ambient air containing no alcohol.

Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols, including methyl or isopropyl alcohol.

Alcohol concentration. The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under this part.

Alcohol confirmation test. A subsequent test using an EBT, following a screening test with a result of 0.02 or greater, that provides quantitative data about the alcohol concentration.

Alcohol screening device (ASD). A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and placed on a conforming products list (CPL) for such devices.

Alcohol screening test. An analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath or saliva specimen.

Alcohol testing site. A place selected by the employer where employees present themselves for the purpose of providing breath or saliva for an alcohol test.

Alcohol use. The drinking or swallowing of any beverage, liquid mixture or preparation (including any medication), containing alcohol.

Aliquot. A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

Blind specimen or blind performance test specimen. A specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from an employee specimen.

Breath Alcohol Technician (BAT). A person who instructs and assists employees in the alcohol testing process and operates an evidential breath testing device.

Cancelled test. A drug or alcohol test that has a problem identified that cannot be or has not been corrected, or which this part otherwise requires to be cancelled. A cancelled test is neither a positive nor a negative test.

Chain of custody. The procedure used to document the handling of the urine specimen from the time the employee gives the specimen to the collector until the specimen is destroyed. This procedure uses the Federal Drug Testing Custody and Control Form (CCF).

Collection container. A container into which the employee urinates to provide the specimen for a drug test.

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

Collector. A person who instructs and assists employees at a collection site, who receives and makes an initial inspection of the specimen provided by those employees, and who initiates and completes the CCF.

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.

Confirmatory validity test. A second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Confirmed drug test. A confirmation test result received by an MRO from a laboratory.

Consortium/Third-party administrator (C/TPA). A service agent that provides or coordinates the provision of a variety of drug and alcohol testing services to employers. C/TPAs typically perform administrative tasks concerning the operation of the employers' drug and alcohol testing programs. This term includes, but is not limited to, groups of employers who join together to administer, as a single entity, the DOT drug and alcohol testing programs of its members. C/TPAs are not “employers” for purposes of this part.

Continuing education. Training for substance abuse professionals (SAPs) who have completed qualification training and are performing SAP functions, designed to keep SAPs current on changes and developments in the DOT drug and alcohol testing program.

Designated employer representative (DER). An employee authorized by the employer to take immediate action(s) to remove employees from safety-sensitive duties, or cause employees to be removed from these covered duties, and to make required decisions in the testing and evaluation processes. The DER also receives test results and other communications for the employer, consistent with the requirements of this part. Service agents cannot act as DERs.

Dilute specimen. A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

DOT, The Department, DOT agency. These terms encompass all DOT agencies, including, but not limited to, the United States Coast Guard (USCG), the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Transit Administration (FTA), the National Highway Traffic Safety Administration (NHTSA), the Pipeline and Hazardous Materials Safety Administration (PHMSA), and the Office of the Secretary (OST). These terms include any designee of a DOT agency.

Drugs. The drugs for which tests are required under this part and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opiates.

Employee. Any person who is designated in a DOT agency regulation as subject to drug testing and/or alcohol testing. The term includes individuals currently performing safety-sensitive functions designated in DOT agency regulations and applicants for employment subject to pre-employment testing. For purposes of drug testing under this part, the term employee has the same meaning as the term “donor” as found on CCF and related guidance materials produced by the Department of Health and Human Services.

Employer. A person or entity employing one or more employees (including an individual who is self-employed) subject to DOT agency regulations requiring compliance with this part. The term includes an employer's officers, representatives, and management personnel. Service agents are not employers for the purposes of this part.

Error Correction Training. Training provided to BATs, collectors, and screening test technicians (STTs) following an error that resulted in the cancellation of a drug or alcohol test. Error correction training must be provided in person or by a means that provides real-time observation and interaction between the instructor and trainee.

Evidential Breath Testing Device (EBT). A device approved by NHTSA for the evidential testing of breath at the .02 and .04 alcohol concentrations, placed on NHTSA's Conforming Products List (CPL) for “Evidential Breath Measurement Devices” and identified on the CPL as conforming with the model specifications available from NHTSA's Traffic Safety Program.

HHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

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.

Invalid result. The result reported by a laboratory for a urine specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

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.

Medical Review Officer (MRO). A person who is a licensed physician and who is responsible for receiving and reviewing laboratory results generated by an employer's drug testing program and evaluating medical explanations for certain drug test results.

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.

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

Office of Drug and Alcohol Policy and Compliance (ODAPC). The office in the Office of the Secretary, DOT, that is responsible for coordinating drug and alcohol testing program matters within the Department and providing information concerning the implementation of this part.

Oxidizing adulterant. A substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drug or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

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.

Primary specimen. In drug testing, the urine specimen bottle that is opened and tested by a first laboratory to determine whether the employee has a drug or drug metabolite in his or her system; and for the purpose of validity testing. The primary specimen is distinguished from the split specimen, defined in this section.

Qualification Training. The training required in order for a collector, BAT, MRO, SAP, or STT to be qualified to perform their functions in the DOT drug and alcohol testing program. Qualification training may be provided by any appropriate means (e.g., classroom instruction, internet application, CD–ROM, video).

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

Refresher Training. The training required periodically for qualified collectors, BATs, and STTs to review basic requirements and provide instruction concerning changes in technology (e.g., new testing methods that may be authorized) and amendments, interpretations, guidance, and issues concerning this part and DOT agency drug and alcohol testing regulations. Refresher training can be provided by any appropriate means (e.g., classroom instruction, internet application, CD–ROM, video).

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.

Screening drug test. See Initial drug test definition above.

Screening Test Technician (STT). A person who instructs and assists employees in the alcohol testing process and operates an ASD.

Secretary. The Secretary of Transportation or the Secretary's designee.

Service agent. Any person or entity, other than an employee of the employer, who provides services specified under this part to employers and/or employees in connection with DOT drug and alcohol testing requirements. This includes, but is not limited to, collectors, BATs and STTs, laboratories, MROs, substance abuse professionals, and C/TPAs. To act as service agents, persons and organizations must meet the qualifications set forth in applicable sections of this part. Service agents are not employers for purposes of this part.

Shipping container. A container that is used for transporting and protecting urine specimen bottles and associated documents from the collection site to the laboratory.

Specimen bottle. The bottle that, after being sealed and labeled according to the procedures in this part, is used to hold the urine specimen during transportation to the laboratory.

Split specimen. In drug testing, a part of the urine specimen that is sent to a first laboratory and retained unopened, and which is transported to a second laboratory in the event that the employee requests that it be tested following a verified positive test of the primary specimen or a verified adulterated or substituted test result.

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).

Stand-down. The practice of temporarily removing an employee from the performance of safety-sensitive functions based only on a report from a laboratory to the MRO of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test, before the MRO has completed verification of the test result.

Substance Abuse Professional (SAP). A person who evaluates employees who have violated a DOT drug and alcohol regulation and makes recommendations concerning education, treatment, follow-up testing, and aftercare.

Substituted specimen. A urine specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine.

Verified test. A drug test result or validity testing result from an HHS-certified laboratory that has undergone review and final determination by the MRO.

Credits

[66 FR 41950, Aug. 9, 2001; 71 FR 49384, Aug. 23, 2006; 71 FR 55347, Sept. 22, 2006; 73 FR 35969, June 25, 2008; 75 FR 49861, Aug. 16, 2010; 76 FR 59577, Sept. 27, 2011]

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (42)

Current through December. 4, 2014; 79 FR 72103.

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart B. Employer Responsibilities

49 C.F.R. § 40.15

§ 40.15 May an employer use a service agent to meet DOT drug and alcohol testing requirements?

Currentness

(a) As an employer, you may use a service agent to perform the tasks needed to comply with this part and DOT agency drug and alcohol testing regulations, consistent with the requirements of Subpart Q and other applicable provisions of this part.

(b) As an employer, you are responsible for ensuring that the service agents you use meet the qualifications set forth in this part (e.g., § 40.121 for MROs). You may require service agents to show you documentation that they meet the requirements of this part (e.g., documentation of MRO qualifications required by § 40.121(e)).

(c) You remain responsible for compliance with all applicable requirements of this part and other DOT drug and alcohol testing regulations, even when you use a service agent. If you violate this part or other DOT drug and alcohol testing regulations because a service agent has not provided services as our rules require, a DOT agency can subject you to sanctions. Your good faith use of a service agent is not a defense in an enforcement action initiated by a DOT agency in which your alleged noncompliance with this part or a DOT agency drug and alcohol regulation may have resulted from the service agent's conduct.

(d) As an employer, you must not permit a service agent to act as your DER.

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (1)

Current through Dec. 11, 2014; 79 FR 73796.

End of Document

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart C. Urine Collection Personnel

49 C.F.R. § 40.33

§ 40.33 What training requirements must a collector meet?

Effective: June 12, 2008
Currentness

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

(a) Basic information. You must be knowledgeable about this part, the current "DOT Urine Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers for whom you perform collections, and you must keep current on any changes to these materials. The DOT Urine Specimen Collection Procedures Guidelines document is available from ODAPC (Department of Transportation, 1200 New Jersey Avenue, SE., Washington DC, 20590, 202–366–3784, or on the ODAPC web site (http://www.dot.gov/ost/dapc).

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

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

(2) "Problem" collections (e.g., situations like "shy bladder" and attempts to tamper with a specimen);

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

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

(c) Initial Proficiency Demonstration. Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections.

(1) The five mock collections must include two uneventful collection scenarios, one insufficient quantity of urine scenario, one temperature out of range scenario, and one scenario in which the employee refuses to sign the CCF and initial the specimen bottle tamper-evident seal.

(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are "error-free." This person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by--

(i) Regularly conducting DOT drug test collections for a period of at least a year;

(ii) Conducting collector training under this part for a year; or

(iii) Successfully completing a "train the trainer" course.

(d) Schedule for qualification training and initial proficiency demonstration. The following is the schedule for qualification training and the initial proficiency demonstration you must meet:

(1) If you became a collector before August 1, 2001, and you have already met the requirements of paragraphs (b) and (c) of this section, you do not have to meet them again.

(2) If you became a collector before August 1, 2001, and have yet to meet the requirements of paragraphs (b) and (c) of this section, you must do so no later than January 31, 2003.

(3) If you become a collector on or after August 1, 2001, you must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

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

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

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

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

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

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

Credits

[66 FR 3885, Jan. 17, 2001; 66 FR 41950, Aug. 9, 2001; 73 FR 33329, June 12, 2008]

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (8)

Current through December. 4, 2014; 79 FR 72103.

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart G. Medical Review Officers and the Verification Process

49 C.F.R. § 40.121

§ 40.121 Who is qualified to act as an MRO?

Effective: October 1, 2010
Currentness

To be qualified to act as an MRO in the DOT drug testing program, you must meet each of the requirements of this section:

(a) Credentials. You must be a licensed physician (Doctor of Medicine or Osteopathy). If you are a licensed physician in any U.S., Canadian, or Mexican jurisdiction and meet the other requirements of this section, you are authorized to perform MRO services with respect to all covered employees, wherever they are located. For example, if you are licensed as an M.D. in one state or province in the U.S., Canada, or Mexico, you are not limited to performing MRO functions in that state or province, and you may perform MRO functions for employees in other states or provinces without becoming licensed to practice medicine in the other jurisdictions.

(b) Basic knowledge. You must be knowledgeable in the following areas:

(1) You must be knowledgeable about and have clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed drug test results.

(2) You must be knowledgeable about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result.

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. The DOT MRO Guidelines document is available from ODAPC (Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, 202–366–3784, or on the ODAPC web site (http://www.dot.gov/ ost/dapc)).

(c) Qualification training. You must receive qualification training meeting the requirements of this paragraph (c).

(1) Qualification training must provide instruction on the following subjects:

(i) Collection procedures for urine specimens;

(ii) Chain of custody, reporting, and recordkeeping;

(iii) Interpretation of drug and validity tests results;

(iv) The role and responsibilities of the MRO in the DOT drug testing program;

(v) The interaction with other participants in the program (e.g., DERs, SAPs); and

(vi) Provisions of this part and DOT agency rules applying to employers for whom you review test results, including changes and updates to this part and DOT agency rules, guidance, interpretations, and policies affecting the performance of MRO functions, as well as issues that MROs confront in carrying out their duties under this part and DOT agency rules.

(2) Following your completion of qualification training under paragraph (c)(1) of this section, 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.

(3) The following is the schedule for qualification training you must meet:

(i) If you became an MRO before August 1, 2001, and have already met the qualification training requirement, you do not have to meet it again.

(ii) If you became an MRO before August 1, 2001, but have not yet met the qualification training requirement, you must do so no later than January 31, 2003.

(iii) If you become an MRO on or after August 1, 2001, you must meet the qualification training requirement before you begin to perform MRO functions.

(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.

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

Credits

[66 FR 41951, Aug. 9, 2001; 73 FR 33329, June 12, 2008; 75 FR 49862, Aug. 16, 2010]

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (1)

Current through Dec. 11, 2014; 79 FR 73796.

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart G. Medical Review Officers and the Verification Process

49 C.F.R. § 40.123

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

Currentness

As an MRO, you have the following basic responsibilities:

(a) Acting as an independent and impartial "gatekeeper" and advocate for the accuracy and integrity of the drug testing process.

(b) Providing a quality assurance review of the drug testing process for the specimens under your purview. This includes, but is not limited to:

(1) Ensuring the review of the CCF on all specimen collections for the purposes of determining whether there is a problem that may cause a test to be cancelled (see §§ 40.199–40.203). As an MRO, you are not required to review laboratory internal chain of custody documentation. No one is permitted to cancel a test because you have not reviewed this documentation;

(2) Providing feedback to employers, collection sites and laboratories regarding performance issues where necessary; and

(3) Reporting to and consulting with the ODAPC or a relevant DOT agency when you wish DOT assistance in resolving any program issue. As an employer or service agent, you are prohibited from limiting or attempting to limit the MRO's access to DOT for this purpose and from retaliating in any way against an MRO for discussing drug testing issues with DOT.

(c) You must determine whether there is a legitimate medical explanation for confirmed positive, adulterated, substituted, and invalid drug tests results from the laboratory.

(d) While you provide medical review of employees' test results, this part does not deem that you have established a doctor-patient relationship with the employees whose tests you review.

(e) You must act to investigate and correct problems where possible and notify appropriate parties (e.g., HHS, DOT, employers, service agents) where assistance is needed, (e.g., cancelled or problematic tests, incorrect results, problems with blind specimens).

(f) You must ensure the timely flow of test results and other information to employers.

(g) You must protect the confidentiality of the drug testing information.

(h) You must perform all your functions in compliance with this part and other DOT agency regulations.

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (5)

Current through December. 4, 2014; 79 FR 72103.

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart G. Medical Review Officers and the Verification Process

49 C.F.R. § 40.151

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

Effective: October 1, 2010
Currentness

As an MRO, you are prohibited from doing the following as part of the verification process:

(a) You must not consider any evidence from tests of urine samples or other body fluids or tissues (e.g., blood or hair samples) that are not collected or tested in accordance with this part. For example, if an employee tells you he went to his own physician, provided a urine specimen, sent it to a laboratory, and received a negative test result or a DNA test result questioning the identity of his DOT specimen, you are required to ignore this test result.

(b) It is not your function to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF (e.g., concerning allegations that the collector left the area or left open urine containers where other people could access them).

(c) It is not your function to determine whether the employer should have directed that a test occur. For example, if an employee tells you that the employer misidentified her as the subject of a random test, or directed her to take a reasonable suspicion or post-accident test without proper grounds under a DOT agency drug or alcohol regulation, you must inform the employee that you cannot play a role in deciding these issues.

(d) It is not your function to consider explanations of confirmed positive, adulterated, or substituted test results that would not, even if true, constitute a legitimate medical explanation. For example, an employee may tell you that someone slipped amphetamines into her drink at a party, that she unknowingly ingested a marijuana brownie, or that she traveled in a closed car with several people smoking crack. MROs are unlikely to be able to verify the facts of such passive or unknowing ingestion stories. Even if true, such stories do not present a legitimate medical explanation. Consequently, you must not declare a test as negative based on an explanation of this kind.

(e) You must not verify a test negative based on information that a physician recommended that the employee use a drug listed in Schedule I of the Controlled Substances Act. (e.g., under a state law that purports to authorize such recommendations, such as the “medical marijuana” laws that some states have adopted).

(f) You must not accept an assertion of consumption or other use of a hemp or other non-prescription marijuana-related product as a basis for verifying a marijuana test negative. You also must not accept such an explanation related to consumption of coca teas as a basis for verifying a cocaine test result as negative. Consuming or using such a product is not a legitimate medical explanation.

(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.

(h) You must not accept, as a legitimate medical explanation for an adulterated specimen, an assertion that soap, bleach, or glutaraldehyde entered a specimen through physiological means. There are no physiological means through which these substances can enter a specimen.

(i) You must not accept, as a legitimate medical explanation for a substituted specimen, an assertion that an employee can produce urine with no detectable creatinine. There are no physiological means through which a person can produce a urine specimen having this characteristic.

Credits
[66 FR 41952, Aug. 9, 2001; 75 FR 49863, Aug. 16, 2010]

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (3)

Current through Dec. 11, 2014; 79 FR 73796.

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart I. Problems in Drug Tests

49 C.F.R. § 40.191

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

Effective: October 1, 2010
Currentness

(a) As an employee, you have refused to take a drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see § 40.61(a));

(2) Fail to remain at the testing site until the testing process is complete; *Provided*, That an employee who leaves the testing site before the testing process commences (see § 40.63 (c)) for a pre-employment test is not deemed to have refused to test;

(3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations; *Provided*, That an employee who does not provide a urine specimen because he or she has left the testing site before the testing process commences (see § 40.63 (c)) for a pre-employment test is not deemed to have refused to test;

(4) In the case of a directly observed or monitored collection in a drug test, fail to permit the observation or monitoring of your provision of a specimen (see §§ 40.67(l) and 40.69(g));

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see § 40.193(d)(2));

(6) Fail or decline to take an additional drug test the employer or collector has directed you to take (see, for instance, § 40.197(b));

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under § 40.193(d). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test; or

(8) Fail to cooperate with any part of the testing process (e.g., refuse to empty pockets when directed by the collector, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector).

(9) For an observed collection, fail to follow the observer's instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process.

(10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process.

(11) Admit to the collector or MRO that you adulterated or substituted the specimen.

(b) As an employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.

(c) As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations.

(d) As a collector or an MRO, when an employee refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the CCF (including, in the case of the collector, printing the employee's name on Copy 2 of the CCF), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating a “shy bladder” condition or a claim of a legitimate medical explanation in a validity testing situation), you must notify the MRO, who in turn will notify the DER.

(1) As the collector, you must note the refusal in the “Remarks” line (Step 2), and sign and date the CCF.

(2) As the MRO, you must note the refusal by checking the “Refusal to Test” box in Step 6 on Copy 2 of the CCF, checking whether the specimen was adulterated or substituted and, if adulterated, noting the adulterant/reason. If there was another reason for the refusal, check “Other” in Step 6 on Copy 2 of the CCF, and note the reason next to the “Other” box and on the “Remarks” lines, as needed. You must then sign and date the CCF.

(e) As an employee, when you refuse to take a non-DOT test or to sign a non-DOT form, you have not refused to take a DOT test. There are no consequences under DOT agency regulations for refusing to take a non–DOT test.

Credits

[66 FR 41953, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 71 FR 49384, Aug. 23, 2006; 73 FR 35974, June 25, 2008; 75 FR 59108, Sept. 27, 2010; 76 FR 59577, Sept. 27, 2011]

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (8)

Current through December. 4, 2014; 79 FR 72103.

End of Document

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart I. Problems in Drug Tests

49 C.F.R. § 40.193

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

Effective: October 1, 2010
Currentness

(a) This section prescribes procedures for situations in which an employee does not provide a sufficient amount of urine to permit a drug test (i.e., 45 mL of urine).

(b) As the collector, you must do the following:

(1) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see § 40.65(b) and (c)).

(2) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. Document on the Remarks line of the CCF (Step 2), and inform the employee of, the time at which the three-hour period begins and ends.

(3) If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER. This is a refusal to test.

(4) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER.

(5) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.

(c) As the DER, when the collector informs you that the employee has not provided a sufficient amount of urine (see paragraph (b)(4) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the employee was required to take a DOT drug test, but was unable to provide a sufficient amount of urine to complete the test;

(ii) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.

(2) [Reserved]

(d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:

(i) Check "Test Cancelled" (Step 6) on the CCF; and

(ii) Sign and date the CCF.

(2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:

(i) Check the "Refusal to Test" box and "Other" box in Step 6 on Copy 2 of the CCF and note the reason next to the "Other" box and on the "Remarks" lines, as needed.

(ii) Sign and date the CCF.

(e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of "situational anxiety" or dehydration.

(f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(g) If, as the referral physician making this evaluation in the case of a pre-employment test, you determine that the employee's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of § 40.195, where applicable.

(h) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. You must report your determination to the DER in writing as soon as you make it.

(i) As the employer, when you receive a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. The employee remains in the random testing pool.

Credits

[66 FR 41953, Aug. 9, 2001; 75 FR 59108, Sept. 27, 2010; 76 FR 59577, Sept. 27, 2011]

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (6)

Current through December. 4, 2014; 79 FR 72103.

End of Document

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart O. Substance Abuse Professionals and the Return–To–Duty Process

49 C.F.R. § 40.285

§ 40.285 When is a SAP evaluation required?

Currentness

(a) As an employee, when you have violated DOT drug and alcohol regulations, you cannot again perform any DOT safety-sensitive duties for any employer until and unless you complete the SAP evaluation, referral, and education/treatment process set forth in this subpart and in applicable DOT agency regulations. The first step in this process is a SAP evaluation.

(b) For purposes of this subpart, a verified positive DOT drug test result, a DOT alcohol test with a result indicating an alcohol concentration of 0.04 or greater, a refusal to test (including by adulterating or substituting a urine specimen) or any other violation of the prohibition on the use of alcohol or drugs under a DOT agency regulation constitutes a DOT drug and alcohol regulation violation.

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (1)

Current through December. 4, 2014; 79 FR 72103.

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Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart Q. Roles and Responsibilities of Service Agents

49 C.F.R. § 40.355

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

Effective: October 1, 2010
Currentness

As a service agent, you are subject to the following limitations concerning your activities in the DOT drug and alcohol testing program.

(a) You must not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory testing, MRO, and SAP services). No one may do so on behalf of a service agent.

(b) You must not act as an intermediary in the transmission of drug test results from the laboratory to the MRO. That is, the laboratory may not send results to you, with you in turn sending them to the MRO for verification. For example, a practice in which the laboratory transmits results to your computer system, and you then assign the results to a particular MRO, is not permitted.

(c) You must not transmit drug test results directly from the laboratory to the employer (by electronic or other means) or to a service agent who forwards them to the employer. All confirmed laboratory results must be processed by the MRO before they are released to any other party.

(d) You must not act as an intermediary in the transmission of alcohol test results of 0.02 or higher from the STT or BAT to the DER.

(e) Except as provided in paragraph (f) of this section, you must not act as an intermediary in the transmission of individual SAP reports to the actual employer. That is, the SAP may not send such reports to you, with you in turn sending them to the actual employer. However, you may maintain individual SAP summary reports and follow-up testing plans after they are sent to the DER, and the SAP may transmit such reports to you simultaneously with sending them to the DER.

(f) As an exception to paragraph (e) of this section, you may act as an intermediary in the transmission of SAP report from the SAP to an owner-operator or other self-employed individual.

(g) Except as provided in paragraph (h) of this section, you must not make decisions to test an employee based upon reasonable suspicion, post-accident, return-to-duty, and follow-up determination criteria. These are duties the actual employer cannot

delegate to a C/TPA. You may, however, provide advice and information to employers regarding these testing issues and how the employer should schedule required testing.

(h) As an exception to paragraph (g) of this section, you may make decisions to test an employee based upon reasonable suspicion, post-accident, return-to-duty, and follow-up determination criteria with respect to an owner-operator or other self-employed individual.

(i) Except as provided in paragraph (j) of this section, you must not make a determination that an employee has refused a drug or alcohol test. This is a non-delegable duty of the actual employer. You may, however, provide advice and information to employers regarding refusal-to-test issues.

(j) As an exception to paragraph (i) of this section, you may make a determination that an employee has refused a drug or alcohol test, if:

(1) You schedule a required test for an owner-operator or other self-employed individual, and the individual fails to appear for the test without a legitimate reason; or

(2) As an MRO, you determine that an individual has refused to test on the basis of adulteration or substitution.

(k) You must not act as a DER. For example, while you may be responsible for transmitting information to the employer about test results, you must not act on behalf of the employer in actions to remove employees from safety-sensitive duties.

(l) In transmitting documents to laboratories, you must ensure that you send to the laboratory that conducts testing only Copy 1 of the CCF. You must not transmit other copies of the CCF or any ATFs to the laboratory.

(m) You must not impose conditions or requirements on employers that DOT regulations do not authorize. For example, as a C/TPA serving employers in the pipeline or motor carrier industry, you must not require employers to have provisions in their DOT plans that PHMSA or FMCSA regulations do not require.

(n) You must not intentionally delay the transmission of drug or alcohol testing-related documents concerning actions you have performed, because of a payment dispute or other reasons.

Example 1 to Paragraph (n): A laboratory that has tested a specimen must not delay transmitting the documentation of the test result to an MRO because of a billing or payment dispute with the MRO or a C/TPA.

Example 2 to Paragraph (n): An MRO or SAP who has interviewed an employee must not delay sending a verified test result or SAP report to the employer because of such a dispute with the employer or employee.

Example 3 to Paragraph (n): A collector who has performed a urine specimen collection must not delay sending the drug specimen and CCF to the laboratory because of a payment or other dispute with the laboratory or a C/TPA.

Example 4 to Paragraph (n): A BAT who has conducted an alcohol test must not delay sending test result information to an employer or C/TPA because of a payment or other dispute with the employer or C/TPA.

(o) While you must follow the DOT agency regulations, the actual employer remains accountable to DOT for compliance, and your failure to implement any aspect of the program as required in this part and other applicable DOT agency regulations makes the employer subject to enforcement action by the Department.

Credits

[66 FR 41955, Aug. 9, 2001; 75 FR 59108, Sept. 27, 2010; 76 FR 59577, Sept. 27, 2011]

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Notes of Decisions (1)

Current through December. 4, 2014; 79 FR 72103.

Code of Federal Regulations
Title 49. Transportation
Subtitle A. Office of the Secretary of Transportation
Part 40. Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Refs & Annos)
Subpart R. Public Interest Exclusions

49 C.F.R. § 40.363

§ 40.363 On what basis may the Department issue a PIE?

Currentness

(a) If you are a service agent, the Department may issue a PIE concerning you if we determine that you have failed or refused to provide drug or alcohol testing services consistent with the requirements of this part or a DOT agency drug and alcohol regulation.

(b) The Department also may issue a PIE if you have failed to cooperate with DOT agency representatives concerning inspections, complaint investigations, compliance and enforcement reviews, or requests for documents and other information about compliance with this part or DOT agency drug and alcohol regulations.

SOURCE: 65 FR 79526, Dec. 19, 2000; 66 FR 28400, May 23, 2001; 69 FR 64867, Nov. 9, 2004; 71 FR 49384, Aug. 23, 2006, unless otherwise noted.

AUTHORITY: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.; 49 U.S.C. 322.

Current through December. 4, 2014; 79 FR 72103.

End of Document

Urine Specimen Collection Guidelines

United States
Department of Transportation

Office of Drug and Alcohol Policy and Compliance

Revised December 2006

DOT Urine Specimen Collection Guidelines for the U.S. Department of Transportation Workplace Drug Testing Programs (49 CFR Part 40)

These guidelines apply only to employers and individuals who come under the regulatory authority of the U.S. Department of Transportation (DOT) and those individuals who conduct urine specimen collections under DOT regulations. The term "employee" is used throughout this document and has the same meaning as "donor" as used on the Federal Drug Testing Custody and Control Form (CCF).

These guidelines are a complete revision of the December 1994 (revised in October 1999) DOT Urine Specimen Collection Procedures Guidelines, 49 CFR Part 40, for Transportation Workplace Drug Testing Programs. These guidelines contain all of the new requirements and procedures contained in the DOT rule published in the *Federal Register* on December 19, 2000, effective August 1, 2001, and in the Technical Amendments, published on August 9, 2001. It contains minimal graphics and formatting to ease transmission and downloading of the document from the Internet. All previous amendments and interpretations are superseded and no longer in effect.

Note: All DOT-required collections are conducted using split specimen procedures. There are no exceptions to this requirement.

Note: If an alcohol test is also required, the alcohol test should be conducted first, if practicable.

This document may be updated or modified based on additional interpretations or other procedural changes. Collectors and service agents should check the DOT web site periodically to ensure that they have the latest version (www.dot.gov/ost/dapc/).

Revised December 2006

Previous editions are obsolete

INTRODUCTION

The Department of Transportation's (DOT) operating administrations (Federal Aviation Administration, Federal Motor Carrier Safety Administration, Federal Railroad Administration, Federal Transit Administration, Research and Special Programs Administration, and the United States Coast Guard) have issued regulations requiring anti-drug programs in the aviation, highway, railroad, mass transit, pipeline, and maritime industries. The DOT operating administrations' rules require that employers conduct drug testing according to provisions of 49 CFR Part 40, "Procedures for Transportation Workplace Drug Testing Programs," Final Rule, published in the Federal Register on December 19, 2000 (65 FR 79462), effective August 1, 2001, together with subsequent technical amendments. Previously published rules, amendments, interpretations, and guidelines are no longer in effect.

The procedures for collection of urine under these rules are very specific and must be followed whenever a DOT-required urine specimen collection is performed. (The only exception is the Federal Railroad Administration's Post-Accident Toxicological Testing Program in which a railroad representative will provide the collector specific instructions and a testing kit.) These procedures, including use of the Federal Drug Testing Custody and Control Form (CCF), apply only to DOT-required testing. While employers may use these collection and testing procedures for testing under employer or state authority, they must not use a Federal CCF nor can they imply that company tests are conducted using DOT authority.

The collector has a major role in the success of the DOT's drug testing program. The collector is the one individual in the testing process with whom all employees have direct, face-to-face contact. Without the collector assuring the integrity of the specimen and collection process, the test itself may lose validity. Without the collector's sensitivity to an employee's privacy, the entire testing program may be subject to criticism. It is imperative that collectors fully understand and follow these procedures. These guidelines, together with 49 CFR Part 40 and the DOT operating administrations' rules, will provide collectors with the information needed in the performance of their collection duties.

The information in this document addresses normal collection procedures and some of the more common problems or situations encountered. However, information contained in this publication should not be used to interpret the legal requirements of the actual rule.

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SECTION 1. COLLECTOR

Part 40 defines a collector as a trained person who instructs and assists employees at a collection site, who receives and makes an initial inspection of the urine specimen provided by those employees, and who initiates and completes the Federal Drug Testing Custody and Control Form (CCF).

> Note: DOT does not require or provide collector certification. Collectors need to have documentation reflecting that they have met appropriate training requirements.

Any individual, who has received training specified in 49 CFR Part 40 (40.33) for conducting the required collection procedure, may serve as a collector except in the following situations:

> 1. The immediate supervisor of a particular employee may not act as the collector when that employee is tested, unless no other collector is available and the supervisor is permitted to do so under a DOT operating administration's drug and alcohol regulation. (The immediate supervisor may act as a monitor or observer (same gender) if there is no alternate method at the collection site to conduct a monitored or observed collection.);
>
> 2. An employee who is in a safety-sensitive position and subject to the DOT drug testing rules should not be a collector, an observer, or a monitor for co-workers who are in the same testing pool or who work together with that employee on a daily basis. This is to preclude any potential appearance of collusion or impropriety;
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> 3. An individual working for an HHS-certified drug testing laboratory (e.g., as a

technician or accessioner) may not act as a collector if that individual can link the employee with the specimen drug test result or laboratory report; and,

4. The employee may not be the collector of his or her own urine specimen.

Note: To avoid a potential conflict of interest, a collector should not be someone that is related to the employee (e.g., spouse, ex-spouse, relative) or a close personal friend (e.g., fiancée).

A collector should have appropriate identification, which includes the collector's name and the name of the Collection Company or clinic. The collector is required to provide his or her identification if requested by the employee. There is no requirement for the collector to have a picture I.D. or to provide his or her driver's license with an address or telephone number. Also, the collector is not required to provide any certification or other documentation to the employee documenting the collector's training. However, the collector must provide this documentation on request to DOT agency representatives and to employers and service agents (SA) or Consortia/Third Party Administrators (C/TPAs) who are using or negotiating to use that collector's services.

As the collector, you must have the name and telephone number of the appropriate Designated Employee Representative (DER) and of the SA or C/TPA, where applicable, to contact about any problems or issues that may arise during the collection process.

SECTION 2. COLLECTION SITE

A collection site is a place (permanent or temporary) selected by the employer where employees present themselves for the purpose of providing a urine specimen for a DOT-required drug test.

Generally, there are two types of collection facilities:

1. A single-toilet restroom, with a full-length privacy door, or

2. A multi-stall restroom, with partial-length doors.

A collection site must have:

1. A restroom or stall with a toilet for the employee to have privacy while providing the urine specimen. Whenever available, a single toilet restroom, with a full-length privacy door, is preferred. All types of restrooms including a mobile facility (e.g., a vehicle with an enclosed toilet) are acceptable.

2. A source of water for washing hands that, if practical, is external to the restroom where urination occurs. If the only source of water available is inside the restroom, the employee may wash his or her hands, and then the collector must secure (e.g., use tamper-evident tape, cut off the water supply) the water source before the collection takes

place. If water is not available at the collection site, the collector may provide moist towelettes outside the restroom.

3. A suitable clean surface for the collector to use as a work area and for completing the required paper work.

A second type of facility for urination, which can be used as a collection site, is a multi-stall restroom. Such a site must provide substantial visual privacy (e.g., a toilet stall with a partial-length door) and meet all other requirements listed above (2 and 3). Additionally, if a multi-stall restroom is used, the collector must either:

1. Secure all sources of water and other substances that could be used for adulteration and substitution (e.g., water faucets, soap dispensers) and place bluing agent in all toilets or secure the toilets to prevent access; or

2. Conduct all collections as monitored collections (See Section 9).

No one but the employee may be present in the multi-stall restroom during the collection, except the monitor in the event of a monitored collection or the observer in the event of a directly observed collection.

Note: The collector's work area may be located outside the restroom. However, if there is no appropriate space available outside the restroom to serve as a secure, clean work area and the restroom is either a multi-stall facility or a single stall facility with a partial door for privacy, and is large enough to accommodate a work area, the collector may locate the work area inside the restroom as long as all procedures for a monitored collection are met.

All collection sites must meet the following security requirements by having:

1. Procedures or restrictions to prevent unauthorized access to the site during the collection;

2. Procedures to prevent the employee or anyone else from gaining unauthorized access to the collection materials/supplies. The collector must also ensure that the employee does not have access to items that could be used to adulterate or dilute the specimen (e.g., soap, disinfectants, cleaning agents, water);

3. Procedures to ensure that all authorized persons are under the supervision of a collector or appropriate site personnel at all times when permitted into the site; and,

4. Procedures to provide for the secure handling and storage of specimens.

Note: The testing site is that portion of the facility where the collector performs the paper work, seals the specimens, and where urination occurs. It does not necessarily include the total physical facility (e.g., clinic). Additionally,

unauthorized personnel are any individuals that are not specifically authorized by the regulation, the collector, or employer to be present at the collection site.

SECTION 3. COLLECTION SUPPLIES

The following items must be available at the collection site in order to conduct proper collections:

1. For each DOT drug test, a collection kit meeting the requirements listed at Appendix A of these guidelines.

2. Federal Drug Testing Custody and Control Forms (CCF).

3. Bluing (coloring) agent to add to the toilet bowl/water tank to prevent an employee from diluting the specimen.

4. Single use disposable gloves are recommended for use by collectors while handling specimens.

5. The collector should have available tamper-evident tape for securing faucets, toilet tank tops, and other appropriate areas, and signs, when necessary, that can be posted to prevent entry into collection areas.

SECTION 4. FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

The Federal Drug Testing Custody and Control Form (CCF OMB No. 0930-0158, Exp. Date: 6/30/2003) must be used to document every urine collection required by the DOT drug testing program. The CCF must be a five-part carbonless manifold form. This form may be viewed on the DOT web site (http://www.dot.gov/ost/dapc/) or the Department of Health and Human Services (HHS) web site http://workplace.samhsa.gov/. CCFs are also available from a number of different sources (e.g., laboratories, service agents) although they are usually part of the urine collection kits provided by a laboratory.

The CCF consists of the following five copies:

Copy 1.	Laboratory Copy - accompanies the specimen to the laboratory
Copy 2.	Medical Review Officer Copy - sent to the MRO
Copy 3.	Collector Copy - retained by the collector
Copy 4.	Employer Copy - sent to the employer
Copy 5.	Employee Copy - given to the employee

The CCF is completed as follows:

Step 1 (Copy 1). This step is completed by the collector or employer representative prior to the employee providing a urine specimen. The employer and MRO names, addresses, and telephone and fax numbers may be preprinted or handwritten. If the employer has designated a service

agent to receive the results from the MRO, the employer's address may be omitted and the service agent's address may be used. However, in all cases, the specific employer's name, telephone and fax numbers must be included. A clinic or collection site name may not be used in lieu of an employer name. The collector enters the employee's social security number or employee's ID number after verifying the employee's identity. The collector also marks the appropriate box to indicate the reason for the test and the appropriate box for the type of drug tests to be performed (all DOT drug tests are for five drugs). The collector then enters the information required for the collection site (this information may also be preprinted). The collector's telephone number is critical, since the laboratory or the MRO may need to contact the collector if they have questions related to a collection.

Step 2 (Copy 1). This step is completed by the collector after receiving the specimen from the employee and observing the temperature of the specimen. This step requires the collector to mark the appropriate box to indicate if the temperature of the specimen was within the required temperature range. This step also requires the collector to indicate whether it is a split specimen or single specimen collection, to indicate if no specimen was collected and why, or to indicate if it was an observed collection and why.

> Note: All DOT collections are split specimen collections and should never have the single specimen collection box checked.

Step 3 (Copy 1). This step instructs the collector to seal and date the specimen bottles, have the employee initial the bottle seals after placing them on the bottles, and then instruct the employee to complete step 5 on the MRO copy (Copy 2).

Step 5 (Copy 2; note this differs from the other steps in that the collector turns to Copy 2 for the employee to fill out and then turns back to Copy 1). This step is completed by the employee (listed as donor on the CCF). The employee reads the certification statement, prints his or her name, provides date of birth, daytime and evening telephone numbers, date of collection, and signs the form. After the employee completes this portion of the CCF, the collector reviews it to ensure that all the required information was provided.

Step 4 (Copy 1). This step is initiated by the collector and then completed by the laboratory after the laboratory accessions the specimen. This step requires the collector to sign the form to certify that the specimen was collected, labeled, sealed, and released for shipment to the laboratory in accordance with Federal requirements. The collector is also required to note the time of the collection, the date of collection, and the specific name of the delivery service to whom the specimen is released for shipment to the laboratory.

> Note: There is no requirement for couriers, express carriers, or postal service personnel to add additional documentation to the chain of custody for the specimens during transit because they do not have direct access to the specimens or the CCF. Chain of custody annotations resume when the shipping container/package is opened and accessioned at the laboratory.

Step 5(a) (Copy 1). This step is completed by the laboratory to report the test result of the

primary specimen.

Step 5(b) (Copy 1). This step is completed by the laboratory to report the test result of the split specimen if the split specimen is tested.

Step 6 (Copy 2). This step is completed by the MRO in reporting the results of the primary specimen to the employer.

Step 7 (Copy 2). This step is completed by the MRO in reporting the results of the split specimen to the employer.

The bottom area of Copy 1 is reserved for the tamper-evident specimen bottle seals/labels. There must be two seals/labels (i.e., one marked with the letter "A" to designate the primary specimen and the other marked with the letter "B" to designate the split specimen) to accommodate collecting split specimens. Each seal/label must have the same preprinted specimen identification number that appears at the top of the CCF. Each seal/label must also have a place for the collector to annotate the date of the collection and a place for the employee to initial each seal/label after it is placed on the specimen bottle.

> Note: No one (including collection site personnel or the collector) is permitted to require an employee to sign a consent, release, or waiver of liability, or indemnification agreement with respect to any part of the drug testing process. Collection sites (clinics) may not use “generic” consent forms for DOT-required urine specimen collections, even if their clinic policy requires consent from the general patient population.

SECTION 5. EMPLOYEE IDENTIFICATION

The employee must provide appropriate identification to the collector upon arrival at the collection site. Acceptable forms of identification include:

1. A photo identification (e.g., drivers license, employee badge issued by the employer, or any other picture identification issued by a Federal, state, or local government agency), or

2. Identification by an employer or employer representative, or

3. Any other identification allowed under an operating administration’s rules.

Unacceptable forms of identification include:

1. Identification by a co-worker,

2. Identification by another safety-sensitive employee,

3. Use of a single non-photo identification card (e.g., social security card, credit card, union or other membership cards, pay vouchers, voter registration card), or

4. Faxed or photocopies of identification document.

Note: If the employee cannot produce positive identification, the collector must contact a DER to verify the identity of the employee. The collection should not proceed until positive identification is obtained. However, if an owner/operator or other self-employed individual does not have proper identification, the collector should record in the remarks section that positive identification is not available. The owner/operator must be asked to provide two items of identification bearing his/her signature. The collector then proceeds with the collection. When the owner/operator signs the certification statement, the collector compares the signature on the CCF with signatures on the identification presented. If the signatures appear consistent, the collection process continues. If the signature does not match signatures on the identification presented, the collector makes an additional note in remarks section stating "signature identification is unconfirmed."

SECTION 6. COLLECTION PROCEDURES

The collector must do the following before each collection to deter potential tampering, adulteration, alteration, or substitution of the specimens:

1. Secure any water sources or otherwise make them unavailable to employees (e.g., turn off water inlet, tape handles to prevent opening faucets);

2. Ensure that the water in the toilet and tank (if applicable) has bluing (coloring) agent in it. Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;

3. Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;

4. Inspect the site to ensure that no foreign or unauthorized substances are present;

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

6. Secure areas and items (e.g., ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants; and

7. Recheck items (1) through (6) following each collection to ensure the site's continued integrity.

If the collection site uses a facility normally used for other purposes, such as a public restroom or hospital examining room, the collector must also ensure before the collection that:

1. Access to collection materials and specimens is effectively restricted; and

2. The facility is secured against access during the procedure to ensure privacy to the employee and prevent distraction of the collector. Limited-access signs must be posted.

To avoid distraction that could compromise security, the collector is limited to conducting a collection for only one employee at a time. However, during the 3 hour time period that an employee is consuming fluids (shy bladder), the collector may conduct a collection for another employee. In this case, the employee with the shy bladder must be properly monitored (see Section 7).

When a specific time for an employee's test has been scheduled, or the collection site is at the employee's work site, and the employee does not appear at the collection site at the scheduled time, the collector must contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, the collector must notify the DER that the employee has not reported for testing.

Note: For a pre-employment test, if an employee fails to appear, fails to provide a urine specimen, or fails to remain at the collection site, this is not considered a refusal provided the employee left the testing site or did not provide a specimen before the testing process commenced (i.e., the employee was given the collection kit or cup by the collector).

The following steps describe a typical urine collection conducted under the DOT-mandated procedures:

1. The collector prepares the collection site to collect urine specimens. All collection supplies must be available, the area properly secured, water sources secured, and bluing (coloring) agent placed in all toilets as specified in Sections 2 and 3 of these guidelines.

2. The collector begins the collection without delay after the employee arrives at the collection site. Do not wait because the employee is not ready or states he or she is unable to urinate. In most cases, employees who state they cannot provide a specimen will, in fact, provide sufficient quantity to complete the testing process. (If an alcohol breath test is also scheduled, the alcohol test should be conducted first, if practicable.)

3. The collector requests the employee to present an acceptable form of identification. If the employee cannot produce positive identification, the collector must contact the DER to verify the identity of the employee (see Section 5). If the employee asks the collector to provide identification, the collector must show the employee some form of identification. It must include the collector's name and the employer's (or collection site) name. It does not have to be a picture identification or include the collector's home address or telephone number.

4. The collector explains the basic collection procedures to the employee and reviews the instructions on the back of the CCF with the employee.

5. The collector ensures that the required information is provided at the top of the CCF (the laboratory name and address and a pre-printed specimen ID number which matches the ID

number on the specimen bottle seals). If the information is not already preprinted, the collector begins entering the required information in Step 1 of the CCF (employer's name, address, telephone and fax number, and I.D. number (if applicable); MRO name, address, telephone and fax number; employee SSN or employee ID number (refusal by the employee to provide a SSN is not a refusal to test, but requires the collector to annotate this in the remarks); reason for test; drug test to be performed; and collection site information).

> Note: Part 40 requires a specific MRO's name and address on the CCF rather than the name of the clinic or medical facility. An employer must provide to the collector the name and telephone number of the appropriate DER. This may be part of the CCF information that is pre-printed or may be under separate documentation. If there is no employer or DER telephone number on the CCF, the collector should write in the DER name and telephone number on the CCF (if this information is available) so that either the collector or the MRO may get in touch with a company representative when any problems arise related to that specimen.

6. The collector asks the employee to remove any unnecessary outer clothing (e.g., coat, jacket, hat, etc.) and to leave any briefcase, purse, or other personal belongings he or she is carrying with the outer clothing. The employee may retain his or her wallet. If the employee asks for a receipt for any belongings left with the collector, the collector must provide one.

> Note: To safeguard employee's belongings, procedures may be established where the belongings are locked (at the collection site or in the bathroom) or other alternate methods may be developed. For example, if an employee comes to the collection site with his or her medications and desires that the collector secure the medication, the collector may place the medication in a locked cabinet, if available, or alternately, could seal the medication in an envelope, secure the envelope with tamper-evident tape and retain the envelope in a secure place.

> Note: The collector may encourage the employee to also leave, with his or her other belongings, any other items that the employee will not need or may be prohibited from carrying into the restroom.

> Note: The employee must not be asked to remove other articles of clothing, such as shirt, pants, dress, or under garments. Additionally, the employee must not be requested or required to remove all clothing in order to wear a hospital or examination gown. An exception may be made, if the employee is also undergoing a physical examination authorized by a DOT operating administration's rule, in conjunction with the drug test, which normally includes wearing a hospital gown. Work boots or cowboy boots do not have to be removed unless the collector has a reason to suspect that the employee has something in them, which may be used to adulterate or substitute a specimen. When an employee is asked to remove his or her hat or head covering, and refuses to do so based on religious practice, the collector may exempt the employee from removal of the head covering, unless the collector has an observable indicator that the employee is attempting

to hide inside the head covering adulterants or other substances which may be used in an attempt to adulterate or substitute a specimen.

7. The collector directs the employee to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee places the items back into the pockets and the collection procedure continues. If the employee refuses to empty his or her pockets, this is considered a refusal to cooperate in the testing process.

Note: If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, a directly observed collection procedure becomes a requirement. If the item appears to be inadvertently brought to the collection site, secure the item and continue with the normal collection procedure. For example, a bottle of eye drops may have been brought inadvertently and would have to be secured by the collector and the collection would proceed. However, a bottle of liquid or urine would suggest intent to tamper with the specimen and a directly observed collection would be required. Whatever the employee brings into the collection site, the collector should return it to the employee at the end of the collection. Items, such as suspected urine, plastic bags with fluid in them, artificial or mechanical objects for providing substituted urine, etc., should be fully described in an attached memorandum for record, copies of which should be sent to the MRO and the employer.

8. The collector instructs the employee to wash and dry his or her hands, under the collector's observation, and informs the employee not to wash his or her hands again until after the employee provides the specimen to the collector. The employee must not be allowed any further access to water or other materials that could be used to put into the specimen.

Note: The employee may use soap and, if practicable, it should be a liquid or cream. A solid bar of soap gives the employee the chance to conceal soap shavings under his or her fingernails and subsequently use them to attempt to adulterate the specimen.

9. The collector either gives the employee or allows the employee to select the collection kit or collection container (if it is separate from the kit) from the available supply. Either the collector or the employee, with both present, then unwraps or breaks the seal of the kit or collection container.

Note: Even if the collection kit is sealed, the collection container must still be sealed or individually wrapped in a plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system. Do not unwrap or break the seal on any specimen bottle at this time. Unwrap only the collection container.

Note: Ensure the employee takes only the collection container into the room used for urination. The sealed specimen bottles remain with the collector.

10. The collector directs the employee to go into the room used for urination, provide a specimen of at least 45 mL, not to flush the toilet, and return with the specimen as soon as possible after

completing the void. (In many restrooms, a toilet tank into which bluing agent may be placed is not accessible to the collector. When the employee flushes the toilet, he or she can use the clear (un-blued) water to potentially dilute the specimen. Inadvertently flushing the toilet does not automatically require any corrective action by the collector or a recollection. However, to guard against this action, the collector may want to place a card with instructions not to flush by the toilet handle or tape or otherwise secure the handle with tamper-evident tape.) The collector may set a reasonable time limit for the employee to be inside the bathroom and this time frame should be explained to the employee.

> Note: The collector should also tell the employee that the temperature of the specimen is a critical factor and that the employee should bring the specimen to the collector as soon as possible after urination. The collector should inform the employee that if it is longer than 4 minutes from the time the employee urinates into the container and the collector takes the specimen temperature, the potential exists that the specimen may be out of range and an observed collection may be required.
>
> Note: The collector should pay close attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to substitute or adulterate a specimen. If the collector detects such conduct, and the employee has already provided a specimen, the collection process for this specimen is completed, and then the collector immediately begins a new collection under direct observation using a second CCF and a new kit. The collector then provides an appropriate comment on the "Remarks" line in Step 2 on the first CCF and second CCF indicating that this is the first of two or second of two (i.e., 1 of 2, 2 of 2) collections, the specimen ID numbers of the first and second CCF, the reason for the second collection, and that the second collection was under direct observation (check appropriate box in Step 2 of the CCF). This will ensure that the laboratory and the MRO know that two separate specimens are being submitted for testing; the first one possibly being adulterated or substituted. Additionally, the collector must inform the collection site supervisor and the DER that a collection took place under direct observation and the reason for having done so.

11. After the employee gives the specimen to the collector, the collector must check the temperature of the specimen, check the specimen volume, and inspect the specimen for adulteration or substitution. The collector should check the temperature of the specimen as soon as the employee hands over the specimen, but no later than four minutes after the employee comes out of the restroom. The acceptable temperature range is 32°-38°C/ 90°-100°F. Temperature is determined by reading the temperature strip originally affixed to or placed on the outside of the collection container. If the temperature is within the acceptable range, the "Yes" box is marked in Step 2 on the CCF and the collector proceeds with the collection procedure. (If the temperature is out of range, the collector marks the “No” box in Step 2 and initiates an observed collection.) The collector then checks to make sure that the specimen contains a sufficient amount of urine (a minimum of 45 mL for all DOT collections). If the volume is sufficient, the collector checks the box on the CCF (Step 2) indicating that this was a split specimen collection. (This may be done at the same time that the collector checks the temperature box.) The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering or adulteration. If it is apparent from this

inspection that the employee has adulterated or substituted the specimen (e.g., the specimen is blue, exhibits excessive foaming when shaken, has smell of bleach), a second collection using direct observation procedures must be conducted immediately. If the temperature is outside the acceptable range, the volume is less than 45 mL, or the specimen may have been adulterated, the collector follows procedures in Section 10. Problem Collections.

12. After the employee hands the collection container to the collector, the collector unwraps or opens the specimen bottles. (The employee may be permitted to do this, however, the recommended "best practice" is for the collector to perform this procedure.) Bottles may be shrink-wrapped or secured by other easily discernable tamper-evident methodology and may be wrapped separately or together.

> Note: Both the collector and employee will maintain visual contact of the specimen to the greatest extent possible until the labels/seals are placed over the specimen bottle caps/lids. If practical, the collector may permit the employee to wash his or her hands right after the employee gives the collection container to the collector (and the collector checked the temperature), provided the employee and the collector can still maintain visual control of the specimen collection container.

13. The collector, not the employee, then pours at least 30 mL of urine from the collection container into a specimen bottle and places the lid/cap on the bottle. This will be the primary specimen or "A" bottle. The collector, not the employee, then pours at least 15 mL into a second bottle and places the lid/cap on the bottle. This will be the "B" bottle used for the split specimen. (The collector may first pour the requisite amount of specimen into each bottle and then secure the lids/caps on each bottle.)

> Note: The collector should not fill the primary or split specimen bottle up to the cap because a completely full bottle is more likely to leak in transit. Additionally, when a split specimen bottle is full and subsequently frozen, it may cause the bottle material to crack and then leak during transit as the specimen thaws.

14. The collector, not the employee, must then remove the tamper-evident seals from the CCF and place them on each bottle, ensuring that the seal labeled as "A" is placed on the primary bottle with at least 30 mL of urine and that the seal labeled as "B" is placed on the bottle with 15 mL of urine. The seal must be centered over the lid/cap and down the sides of the bottle to ensure that the lid/cap cannot be removed without destroying the seal. The collector, not the employee, writes the date on the seals. The employee is then requested to initial the seals. The employee must be present to observe the sealing of the specimen bottles. If the employee fails or refuses to initial the seals, the collector must note this in the "Remarks" line of the CCF and complete the collection process; this is not considered a refusal to test.

> Note: The collector must not ask the employee to initial the labels/seals while they are still attached to the CCF; they must be initialed after they are placed on the bottles. The collector should also inform the employee to use care during the initialing process to avoid damaging the labels/seals.

Note: Occasionally, the tamper-evident label/seal provided with the CCF will not properly adhere to the specimen bottle because of environmental conditions (e.g., moisture, temperature, specimen bottle material) or may be damaged or broken during the collection process. When this occurs, the collector should use the following corrective procedures:

(a) If the seal is broken while being removed from the chain of custody form or during the application of the first seal on the primary bottle, the collector should transfer the information to a new CCF and use the seals from the second form.

(b) If one seal is already in place on a bottle and the second seal is broken while being removed from the CCF or is broken during application on the second bottle or while the employee is initialing either seal, the collector should initiate a new CCF and provide an appropriate comment on the "Remarks" line in Step 5. The seals from the second CCF should be placed perpendicular to the original seals to avoid obscuring information on the original seals and must be initialed by the employee (both sets of employee initials should match). The collector should draw a line through the Specimen ID number and bar code (if present) on the original seals to ensure that the laboratory does not use that number for reporting the results. The collector should not pour the specimen into new bottles.

(c) In both cases, the collector should ensure that all copies of the original (first) chain of custody form are destroyed or disposed of properly (e.g., shredded, torn into pieces).

(d) If the collector inadvertently reverses the seals (i.e., places the "A" bottle seal on the split bottle and vise-versa) and the collector subsequently notices this, the collector should note this in the "Remarks" line and continue the collection process. Laboratories have procedures that permit them to "re-designate" the bottles.

Note: There is no corrective procedure available if the seal is broken after the employee leaves the collection site.

Note: Since the specimen bottle is now sealed with tamper-evident tape and does not have to be under the employee's direct observation, the employee is allowed to wash his or her hands if he or she desires to do so.

15. The collector directs the employee to read, sign, and date the certification statement, and provide date of birth, printed name, and day and evening contact telephone numbers in Step 5 of Copy 2 of the CCF.

Note: If the employee refuses to sign the form or provide date of birth, printed name, or telephone numbers, the collector must make a notation on the "Remarks" line to that effect and complete the collection. If the employee refuses to fill out any information, the

collector must, as a minimum, print the employee's name in the appropriate place. This does not constitute a refusal to test.

16. The collector completes the collector's portion of the chain of custody on the CCF (Copy 1, Step 4) by printing his or her name (the name may be pre-printed), recording the date and time of the collection, signing where indicated, and entering the specific name of the delivery or courier service transferring the specimens to the laboratory.

17. The collector then ensures that all copies of the CCF are legible and complete. The collector removes Copy 5 from the CCF and gives it to the employee.

Note: At this time, the collector can suggest that the employee list any prescription and over-the-counter medications he or she may be taking on the employee's copy (Copy 5) of the CCF, but not on any other copy. This information may help the employee remember what medications he or she may have taken if a positive result is reported by the laboratory to the MRO.

18. The collector places the specimen bottles and Copy 1 of the CCF inside the appropriate pouches of the leak-resistant plastic bag, and seals both pouches. If the employee has not had the opportunity to wash his or her hands, they may do so now. The collector then informs the employee that he or she may leave the collection site.

19. Any urine specimen left over in the collection container after both specimen bottles have been appropriately filled and sealed should be discarded at this time. Excess urine may be used to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT operating administration's regulation. No further testing (e.g., adulteration testing, DNA, additional drugs) may be conducted on this excess urine and the employee has no right to demand that the excess urine be turned over to the employee.

20. The collector places the sealed plastic bag in an appropriate shipping container (e.g., box, express courier mailer) designed to minimize the possibility of damage during shipment. More than one sealed plastic bag can be placed into a single shipping container if there are multiple collections. The collector seals the shipping container as appropriate. If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, the collector prepares the shipment as directed by the courier service. In this case, the plastic bag may not need to be placed into a shipping container, but still needs to be transported by the courier in a manner that protects the bottles from damage.

Note: If the laboratory courier does not hand-deliver the specimens to the laboratory, but subsequently places the specimens into a commercial delivery system, the specimens must be placed into a shipping container to minimize damage in transit.

21. The collector then sends Copy 2 of the CCF to the MRO and Copy 4 to the DER (or service agent if authorized by the employer). The collector must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day and keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT operating administration's regulations.

Note: The MRO copy (Copy 2) may be faxed to the MRO's secure fax machine, it may be scanned and the image sent to the MRO's secure computer, or it may be mailed or sent by courier to the MRO. (It is recommended that the MRO copy be faxed, since it is critical for the MRO to have this document to expeditiously conduct the verification process.) In the case where the MRO copy (Copy 2) is faxed or the scanned image is sent securely to the MRO, the collector or the collection site should maintain the MRO copies together with the collector's copies for 30 days. Retention is in case the MRO's copy is lost in the mail or the faxed or scanned copy is not legible and another copy is required by the MRO. The transmission process must be coordinated between the collection site and the MRO to ensure that transmission procedures meet the MRO's requirements (e.g., MROs must provide secure fax numbers to collection sites, some MROs may want hard copies mailed; others may want only faxed copies).

22. The collector or collection site must ensure that each specimen collected is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

23. If the specimen will not be shipped immediately, the collector is responsible for ensuring its integrity and security. Specimens in plastic bags, which have not been placed into shipping containers or which are awaiting a laboratory courier, must be kept in a secure location. The specimens need not be under lock and key, however, procedures must exist that would ensure specimens cannot be subject to tampering.

Note: After specimens are placed into shipping containers that are subsequently sealed, the shipping containers may be placed with other containers or packages that the collection site has waiting to be picked up by a courier. It is expected that collection sites will use reasonable security to ensure that all of their packages are relatively secure and not subject to damage, theft, or other actions that would potentially raise questions related to the integrity of the specimens.

Note: Couriers, postal employees, and other personnel involved in the transportation of the sealed shipping container are not required to make, and should not attempt to make, additional chain of custody entries on the custody and control form.

The collection process is now complete.

SECTION 7. SHY BLADDER PROCEDURES

The term "shy bladder" refers to a situation when the employee does not provide a sufficient amount of urine (45 mL) for a DOT-required drug test. If an employee tells the collector, upon arrival at the collection site, that he or she cannot provide a specimen, the collector must still begin the collection procedure regardless of the reason given. The collector should tell the employee that most individuals can provide 45 mL of urine, even when they think they cannot urinate, and direct the employee to make the attempt to provide the specimen.

At the point in the collection procedure where the collector and employee unwrap/open a collection container, the collector does the following:

1. The collector requests the employee to go into the rest room and try to provide a specimen.

> Note: The employee demonstrates his or her inability to provide a valid specimen when the employee comes out of the rest room with an insufficient quantity of specimen or an empty collection container.

2. If the employee provided an initial insufficient specimen, the collector discards the insufficient specimen. The collector then annotates in the "Remarks" line the time when the employee provided the insufficient specimen. This is the time when the "shy bladder" collection process starts.

> Note: If there was actually no specimen provided on an attempt, the same collection container may be used for the next attempt (the employee may keep possession of the container during the waiting period). The collector uses the same CCF and continues to document subsequent collections on the same form.

> Note: If the insufficient specimen is also out of temperature range (assuming there was sufficient specimen to activate the temperature strip) or shows evidence of adulteration or tampering, the collector completes the collection process, sends the insufficient specimen (temperature out of range or adulterated) to the laboratory and immediately initiates another collection under direct observation.

3. The collector explains to the employee the process for a shy bladder collection and urges the employee to drink up to 40 ounces of fluids, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink.

> Note: Collectors should be sensitive to how frequently they should ask the employee to provide a specimen. For example, asking the employee to provide a specimen every half hour may not produce sufficient specimen, although in total, the amount would have been at least 45 mL. In this case, the collector needs to determine if a longer time is needed for the employee to consume fluids and produce a sufficient volume of specimen. If the employee refuses to drink fluids, this is not considered a refusal to test, although the collector should explain to the employee that not drinking sufficient fluids may result in the employee's inability to provide a sufficient specimen and would require a medical evaluation. Under no circumstances can a collector "combine" urine collected from separate voids to create one specimen of sufficient volume.

4. If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is completed, the collector must

discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER. This is a refusal to test.

5. If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, the collector must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER.

Note: The collector should maintain a record in the "Remarks" line on the CCF of the time of each attempt, whether there was any specimen provided or the quantity of specimen provided, and the amount of fluids that the employee was given to drink. During the waiting time, the employee must be monitored by the collector (the one conducting the collection or another collector at the site) or by another responsible collection site staff member or a company representative. The collector must specifically tell the employee that he or she is not permitted to leave the collection site and if they do so, that it will be considered a refusal to test.

6. The collector then sends Copy 2 of the CCF to the MRO and Copy 4 to the DER. This is done even if the employee did not provide any specimen in order to notify the MRO and the employer of the problem. The collector must send or fax these copies to the MRO and DER within 24 hours or the next business day.

SECTION 8. DIRECTLY OBSERVED COLLECTION

A directly observed collection procedure is the same as a routine collection procedure with the additional requirement that an observer physically watches the employee urinate into the collection container. The observer must be the same gender as the employee; there are no exceptions to this requirement.

An observed collection is required when:

1. The employer or DER directs the collector (or collection site) to conduct a collection under direct observation.

Note: The employer is required to conduct a directly observed collection when the laboratory reports an invalid specimen and the MRO reports that there was not an adequate medical explanation for the result, or because the split specimen test could not be performed (e.g., split lost, inadequate volume). The employer may direct an observed collection if the test is a return-to-duty or follow-up test. An employee may not "volunteer" to have his or her specimen collected under direct observation.

2. The collector observed materials brought to the collection site or the employee's conduct clearly indicated an attempt to tamper with a specimen.

3. The temperature on the original specimen was out of range or the specimen appeared to have been tampered with.

> Note: The collector may serve as the observer when the collector is the same gender as the employee. If not, the collector must call upon another individual (who is the same gender as the employee) to act as the observer. The collector must verbally instruct the observer as to the procedures the observer must follow and specifically inform the observer not to take the specimen from the employee, but have the employee bring it to the collector. It is recommended that the collector have a short written outline of the procedures to be used for an observed collection, review these procedures with the observer, and provide a copy of the written procedures to the observer, if the observer requests it.

An observed collection is conducted in the following manner:

1. The collector must explain to the employee why a directly observed collection is being conducted. If the directly observed collection is requested by the employer, the collector may state the reason (if known) or may only state that the employer requested a directly observed collection.

2. The collector must complete a new CCF for the directly observed collection and mark the "reason for test" block (Step 1) the same as for the first collection (unless it is a return-to-duty or follow-up test).

3. The collector then checks the "Observed, (Enter Remark)" box and enters the reason in the "Remarks" line (Step 2) and the name of the observer if it is someone other than the collector.

4. In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the first specimen, the collector enters on the "Remarks" line of the CCF (Step 2) for each specimen a notation to this effect (e.g., collection 1 of 2, or 2 of 2) and the CCF specimen ID number of the other specimen.

5. The collector, if the same gender as the employee, or the same gender observer enters the restroom or facility where urination occurs with the employee. If it is a multi-stall restroom, the collector/observer must enter the stall with the employee. The collector/observer must watch the employee urinate into the collection container. Specifically, the collector/observer must personally and directly watch the urine go from the employee's body into the collection container (use of mirrors or video cameras is not permitted).

6. After the employee has completed urinating into the collection container, the employee and observer leave the enclosed toilet stall/restroom and the employee hands the collection container directly to the collector. The observer must maintain visual contact of the collection container until the employee hands the container to the collector. If the

observer is the collector, the collector may receive the collection container from the employee while they are both in the enclosed toilet stall/restroom.

7. If the employee declines to allow a directly observed collection required or permitted by Part 40 to occur, the collector discards any specimen the employee provided previously and notifies the DER as soon as possible. This is considered a refusal to test.

8. If the collector learns that a directly observed collection should have taken place, but was not, the collector must inform the employer that the employee must be directed to return for an immediate recollection under direct observation.

SECTION 9. MONITORED COLLECTIONS

A monitored collection is one that is conducted under less than completely private conditions, utilizing a multi-stall restroom. If there is no practicable work place outside of the restroom, the collector may set up an area within the multi-stall restroom to be used as a work area and for finalizing the required paper work. (A collection which is not monitored may also be conducted in a multi-stall restroom, provided that the collector secures all of the stalls (bluing agent, etc.), secures all water sources and other potential sources of adulterants (soap dispensers) in the restroom, and posts signs or otherwise secures the restroom from entry by unauthorized personnel.)

A monitored collection is conducted in the following manner:

1. The collector must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

2. The monitor must be the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.

3. If someone other than the collector is to monitor the collection procedure (i.e., the collector is not a medical professional), the collector must verbally instruct that person to use the following procedures (if the collector is the monitor, the collector must also follow these procedures):

(a) A monitor stands outside the stall and does not watch the employee urinate. If the monitor hears sounds or makes other observations indicating an attempt to tamper with a specimen by the employee, there must be an additional collection conducted under direct observation.

(b) A monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

4. When someone besides the collector has acted as the monitor, the collector must note that person's name in the "Remarks" line of the CCF (Step 2).

5. If the employee declines to permit a collection authorized under Part 40 to be monitored, it is a refusal to test.

SECTION 10. PROBLEM COLLECTIONS

CATHETERIZATION.
If an employee needs medical attention (e.g., an injured employee in an emergency medical facility who is required to have a post-accident test), treatment takes priority and should not be delayed to collect a specimen. If an employee is catheterized as part of a medical procedure (following an accident), once the employee's medical condition is stabilized and the employee can give his or her consent to the collection (e.g., understand that a DOT collection is required, can sign the CCF), a urine specimen should be obtained from that employee. Procedures similar to those listed below may be used when an external urine bag is involved. A urine specimen must not be collected, by catheterization or other means, from an unconscious employee to conduct a DOT-required drug test. Catheterization of a conscious employee to obtain a urine specimen for a DOT-required test is also not authorized. However, an employee who normally voids through intermittent or self-catheterization is required to provide a specimen in that manner if he or she is required to produce a specimen for a DOT test. If able to, the employee may provide the specimen directly from the catheter into the collection container in the privacy of a restroom. If an employee, who normally voids through self-catheterization, declines to do so, this would constitute a refusal to test.

EXTERNAL URINE BAG.
The following procedures should be used in the collection of a urine specimen from an employee who has a medical condition requiring an indwelling catheter or excretion of urine into an external bag. The urine specimen should be a freshly voided specimen. If an employee with an indwelling catheter may urinate directly into a collection container. In the case of an employee with an external bag, the employee should be asked to empty his or her bag in the privacy of a bathroom, show the empty bag to the collector, and then drink sufficient fluids at the collection site to provide 45 mL of urine, which can be subsequently poured by the employee from the bag into a collection container in the privacy of a bathroom. In this case, the temperature of the specimen would not be a critical factor. The collector should be keenly aware of the potential embarrassment that this type of collection can cause the employee and should conduct the collection with appropriate decorum.

This procedure would not have to be done in a medical environment/health clinic or by a collector of the same gender, although the collector may try to accommodate the employee (e.g., conduct the collection at a medical facility, have the same gender collector) if the employee requests this and if it would not significantly delay the collection process. If the employer is aware of this situation prior to the actual collection (e.g., because the employee had previously expressed a desire to provide the specimen in a medical setting, requested a same gender collector, told the employer about the medical condition and its impact on urine collection for drug testing), the employer (collection site) may establish or modify procedures as needed to

permit the employee to provide a specimen in a way consistent with the employee's privacy while still meeting regulatory requirements. In the case of a collection based on a post-accident or reasonable suspicion requirement, the collector may attempt to honor the employee's request (for the collection to be conducted in a medical setting or for the collector to be the same gender) if the collection can be accomplished within a reasonable time frame.

The above scenario assumes that the employee's medical condition is not one that decreases or completely prohibits renal output, and that the employee can produce normal amounts of urine that is excreted into an external bag. Therefore, an employee with this or similar medical conditions would be subject to the same testing requirements (e.g., pre-employment, random) and to the "shy bladder" protocol (three hours and 40 ounces of fluids) as an employee with no medical condition. If an employee who normally voids in this manner declines to provide a urine specimen under these conditions, it would constitute a refusal to test.

TEMPERATURE. The collector should check the temperature of the specimen as soon as the employee hands over the specimen, but no later than four minutes after the employee comes out of the restroom. The acceptable temperature range is 32°-38°C/ 90°-100°F. Temperature is determined by reading the temperature strip originally affixed to or placed on the outside of the collection container after the employee hands the specimen to the collector.

(a) If the temperature is within the acceptable range, the "Yes" box is marked in Step 2 on the CCF and the collector proceeds with the collection procedure.

(b) If the temperature is outside the acceptable range, the "No" box is marked in Step 2 on the CCF and if the temperature was below or above the acceptable range should be noted in the "Remarks" line. The collector completes the collection process for the "first" specimen and immediately begins a "second" collection under direct observation using a second CCF and a new kit. The collector then provides an appropriate comment on the "Remarks" line in Step 2 on the first CCF and second CCF indicating that this is the first of two or second of two collections, the specimen ID numbers of the first and second CCF, the reason for the second collection, and that the second collection was under direct observation. This will ensure that the laboratory and the MRO know that two separate specimens are being submitted for testing; the first one possibly being adulterated or substituted. Additionally, the collector must inform the collection site supervisor and the DER that a collection took place under direct observation and the reason for doing so.

Note: There is no requirement to take the employee's body temperature if the specimen temperature is out of range. If the collector suspects that the temperature strip was not activated, the collector should pour the urine specimen into another collection container with a temperature strip or into a specimen bottle which has a temperature strip attached, and use this method to determine the specimen temperature. Collectors should not introduce any other object (e.g., litmus paper, testing strips, etc.) into the specimen in the collection container or the bottles.

SPECIMEN VOLUME. The collector checks to make sure that the specimen contains a sufficient amount of urine (a minimum of 45 mL for all DOT collections). If the volume is sufficient, the collector checks the box on the CCF (Step 2) indicating that this was a split specimen collection. (This may be done at the same time that the collector checks the temperature box.)

If the volume is less than 45 mL, the action taken will depend on whether the temperature of the specimen is in or outside the acceptable temperature range.

(a) If the temperature is in the acceptable range, the specimen is discarded and a second specimen is collected. The collector may use the original CCF for the second specimen, but should annotate in the "Remarks" line the time that the first insufficient specimen was provided by the employee and the fact that this is a second collection (the time annotation is important since this may become a "shy bladder" situation). The collector should use a new specimen collection container, if these are available separately or a new kit.

(b) If the temperature is outside the acceptable range, a second specimen must be collected under direct observation and both specimens are sent to the laboratory for testing. The collector must use a separate CCF and kit for each specimen and provide an appropriate comment on each CCF to indicate why two specimens were collected.

ADULTERATION OR SUBSTITUTION. The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering or adulteration. If it is apparent from this inspection that the employee has adulterated or substituted the specimen (e.g., the specimen is blue, exhibits excessive foaming when shaken, has smell of bleach), a second collection using direct observation procedures must be conducted immediately. The first specimen and the second specimen collected using direct observation are both sent to the laboratory for testing. The first specimen is always sent to the laboratory even though it may have had an insufficient volume, but showed signs of tampering.

If the employee does not provide the required amount of urine for the second collection using direct observation, the collector annotates the time the second specimen was not provided and initiates the shy bladder procedures. If after 3 hours the employee still cannot provide a sufficient amount of specimen, the collector ends the collection process and informs the DER. The collector must send or fax Copy 2 of the CCF to the MRO and Copy 4 to the DER within 24 hours or the next business day. The collector must send the original specimen to the laboratory with an annotation that the specimen was suspected of being adulterated or substituted, that a second collection was attempted, but that a shy bladder prevented collection of a second specimen.

Note: In a case where the employee refuses to provide another specimen or refuses to provide a specimen under direct observation, the collector discards any specimen the employee provided previously during the collection and then notifies the DER that the employee refused to comply with a DOT test.

SECTION 11. BLIND QUALITY CONTROL SAMPLES

An employer or Consortia/Third Party Administrator (C/TPA) with an aggregate of 2000 or more DOT-covered employees, must send blind quality control samples to laboratories they use. If the employer or C/TPA have an aggregate of fewer than 2000 DOT-covered employees, they are not required to provide blind quality control samples.

To each laboratory to which an employer or C/TPA sends at least 100 specimens in a year, they must transmit a number of blind quality control samples equivalent to one percent of the specimens sent to that laboratory, up to a maximum of 50 blind quality control samples in each quarter (i.e., January-March, April-June, July-September, October-December). A C/TPA must apply this percentage to the total number of DOT-covered employees' specimens it sends to the laboratory. Blind quality control sample submissions must be evenly spread throughout the year.

> Note: In general, the employer determines who will conduct the regulatory requirement for the employer to submit blind quality control samples. It may be the employer itself, the collection site, MRO, or the C/TPA. However, regardless of who purchases the blind quality control samples, they must be submitted through the normal collection procedures used by the employer and must be indistinguishable by the laboratory from normal specimens sent by the collection site for DOT testing.

The collector always submits the blind quality control sample using the same CCF as that used for an employee specimen. The collector provides the required information to ensure that the CCF has been properly completed as well as providing fictitious initials on the specimen bottle labels/seals. Since there is no employee, the collector must indicate that the sample is a "blind quality control" on the MRO copy where the employee would normally provide a signature (Step 5 on Copy 2 of the CCF).

> Note: For a blind quality control sample, Copies 4 and 5 of the CCF (the employer and employee copy) may be discarded by the collector, unless the employer or the service agent requires the employer copy (in this case, the collector must ensure that the employer copy has the same “blind quality control” annotation as the MRO copy). All blind quality control samples must be submitted as DOT split specimen collections. Blind quality control samples may be obtained from companies listed on the HHS Internet web site (http://workplace.samhsa.gov/).

SECTION 12. CORRECTING COLLECTION PROBLEMS

When an HHS certified laboratory receives specimen bottles and the associated CCF, it checks to see if the specimen ID number on the specimen bottle labels/seals matches the number on the CCF, that the specimen bottle seals are intact, that there is sufficient specimen volume, and that the CCF has been properly completed by the collector. If there is any discrepancy and/or error of omission (i.e., the collector did not sign the chain of custody, the collector did not check the temperature box), the laboratory will contact the collector to determine if the discrepancy and/or missing information can be recovered. That is, the collector can provide a written memorandum attesting to the fact that he or she inadvertently forgot to properly document the CCF.

Note: If a fatal flaw exists in the collection process or a memorandum for record or other written statement cannot be provided by the collector to related to a correctable flaw, the laboratory will report "Rejected for Testing" to the MRO and provide an appropriate comment as to why the specimen was not tested. If the reason for rejecting the test was a collector error, when a test is cancelled by the MRO, the collector who collected the specimen will need to go through an error correction training process within 30 days addressing the specific problem that caused the specimen to be cancelled.

Note: Once contacted by the laboratory or the MRO, the collector should immediately provide a statement or memorandum to recover the discrepancy and/or error of omission. Laboratories are required by HHS to retain these specimens for a minimum of 5 business days before they may be discarded; therefore, it is critical that the collector respond immediately to the laboratory's request for corrective action.

The collector has the responsibility of trying to successfully complete a collection procedure for each employee.

1. If, during or shortly after the collection process, the collector becomes aware of any event that prevents the completion of a valid test or collection (e.g., a procedural or paperwork error), the collector must try to correct the problem promptly, if doing so is practicable. The collector may initiate another collection as part of this effort. However, the collector must not recall an employee for another collection once the employee has left the collection site. There is one exception: when the collector learns that a directly observed collection should have been conducted, but was not, the collector must notify the employer to direct the employee to return for an immediate recollection under direct observation.

2. If another collection is necessary, the collector must begin the new collection procedure as soon as possible, using a new CCF and a new collection kit.

Note: If the collector becomes aware of a problem that can be corrected, but which has not already been corrected, the collector must take all practicable actions to correct the problem so that the test is not cancelled.

3. If the problem resulted from the omission of required information, the collector must, as the person responsible for providing that information, supply in writing the missing information and a statement that it is true and accurate. For example, suppose the collector forgot to make a notation on the "Remarks" line of the CCF that the employee did not sign the certification. The collector would, when the problem is called to his or her attention, supply a signed statement that the employee failed or refused to sign the certification and that the collector's statement is true and accurate. The collector must supply this information on the same business day on which he or she is notified of the problem, transmitting it by fax or courier.

Note: If the problem is the use of a non-Federal form, the collector must, as the person responsible for the use of the incorrect form, provide a signed statement that the incorrect form contains all the information needed for a valid DOT drug test, that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond the collector's control. The statement must also list the steps the collector has taken to prevent future use of non-Federal forms for DOT tests. For this flaw to have been corrected, the test of the specimen must have occurred at a HHS-certified laboratory where it was tested using the testing protocol in this part. The collector must supply this information to the laboratory on the same business day on which he or she is notified of the problem, transmitting it by fax or courier.

4. If the problem is the use of a non-Federal CCF or an expired Federal form, the collector must provide a signed statement (e.g., a memorandum for record). The documentation must state that the incorrect form contains all the information needed for a valid DOT drug test, and that the incorrect CCF was used inadvertently or as the only means of conducting a test, in circumstances beyond the collector's control. The memorandum must also list the steps the collector took to prevent future use of non-Federal or expired Federal CCFs for DOT tests. This information must be supplied to the laboratory on the same business day that the collector is notified of the problem, and may be transmitted by fax or courier.

5. The collector must maintain a copy of the written and dated documentation of correction with the appropriate CCF. The collector must also mark the CCF in such a way (e.g., stamp noting correction, written notation) that it would be obvious on the face of the CCF that the corrected (missing) information was supplied.

SECTION 13. DOT-REGULATED AND NON-REGULATED EMPLOYERS

Employers regulated by the Department of Transportation (as well as Federal agencies) are required to use the OMB approved Federal Drug Testing Custody and Control Form for their workplace drug testing programs. All other employers or private sector companies and non-DOT testing conducted by DOT-regulated employers are prohibited from using the Federal CCF. (The Federal Railroad Administration has specific CCFs, which must be used for post-accident testing in the railroad industry.)

In the rare instance where the collector, either by mistake or as the only means to conduct a test under difficult circumstances (e.g., post-accident test with insufficient time to obtain the CCF), uses a non-Federal form for a regulated collection, the use of a non-Federal form does not, in and of itself, present a reason for the laboratory to reject the specimen for testing or for the MRO to cancel the test. However, if the laboratory or the MRO discovers the use of the incorrect form, a signed statement must be obtained from the collector stating the reason why the Federal CCF was not used for the regulated collection.

APPENDIX A - DOT STANDARDS FOR URINE COLLECTION KITS

1. Collection Container

a. Single-use container, made of plastic, large enough to easily catch and hold at least 55 mL of urine voided from the body.

b. Must have graduated volume markings clearly noting levels of 45 mL and above.

c. Must have a temperature strip providing graduated temperature readings 32-38 º C / 90-100 º F, that is affixed or can be affixed at a proper level on the outside of the collection container. Other methodologies (e.g., temperature device built into the wall of the container) are acceptable provided the temperature measurement is accurate and such that there is no potential for contamination of the specimen.

d. Must be individually wrapped in a sealed plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system.

e. May be made available separately at collection sites to address shy bladder situations when several voids may be required to complete the testing process.

2. Plastic Specimen Bottles

a. Each bottle must be large enough to hold at least 35 mL; or alternatively, they may be two distinct sizes of specimen bottles provided that the bottle designed to hold the primary specimen holds at least 35 mL of urine and the bottle designed to hold the split specimen holds at least 20 mL.

b. Must have screw-on or snap-on caps that prevent seepage of the urine from the bottles during shipment.

c. Must have markings clearly indicating the appropriate levels (30 mL for the primary specimen and 15 mL for the split) of urine that must be poured into the bottles.

d. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit with no damage to the seal when the employee initials it nor with the chance that the seal overlap would conceal printed information.

e. Must be wrapped (with caps) together in a sealed plastic bag or shrink wrapping separate from the collection container; or must be wrapped (with cap) individually in sealed plastic bags or shrink wrapping; or must have peelable, sealed lid or other easily visible tamper-evident system.

f. Plastic material must be leach resistant.

3. Leak-resistant Plastic Bag

a. Must have two sealable compartments or pouches which are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.

b. The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident.

4. Absorbent material

Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. Shipping Container

a. Must be designed to adequately protect the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory (e.g., standard courier box, small cardboard box, plastic container).

b. May be made available separately at collection sites rather than being part of an actual kit sent to collection sites.

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimen bottles in the plastic leak-proof bags from the collection site to the laboratory.

APPENDIX B - TRAINING REQUIREMENTS FOR COLLECTORS

To be permitted to act as a collector in the DOT drug testing program, you must meet the following requirements:

(a) Basic information. You must be knowledgeable about 49 CFR Part 40, the current "DOT Urine Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers for whom you perform collections, and you must keep current on any changes to these materials. The DOT Urine Specimen Collection Procedures Guidelines document is available from ODAPC (Department of Transportation, 400 7th Street, S.W., Room 10403, Washington DC, 20590, 202-366-3784, or on the ODAPC web site (http://www.dot.gov/ost/dapc).

(b) Qualification training. You must receive qualification training which provides instruction on the following subjects:

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

(2) "Problem" collections (e.g., situations like "shy bladder" and attempts to tamper with a specimen);

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

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

(c) Initial Proficiency Demonstration. Following your completion of qualification training under paragraph (b) above, you must demonstrate proficiency in collections by completing five consecutive error-free mock collections.

(1) The five mock collections must include two uneventful collection scenarios, one insufficient quantity of urine scenario, one temperature out of range scenario, and one scenario in which the employee refuses to sign the CCF and initial the specimen bottle tamper-evident seal.

(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are "error-free." This person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by --

(i) Regularly conducting DOT drug test collections for a period of at least a year;

(ii) Conducting collector training under this part for a year; or

(iii) Successfully completing a "train the trainer" course.

(d) Schedule for qualification training and initial proficiency demonstration. The following is the schedule for qualification training and the initial proficiency demonstration you must meet:

(1) If you became a collector before August 1, 2001, and you have already met the requirements of paragraphs (b) and (c) of this section, you do not have to meet them again.

(2) If you became a collector before August 1, 2001, and have yet to meet the requirements of paragraphs (b) and (c) of this section, you must do so no later than January 31, 2003.

(3) If you become a collector on or after August 1, 2001, you must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

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

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

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

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

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

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

APPENDIX C – QUESTIONS AND ANSWERS

Periodically, DOT will publish questions and answers specific to the collector and the collection process. These will be posted on the DOT Internet web site (www.dot.gov/ost/dapc/). All collectors are encouraged to check the site to ensure that they have the most current information to help them conduct DOT-required specimen collections appropriately. Collectors who do not have access to the Internet may obtain copies of the questions and answers from a fax-on-demand system by calling 1-(800)-225-3784. Collectors who do not have access to the Internet may obtain copies of the Questions and Answers from a fax-on-demand system by calling 1-(800)-225-3784.

APPENDIX D – OPERATING ADMINISTRATIONS' RULES (SUMMARY)

49 CFR Part 40 (40.33(a)) states that collectors must be knowledgeable about the DOT agency regulations applicable to the employers for whom the collectors conduct urine specimen collections. The following is a list of regulations which govern an employer's implementation of the DOT drug and alcohol testing rules:

The FMCSA regulation is 49 CFR Part 382.

The FRA regulation is 49 CFR Part 219.

The FAA regulation is 14 CFR Part 121.

The FTA regulation is 49 CFR Part 655.

The PHMSA regulation is 49 CFR Part 199.

The USCG regulation is 46 CFR Parts 4, 5, and 16.

Drug and alcohol testing (including SAP) procedures are 49 CFR Part 40.

The following pages contain a short summary of some of the operating administrations' requirements. Copies of the complete rule texts are available on the DOT Internet web site (www.dot.gov/ost/dapc/).

Federal Motor Carrier Safety Administration
(FMCSA)

Covered employee: A person who ***operates (i.e., drives)*** a Commercial Motor Vehicle(CMV) with a gross vehicle weight rating (gvwr) of 26,001 or more pounds; or is designed to transport 16 or more occupants (to include the driver); or is of any size and is used in the transport of hazardous materials that require the vehicle to be placarded.

Types of tests for drugs: Pre-employment, random, reasonable suspicion, post-accident, return-to-duty, and follow-up.

Types of tests for alcohol: Pre-employment (optional), random, reasonable suspicion, post-accident, return-to-duty, and follow-up.

Definition of accident requiring testing: Any accident involving a fatality requires testing. Testing is also required in accidents in which one or more motor vehicles are towed from the scene or in which someone is treated medically away from the scene; ***and*** a citation is issued to the CMV driver.

Reasonable-suspicion determination: One trained supervisor or company official can make the decision based upon specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the employee.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of duty.

Actions for BACs 0.02 – 0.039: The employee cannot be returned to duty until the next day or the start of the employee's next regularly scheduled duty period, but not less than 24 hours following the test.

Employee training: Employer must provide educational materials explaining drug and alcohol regulatory requirements and employer's policies and procedures for meeting regulation requirements. Distribution to each employee of these educational materials and the employer's policy regarding the use of drugs and alcohol is mandatory.

Supervisor training: One-hour of training is required on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use. One-hour of training is also required on the specific, contemporaneous physical, behavioral, and performance indicators of probable alcohol use.

Reportable employee drug and alcohol violations: No requirements to report violations to FMCSA.

Other**: Drivers are prohibited from using alcohol for eight hours following an accident (as described above) or until they have undergone a post-accident alcohol test, whichever occurs first.**

Federal Railroad Administration (FRA)

Covered employee: A person who performs *hours of service* functions at a rate sufficient to be placed into the railroad's random testing program. Categories of personnel who normally perform these functions are ***locomotive engineers, trainmen, conductors, switchmen, locomotive hostlers/helpers, utility employees, signalmen, operators,*** **and** ***train dispatchers.***

Types of tests for drugs: Pre-employment, random, reasonable suspicion, reasonable cause, post-accident, return-to-duty, and follow-up.

Types of tests for alcohol: Pre-employment (optional), random, reasonable suspicion, reasonable cause, post-accident, return-to-duty, and follow-up.

Definition of accident requiring testing: FRA's post-accident testing rule requires urine and blood specimen collection from surviving employees and also tissue from deceased employees (these collection procedures go well beyond the normal Part 40 procedures). For surviving employees, these specimens are collected at an independent medical facility. FRA regulation, 49 CFR Part 219 Subpart C, stipulates the level of events requiring testing and who has to be tested. The collected specimens are analyzed only at FRA's contract laboratory. Post-accident testing provides FRA with accident investigation and usage data.

Reasonable-suspicion determination: One trained supervisor can make the decision for alcohol testing based upon specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the employee. A decision to conduct a drug test requires two supervisors (only the on-site supervisor must be trained).

Reasonable-cause determination: Employers are authorized to use federal authority to test covered employees after specific operating rule violations or accidents/incidents which meet the criteria in 49 CFR Part 219 Subpart D.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of duty or after receiving notice to report for covered service, whichever is the shorter period.

Actions for BACs 0.02 – 0.039: The employee cannot be returned to duty until the start of the employee's next regularly scheduled duty period, but not less than 8 hours following the test. Railroads are prohibited from taking further disciplinary action under their own authority.

Employee training: Employer must provide education materials that explain the requirements of the FRA rules as well as railroad policies and procedures with respect to meeting these requirements.

Supervisor training: A total of three hours of training is required: one-hour on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use; one-hour of similar training on probable indicators of alcohol use; and one-hour of training on how to determine if an accident qualifies for post-accident testing.

FRA (continued)

Reportable employee drug and alcohol violations: No requirements to report violations to FRA. Engineers, who are the only certificate holders in the rail industry, will have their certificates reviewed for suspension or revocation by the employer when a FRA violation occurs. Note that a FRA alcohol violation occurs at 0.04 percent or greater. When a locomotive engineer is in a voluntary referral program, the counseling professional must report the engineer's refusal to cooperate in the recommended course of counseling or treatment.

Other:
Anyone with direct or immediate supervisory authority over an employee may not collect that person's urine, saliva, or breath.

Refusal to test results in a mandatory minimum nine-month removal from covered service. During this nine-month period, there is no prohibition against the employee working a non-covered service position if agreeable to the employer.

Locomotive engineers (or other employees certified as a locomotive engineer at the time of the alcohol or drug violation) required both alcohol and drug return-to-duty tests; and both alcohol and drug follow-up tests.

Locomotive engineers who have a DUI are required by Part 240 to be evaluated to determine whether they have an active substance abuse disorder. A DUI is not considered to be a violation of FRA regulations if it occurred during the employee's off-duty time; therefore, any testing would be conducted under employer authority.

Employers must provide a ***voluntary referral program*** which allows an employee to self-refer for treatment, and a ***co-worker report program*** which allows one employee to refer another for treatment before the employer identifies a problem. Both of these ***employee assistance programs*** guarantee that employees will retain their jobs if they cooperate and complete the required rehabilitation program. For an engineer who is in a voluntary referral program, the counseling professional must report the engineer's refusal to cooperate in the recommended course of counseling or treatment to the employer.

Federal Aviation Administration (FAA)

Covered employee: A person who performs ***flight crewmember duties***, ***flight attendant duties***, ***flight instruction duties***, ***aircraft dispatch duties***, ***aircraft maintenance*** or ***preventive maintenance duties***; ***ground security coordinator duties***; ***aviation screening duties***; and ***air traffic control duties***. Note: Anyone who performs the above duties directly or by contract for part 121 or 135 certificate holders, ***sightseeing operations*** as defined in 135.1(c), and ***air traffic control*** facilities not operated by the Government are considered covered employees.

Types of tests for drugs: Pre-employment, random, reasonable cause, post-accident, return to duty, and follow-up.

Types of tests for alcohol: Pre-employment (optional), random, reasonable suspicion, post-accident, return to duty, and follow-up.

Definition of accident requiring testing: Accident means an occurrence associated with the operation of an aircraft which takes place between the time any person boards the aircraft with the intention of flight and all such persons have disembarked, and in which any person suffers death or serious injury, or in which the aircraft receives substantial damage. Testing must occur if employee's performance either contributed to the accident or cannot be completely discounted as a contributing factor of the accident. The decision not to test an employee must be based on a determination, using the best information available at the time of the determination, that the employee's performance could not have contributed to the accident.

Reasonable cause determination (drugs): Two of the employee's supervisors, one of whom is trained, shall substantiate and concur in the decision to test the employee. If the employer is not an air carrier operating under 14 CFR part 121 and has 50 or fewer employees, a single trained supervisor can make the determination. A trained supervisor makes the determination based upon specific contemporaneous physical, behavioral or performance indicators of probable drug use.

Reasonable suspicion determination (alcohol): One trained supervisor makes the determination based upon specific, contemporaneous, articulable observations concerning the employee's appearance, behavior, speech, or body orders.

Pre-duty alcohol use prohibitions: Eight (8) hours prior to performance of flight crewmember duties, flight attendant duties, and air traffic controller duties. Four (4) hours prior to performance of other duties.

Actions for BACs 0.02 - 0.039: If the employer chooses to return the employee to covered services within 8 hours, the BAC retest must be below 0.02.

Employee training (drugs): An employer must train all employees who perform safety-sensitive duties on the effects and consequences of prohibited drug use on personal health, safety, and work environment, and on the manifestations and behavioral cues that

FAA (continued)

may indicate drug use and abuse. Employers must also implement an education program for safety-sensitive employees by displaying and distributing informational materials, a community service hot-line telephone number for employee assistance and the employer's policy regarding drug use in the work place which must include information regarding the consequences under the rule of using drugs while performing safety-sensitive functions, receiving a verified positive drug test result, or refusing to submit to a drug test required under the rule.

Employee training (alcohol): Employers must provide covered employees with educational materials that explain the alcohol misuse requirements and the employer's policies and procedures with respect to meeting those requirements. The information must be distributed to each covered employees and must include such information as the effects of alcohol misuse on an individual's health work, personal life, signs and symptoms of an alcohol problem; and the consequences for covered employees found to have violated the regulatory prohibitions.

Supervisor training (drugs): One-hour of training is required on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use. In addition, supervisors must receive employee training as defined above. Reasonable recurrent training is also required.

Supervisor training (alcohol): One-hour of training is required on the physical, behavioral, speech, and performance indicators of probable alcohol misuse.

Reportable employee drug and alcohol violations:

Each employer must notify the FAA about any covered employee who holds a certificate issued under 14 CFR Parts 61 (pilots and flight and ground instructors), 63 (flight engineers and navigators), or 65 (air traffic control tower operators, aircraft dispatchers, airframe or power plant mechanics, and repairmen) who has refused to take a drug or alcohol test. The MRO may report a positive or refusal (i.e. adulterated, substituted results or no medical explanation for providing an insufficient specimen) on behalf of the employer.

Each employer must notify the FAA about any safety-sensitive employee who is required to hold an airman medical certificate issued under 14 CFR Part 67 who has a positive drug test result, an alcohol test result of 0.04 or greater, or who has refused to submit to testing. The MRO may report a positive or refusal (i.e. adulterated, substituted results or no medical explanation for providing an insufficient specimen) on behalf of the employer.

Each employer must not permit an employee who is required to hold a medical certificate under part 67 to perform a safety-sensitive function to resume that duty until the employee has received a new medical certificate issued by the FAA Federal Air Surgeon ***and*** the employer has ensured that the employee meets the return to duty requirements of Part 40. (Medical certificates are not operating certificates but employees cannot continue to perform airman duties without a medical certificate.)

FAA (continued)

According to FAA's regulation 14 CFR part 121 Appendix I, Section VII.C.1 & 2, when a MRO verifies a drug test result or a SAP performs the initial evaluation, they must ask the employee whether he or she holds or would be required to hold an airman medical certificate issued under 14 CFR part 67 of this chapter to perform a safety-sensitive function for the employer. [This requirement only applies to MROs and SAPs who provide services for FAA regulated employers.] If the employee answers in the affirmative, the employee must obtain an airman medical certificate issued by the Federal Air Surgeon dated after the drug and/or alcohol violation date.

The SAP must wait until the employee obtains their airman medical certificate before reporting to an employer that the employee demonstrated successful compliance with the SAP's treatment and/or education recommendations.

Federal Transit Administration (FTA)

Covered employee: A person who performs a ***revenue vehicle operation***; ***revenue vehicle and equipment maintenance; revenue vehicle control or dispatch (optional); Commercial Drivers License non-revenue vehicle operation;*** or ***armed security duties.***

Types of tests for drugs: Pre-employment, random, reasonable suspicion, post-accident, return-to-duty, and follow-up.

Types of tests for alcohol: Pre-employment (optional), random, reasonable suspicion, post-accident, return-to-duty, and follow-up.

Definition of accident requiring testing: Any accident involving a fatality requires testing. Testing following a non-fatal accident is discretionary: If the employer can show the employee's performance could not have contributed to the accident, no test is needed. Non-fatal accidents that may require testing must have disabling damage to any vehicle or immediate medical attention away from the scene to meet the testing threshold.

Reasonable-suspicion determination: One trained supervisor or company official can make the decision based upon specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the employee.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of duty.

Actions for BACs 0.02 – 0.039: If the employer chooses to return the employee to covered service within 8 hours, the BAC re-test must be below 0.02.

Employee training: Employer must provide education with display and distribution of informational materials and a community service hot-line telephone number, if available. One-hour of training on the effects and consequence of prohibited drug use on personal health, safety, and the work environment, and on the signs and symptoms that may indicate prohibited drug use. Distribution to each employee of the employer's policy regarding the use of drugs and alcohol with signed receipt is mandatory.

Supervisor training: One-hour of training is required on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use. One-hour of training is also required on the specific, contemporaneous physical, behavioral, and performance indicators of probable alcohol use.

Reportable employee drug and alcohol violations: No requirements to report violations to FTA.

Other**: Anyone with direct or immediate supervisory authority over an employee may not collect that person's urine, saliva, or breath.**

Pipeline and Hazardous Materials Safety Administration (PHMSA)

Covered employee: A person who performs on a pipeline or liquefied natural gas (LNG) facility an ***operation, maintenance, or emergency-response*** function.

Types of tests for drugs: Pre-employment, random, reasonable cause, post-accident, return-to-duty, and follow-up.

Types of tests for alcohol: Post-accident, reasonable suspicion, return-to-duty, and follow-up.

Definition of *accident* requiring testing: An accident is one involving gas pipeline facilities or LNG facilities or involving hazardous liquid or carbon dioxide pipeline facilities.

Reasonable-suspicion determination: One trained supervisor can make the decision based upon signs and symptoms.

Reasonable-cause determination: One trained supervisor can make the decision based upon reasonable and articulable belief that the employee is using prohibited drugs on the basis of specific, contemporaneous physical, behavioral, or performance indicators of probable drug use.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of duty.

Actions for BACs 0.02 – 0.039: If the employer chooses to return the employee to covered service within 8 hours, the BAC retest must be below 0.02.

Employee training (Drugs): Employer must provide EAP education with display and distribution of informational materials; display and distribution of a community service hot-line telephone number; and display and distribution of the employer's policy regarding the use of prohibited drugs.

Employee Training (Alcohol): Employer must develop materials that explain policies and procedures (as well as names of those who can answer questions about the program) and distribute them to each covered employee.

Supervisor training: One-hour of training is required on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use. One-hour of training is also required on the specific, contemporaneous physical, behavioral, and performance indicators of probable alcohol use.

Reportable employee drug and alcohol violations**: No requirements to report violations to PHMSA.**

United States Coast Guard (USCG)

Covered employee: A person who is ***on board a vessel*** acting under the authority of a ***license***, ***certificate of registry***, or ***merchant mariner's document***. Also, a person ***engaged*** or ***employed on board a U.S. owned vessel*** and such vessel is required to engage, employ or be operated by a person holding a license, certificate of registry, or merchant mariner's document.

Types of tests for drugs: Pre-employment, periodic, random, reasonable cause, and post-serious marine incident (SMI), return-to-duty, and follow-up.

Types of tests for alcohol: 49 CFR Part 40 alcohol-testing requirements do not apply to the Maritime Industry. 46 CFR Part 4.06 requires post-SMI chemical testing for alcohol use. 33 CFR Part 95.035 allows for a marine employer or a law enforcement officer to direct an individual to undergo a chemical test for intoxicants when reasonable cause exists or a marine casualty has occurred.

Definition of incident requiring testing: An SMI is defined in 46 CFR 4.03-2. In general, an SMI is: A discharge of 10,000 gallons or more of oil into the navigable waters of the United States, whether or not resulting from a marine casualty; a discharge of a reportable quantity of a hazardous substance into the navigable waters or into the environment of the United States, whether or not resulting from a marine casualty; or a marine casualty or accident required to be reported to the Coast Guard, involving a vessel in commercial service, and resulting in any of the following: One or more deaths; an injury to any person (including passengers) which requires professional medical treatment beyond first aid, and, in the case of a person employed on board a commercial vessel, which renders the person unable to perform routine vessel duties; damage to property in excess of $100,000; actual or constructive total loss of any inspected vessel; or actual or constructive total loss of any uninspected, self-propelled vessel of 100 gross tons or more.

Reasonable-cause determination (drugs): The marine employer must have a reasonable and articulable belief that the individual has used a dangerous drug. This belief should be based on the direct observation of specific, contemporaneous physical, behavioral, or performance indicators of probable use and where practicable based on the observation of two persons in supervisory positions.

Reasonable-cause determination (alcohol): The employee was directly involved in the occurrence of a marine casualty or the individual operated a vessel and the effect of the intoxicant(s) consumed by the individual on the person's manner, disposition, speech, muscular movement, general appearance or behavior is apparent by observation.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of scheduled duty.

USCG (continued)

Employee training: Employer must provide education with display and distribution of informational materials and a community service hot-line telephone number. Distribution to each employee of the employer's policy regarding the use of drugs and alcohol is mandatory. Training must include the effects of drugs and alcohol on personal heath, safety, and work environment; and manifestations and behavioral cues that may indicate drug and alcohol use and abuse.

Supervisor training: One-hour of training is required on the effects of drugs and alcohol on personal heath, safety, and work environment; and manifestations and behavioral cues that may indicate drug and alcohol use and abuse.

Reportable employee drug and alcohol violations: Results of all post-SMI tests and positive drug test results for all mariners who hold a license, certificate of registry or merchant mariner's document must be reported to the nearest Coast Guard Officer in Charge, Marine Inspection.