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 Rule 156 Stage 3 Episode Actions (Adopted 09/17/91)
 Rule 158 Source Abatement Plans (Adopted 09/17/91)
 Rule 159 Traffic Abatement Procedures (Adopted 09/17/91)
 Rule 220 General Conformity (Adopted 05/09/95)
 Rule 230 Notice to Comply (Adopted 11/09/99)
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SUPPLEMENTARY INFORMATION:

Background

On October 31, 2005, the Department of Transportation issued a notice of proposed rulemaking (NPRM) to amend 49 CFR Part 40, the Department's drug and alcohol testing procedures rule (70 FR 62276). The primary purpose of the NPRM was to propose making specimen validity testing (SVT) mandatory.

Mandatory SVT is an important step in combating the safety problem of cheating on drug tests. Based on this NPRM, the Department issued a final rule on June 25, 2008 (73 FR 35961). The final rule included two provisions (49 CFR 40.67(b) and (i)) concerning the use of direct observation (DO) collections, another significant tool the Department uses to combat cheating.

Petitioners, including the Association of American Railroads (AAR), joined by the American Short Line and Regional Railroad Association; the Transportation Trades Department (TTD) of the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO); the International Brotherhood of Teamsters; and the Air Transport Association (ATA), joined by the Regional Airline Association (RAA), asked the Department to delay the effective date of these two provisions, seek further comment on them, and reconsider them. In response to these petitions, the Department issued a notice delaying the effective date of 49 CFR 40.67(b) until November 1, 2008 (73 FR 50222; August 26, 2008). We opened a comment period on that provision, which closed on September 25, 2008. The Department did not delay the effective date of 49 CFR 40.67(i), which went into effect, as scheduled, on August 25, 2008.

The history of DO collections under Part 40 goes back to the beginnings of the Department's drug testing program. The principle that animates this history is that DO, because it is intrusive, is not appropriate to use in the great mass of testing situations (e.g., all pre-employment and random tests), but only in those situations in which there is a heightened incentive to cheat or circumstances demonstrating the likelihood of cheating. In this way, the Department has maintained the proper balance between the legitimate privacy

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST-2003-15245]

RIN 2105-AD55

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Response to comments.

SUMMARY: The Department is issuing this notice to respond to comments on the amendment to 49 CFR 40.67(b) issued as part of a final rule on June 25, 2008. The Department is not changing this amendment, which will go into effect, as scheduled, on November 1, 2008. Beginning on that date, direct observation collections will be required for all return-to-duty and follow-up tests. When additional testing methodologies appropriate for use in return-to-duty and follow-up testing (e.g., oral fluid and sweat specimens) are approved by the Department of Health and Human Services and adopted by the Department, the Department intends to make these methods available to employers and employees as an alternative to direct observation urine testing in these situations.

DATES: The effective date of 49 CFR 40.67(b), as amended by the Department on June 25, 2008, and delayed on August 26, 2008, is November 1, 2008.

FOR FURTHER INFORMATION CONTACT: Jim L. Swart, Director, U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200

expectations of employees and the safety and program integrity interests of the Department. As a result, DO collections constitute only a tiny percentage of the drug collections conducted each year under DOT drug testing rules. DO collections have always required the use of a same-gender observer and for the observer to watch the flow of urine from the individual's body into the collection container.

In the December 1, 1989, preamble to Part 40 (54 FR 49854), we said that the limitations on using observed collections in only four circumstances would be maintained despite the fact that some comments requested that the Department allow greater discretion for observed collections. The Department decided that "existing safeguards in Part 40 are adequate to prevent tampering and that direct observation, because of its increased intrusiveness, should be strictly limited." The Department considered that limiting the circumstances that would result in a DO collection is "one factor in the balance between privacy and safety necessity considered by the courts."

The preamble went on to say that some commenters specifically opposed direct observation "as part of follow-up (i.e., post-positive) testing, while other commenters favored this practice." We said that the Department "believes that direct observation may be a useful tool in follow-up testing." There was concern expressed about drug use relapses, especially for cocaine. We went on to say, "An individual who has returned to work after rehabilitation but has suffered such a relapse may have a greater incentive to attempt to beat a follow-up test, because the employer may not provide a second opportunity for rehabilitation." Regarding directly observed follow-up testing, the preamble concludes, "If the employer or EAP [employee assistance program] counselor believes that this may be the case, the opportunity for direct observation should exist."

Currently, section 40.67(a) requires that employers direct immediate collections under direct observation in three circumstances: (1) When the laboratory reported an invalid specimen (e.g., one that has an interfering substance preventing a normal result but the laboratory cannot identify a specific adulterant) and the Medical Review Officer (MRO) reported that there was not an adequate medical explanation for the result; (2) when the MRO reports to the employer that the original positive, adulterated, or substituted test result had to be cancelled because there was not a split

specimen available for testing; and (3) when the MRO reports a negative-dilute specimen with a creatinine concentration greater than or equal to 2 mg/dL or less than or equal to 5 mg/dL. We added the third provision in 2003 in an interim final rule (68 FR 31624) and revised it in an interim final rule (69 FR 64865). All these situations involve results indicating a heightened risk of cheating or that an attempt to cheat had taken place.

Direct observation is also mandated at collection sites if the collector finds materials brought to the collection site to tamper with a specimen (section 40.61(f)(5)(i)), determines that a specimen is out of temperature range (section 40.65(b)(5)) or detects other evidence indicating an attempt to tamper with a specimen (section 40.65(c)(1)). These are also situations involving evidence indicating an attempt to cheat. In addition, employers are currently allowed, but not required, to order a directly observed test under section 40.67(b) for return-to-duty and follow-up tests.

We acknowledge that DO collections are, and always have been, controversial. The Department is well aware that they intrude on personal privacy to a greater extent than non-observed collection methods, and consequently we have limited the use of DO to situations where we believe using this approach is necessary to protect the integrity of the testing process and strengthen the safety objectives of the program. In the December 19, 2000 preamble to a major update to part 40 (65 FR 79462), about observed collections we said, "Directly observed specimens are controversial because of their greater impact on employee privacy. They can be useful because they reduce the opportunity for tampering. On privacy grounds, some commenters, including unions and some service agents, would prefer not to conduct directly observed collections at all." (65 FR at 79489) These commenters opposed adding any situations in which direct observation was authorized or required.

The 2000 preamble went on to say, "Other commenters said that the benefit of greater protection against specimen tampering warranted direct observation in situations that suggested a heightened risk of tampering." (65 FR at 79489) The Department agreed with these commenters. In circumstances that pose a higher risk or greater risk for tampering, "the interests of the integrity of the testing process, with its safety implications, outweigh the additional privacy impact of the direct observation process." (65 FR at 79489-79490)

More recently, there has been a sharply increased emphasis, at the level of national policy, on the problem of cheating and how to deal with it. The Department has been aware for several years of the increasing proliferation of products designed and sold to help workers who use drugs defeat drug tests. As a result we have worked on specimen validity testing rulemaking.

Also, based upon our concerns and those expressed to us by collection site personnel and medical review officers about use of these products, we issued in July 2007 an interpretation outlining additional examples of an employee's failure to cooperate with the testing process that would cause a refusal to test. In that interpretation we said that one refusal to test would be: "The employee is found to have a device—such as a prosthetic appliance—the purpose of which is to interfere with providing an actual urine specimen." We also gave instructions to collectors about how to handle this situation.

Not only was the Department working on the specimen validity testing rulemaking between 2005 and 2008, but also the United States Congress was conducting its own inquiries on the issues. During a May 17, 2005 hearing before the Investigations Committee on Energy and Commerce, the Department of Health and Human Services (HHS) provided the following testimony regarding prosthetic devices delivering synthetic or drug-free human urine:

The most cumbersome, yet highly effective, way to beat a urine drug test is to use a physical belt-like device hidden under the clothing which contains a reservoir to unobtrusively hold real human urine from another person that is free from drugs, and deliver that bogus specimen into the collection container through a straw-like tube, or through a prosthetic device that looks like real human anatomy, color-matched. This last described device is heavily marketed for workplace drug testing and criminal justice urine collection situations that require directly observed urine specimens to be provided. Synthetic urine can be used in place of real human drug free urine. [Testimony before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce United States House of Representatives Products Used to Thwart Detection in Drug Testing Programs, Statement of Robert L. Stephenson II, M.P.H., Director, Division of Workplace Programs Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services at pages 4-5].

Also at the 2005 hearing, the United States Government Accountability Office (GAO) testified that:

In summary, we found that products to defraud drug tests are easily obtained. They

are brazenly marketed on Web sites by vendors who boast of periodically reformulating their products so that they will not be detected in the drug test process. In addition to an array of products designed to dilute, cleanse, or substitute urine specimens submitted to testers by drug users, approximately 400 different products are available to adulterate urine samples. The sheer number of these products, and the ease with which they are marketed and distributed through the Internet, present formidable obstacles to the integrity of the drug testing process. [Testimony Statement of Robert J. Cramer, Managing Director, Office of Special Investigations, the United States Government Accountability Office (GAO), before the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, GAO-05-653T, May 1, 2005.]

On November 1, 2007, following media coverage regarding compromised collection integrity and security issues, the Congressional Subcommittee on Transportation and Infrastructure held a hearing on the problem of cheating on DOT-required tests. At the hearing, the GAO testified about the threat to the integrity of the testing program posed by the devices being used to substitute urine in DO collections. In its final report issued in May 2008, the GAO noted that the ease of subverting the testing process was a factor contributing to failures to detect drug use. Specifically, GAO noted that transportation employees "are successfully adulterating or substituting their urine specimens with products that are widely available and marketed as * * * [ways to beat a test.]" [GAO Report No. GAO-08-600, Motor Carrier Safety: Improvements to Drug Testing Programs Could Better Identify Illegal Drug Users and Keep them off the Road, May 2008 at pages 2-3.] The GAO further found that "Several hundred products designed to dilute, cleanse, or substitute urine specimens can be easily obtained." [GAO Report No. GAO-08-600 at page 20.]

In light of the by-now well-recognized availability of substances and devices for substituting or adulterating specimens, the Department's premise for the changes it made to section 40.67 was that taking additional steps to combat cheating on drug tests was appropriate. Such steps are needed to avoid placing the traveling public in danger of workers who try to cheat on their drug tests. Given the greater availability of means to cheat on tests, compared to the late 1980s, the Department took the position in the June 25 final rule that it is appropriate to strike the balance between the Department's interests in safety and

program integrity and employees' interest in privacy at a different point than it did two decades ago.

In the Omnibus Transportation Employee Testing Act of 1991, Congress recognized that, while privacy is a very important value in the drug testing process, it is not an absolute value. The Act directs the Department to "promote, to the maximum extent practicable, individual privacy in the collection of specimens" (49 U.S.C. 20140(c)(1), emphasis added). In issuing the June 25 final rule, the Department, took the position that it is no longer "practicable" to operate a drug testing program without adding countermeasures to well-publicized cheating techniques and devices.

With respect specifically to the new section 40.67(b), the Department, in the June 25 final rule, said that DO collections would be required for all follow-up and return-to-duty tests. The new requirement, aimed at counteracting cheating in these tests, was included as section 40.67(b). It read, "As an employer, you must direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test." Under Part 40 as it existed before this amendment, employers had the discretion to require direct observation in follow-up and return-to-duty tests, but were not mandated to do so. It is significant that employers rarely exercised this important option.

Notably, the November 1, 2007 GAO report indicated that even when collectors followed the appropriate procedures for integrity and security of specimens, the GAO inspectors were able to bring adulterants into the collection sites and successfully adulterate their specimens. These adulterants went undetected during laboratory testing. The GAO report said:

Even in cases where the collector followed DOT protocol and asked our investigator to empty his pockets, our investigators simply hid these products in their pockets and elsewhere in their clothing.* * * Investigators determined that there is information on the Internet about concealing drug-masking products. For example, one Web site noted that "although most testing sites will require you to remove items from your pockets, it is still possible to sneak in another specimen."

In the Department's view, this new requirement mandating DO for return-to-duty and follow-up testing was a logical outgrowth of the development of the Department's increasing efforts to deal with the problem of cheating in drug tests. Even though we did not foresee in 1989 the degree to which products designed to beat the drug test

would later become available, the Department was concerned about specimen tampering and about the heightened motivation of those employees returning to safety sensitive positions after positive tests or refusals to tamper with their specimens. That concern has increased in recent years as information about the widespread availability of cheating products has become available.

As a consequence, the Department believed, in adding this provision, that it was important for us to be consistent with the other DO collection provisions, which make DO collections mandatory in circumstances involving heightened motivation for or evidence suggesting attempts to cheat (see sections 40.61(f)(5)(i); 40.65(b)(5) and (c)(1); 40.67(a)). In all these cases, use of DO is mandatory. If safety necessitates a DO in one of these circumstances, then, the Department believed, safety likewise necessitates DO collections as part of follow-up and return-to-duty tests. The Department was mindful that everyone who has to take a return-to-duty or follow-up test had already violated the rule (e.g., by testing positive or refusing to test), showing that he or she has knowingly chosen to act in a way that presents an increased risk to transportation safety. Such employees will be acutely aware that they must test negative on all return-to-duty and follow-up tests in order to regain or retain their ability to perform safety-sensitive functions. These circumstances, the Department believed, present just the sort of heightened incentive for cheating on a test that DO collections are intended to combat.

It was but a modest, incremental step from the current regulation's *authorization* of DO in follow-up and return-to-duty situations to the June 25 final rule's *requirement* for DO in these situations. Consequently, the Department believed that taking this step was timely and appropriate. Nevertheless, the NPRM had not specifically requested comments on this subject, and the Department consequently opened a comment period on this provision and delayed its effective date until November 1, 2008.

In considering all issues regarding drug testing, the Department keeps squarely in mind the vital safety purposes of its program. Recent multi-fatal transportation accidents in which drug use by safety-sensitive personnel was involved underline the importance of deterring use of illegal drugs by transportation workers. When workers who use drugs believe they can get away with their misconduct by cheating, the deterrent effect of the

Department's rules is undermined. This is detrimental to public safety, and the Department cannot tolerate it.

Comments and DOT Responses

The docket includes 86 comments. The breakdown of comments by source is the following:

Substance Abuse Professionals: 20
Unions or other employee organizations:

17

Collection sites or collection site organizations: 16

Individual employees: 10

Other individuals: 9

Employers or employer organizations: 9

Third-party Administrators: 3

Laboratories: 1

Medical Review Officers: 1

Some union and employer commenters are represented twice in this breakdown (e.g., because the docket includes a petition requesting an opportunity for further comment and an additional comment from the same organization once the docket was opened). Many of the individual comments from employees and others were submitted anonymously.

Comments on Direct Observation Procedure (Section 40.67(I))

The August 26, 2008, notice opening a comment period sought comments only on the provision of section 40.67(b) that would make DO mandatory, rather than optional, in follow-up and return-to-duty testing. The notice specifically said that comments were not sought on the provisions of section 40.67(i). This section, which went into effect August 25, 2006, requires observers in directly observed collections to direct employees to raise and lower clothing and turn around, so that the observer can note any prosthetic or other device that the employee may possess in an attempt to cheat on the test.

Nevertheless, a number of parties did comment on 40.67(i). One union and a comment from two employer organizations said that the Department should have postponed the effective date for this provision and opened a comment period, since in their view the notice of proposed rulemaking leading to the June 25 rule did not provide sufficient notice concerning the provision. Twenty commenters, mostly unions and individual employees, but also including a few collection sites, objected to the idea of the revised observation procedure, saying that it was too great an intrusion on employees' privacy. Many of these commenters also said that there was insufficient evidence that people in transportation industries were actually

using prosthetic and other devices, and that therefore the Department's countermeasure was unnecessary. Two commenters expressed the concern that the rule could create confusion among collectors between cheating devices and medically-necessary prostheses, or devices used as a form of sexual expression, with the result that users of legitimate devices could unfairly be determined to have refused to test. Two Substance Abuse Professionals (SAPs) who commented on the provision and a Third Party Administrator (TPA) supported its inclusion, as a useful measure to counter attempts to cheat.

DOT Response

Because matters concerning section 40.67(i) are outside the scope of the August 26 notice, these comments are not relevant to the decision the Department is making in this document: whether the provisions of section 40.67(b) should be retained, removed, or modified.

We would note, however, that the basic procedure of body-to-bottle direct observation of certain tests involving a heightened risk of cheating, or evidence of a possible attempt to cheat, has been part of the Department's testing procedure since the program's beginnings in the 1980s. As attempts to cheat even on direct observation tests have become more sophisticated over the years—the Department's 1988–89 testing procedure rules did not need to take prosthetic and other cheating devices into account, in particular—it is important for the Department's procedures to change to accommodate new circumstances. People who believe they can use cheating devices to get away with using illegal drugs while continuing to perform safety-sensitive functions are a threat to public safety.

Some commenters argued that the Department has not provided data on how often prosthetic and other cheating devices are being used, so the Department need not take measures to prevent their use. The anecdotal evidence provided by several commenters to the docket, along with experience the Department has gained through the compliance activities of the DOT Agencies, provides sufficient justification to us that such devices are not only readily available, but are actually being used. The successful use of prosthetic and other cheating devices is, by nature, a matter of stealth. If someone uses such a device, and gets away with it, the drug test result will be a negative test result. Consequently, the cheater's action will never turn up in drug testing statistics. It is illogical to argue that the Department cannot take

action to prevent cheating because successful cheating is absent from the program's statistics.

The Department disagrees with commenters who said that there was insufficient notice of this anti-prosthetic provision in the NPRM. The Department explicitly sought comment in its October 2005 NPRM (70 FR 62281) on whether collectors should check to make sure that employees providing a specimen under DO are not using a prosthetic or other device to cheat on the test (e.g., by having an employee lower his pants and underwear so that the collector or observer could determine whether the employee was using such a device). This notice fully meets the requirement of the Administrative Procedure Act (APA) for a meaningful participation from the public by fairly apprising interested persons of the issues in the rulemaking. While DOT and agencies commonly do publish proposed rule text, there is no statutory requirement in the APA to do so, and doing so is not a mandatory prerequisite to issuing a final rule. A "description of the subjects and issues involved" (5 U.S.C. 553(b)(3)) is sufficient. That the notice did provide interested persons a meaningful opportunity to comment on this issue is evidenced by the comments that the Department in fact received.

In the preamble to the Department's final rule based on this NPRM (73 FR 35968), the Department responded to comments on this proposal. This response set forth the Department's rationale for adopting the new provision, found in section 40.67(i), requiring employees to raise and lower their clothing to show the collector or observer that the employee does not possess a prosthetic or other device designed to beat the test.

The Department has fully explained in regulation text, guidelines, and supportive materials that the devices subject to the new procedures would be those expressly designed to interfere with the collection process (e.g., designed to carry "clean" urine or urine substitutes into the collection site). Likewise, our guidelines have always had provisions for those employees whose medical conditions require them to provide urine via indwelling catheters or external urine bags.

Comments Favoring Mandatory Direct Observation Testing on Return-to-Duty and Follow-Up Tests

The Department received 29 comments favoring the concept of DO collections in general and/or the mandatory application of DO to follow-up and return-to-duty testing. The

majority of these comments were from SAPs, though a few collection sites, a testing industry association, an MRO, an employer, and a few individuals took this view as well. The common theme among these commenters was that conducting direct observations on return-to-duty and follow-up tests is important to safety.

SAP commenters generally said, based on their personal experience of working with individuals who had failed or refused drug tests, that people with addiction or other substance abuse problems had a great deal of difficulty in changing their behavior. They often exhibit denial of their problems and have a powerful drive to cheat in order to continue using the substances to which they are attached while continuing to work. One of the SAPs commented that for an individual who had failed or refused a drug test, being subject to DO and a return-to-duty or follow-up test is a consequence of substance abuse problems and/or a violation of Federal law, and as such was justified. Some commenters pointed to the fact that many treatment programs use direct observations for their own testing during rehabilitation, so many who have undergone treatment would expect direct observations.

A number of SAPs indicated that when they recommended DO, employers responded by saying they would not have employees observed. Some employers were alleged to have stopped using SAPs who made these recommendations. In essence, SAPs said that employers were undermining the entire purpose of having the DO option. For this reason, one SAP recommended that any violation related to an employee's attempt to beat the test by adulteration, substitution, or other refusal should be met with long-term, if not permanent, removal from safety sensitive duties.

The collection site organization that commented noted that DO collections make up a very small number of all DOT tests and can be an effective deterrent against cheating on return-to-duty and follow-up tests. One SAP commented that making DO mandatory in the return-to-duty and follow-up contexts would counteract what he viewed as hesitancy on the part of many employers under the present discretionary rule. This timidity, in his view, has led to a significant amount of cheating on these tests. Finally, some employer associations, while objecting to making DO mandatory for all follow-up and return-to-duty tests, supported requiring DO when the follow-up and return-to-duty tests resulted from a

refusal to test, as distinct from a positive test.

DOT Response

The Department believes that the expertise of SAPs—the individuals in the drug testing system who most often have first-hand, day-to-day observation of the individuals who violate DOT drug testing rules and the behaviors and motivations of these individuals—carries a great deal of weight in this discussion. They are the “Gatekeepers” of the return-to-duty process. SAPs have the education, qualifications, and experience that vest them with a significant role in evaluation, treatment, return-to-duty recommendations, and follow-up testing plans of the individuals who have violated Part 40 through their refusals and/or positive test results. Their nearly unanimous view that DO collections, particularly in the context of return-to-duty and follow-up testing, is a necessary and appropriate response to the predictable behaviors of many violators strongly supports the Department's view that there is a heightened risk of cheating by individuals who are seeking to reclaim or retain the ability to perform safety-sensitive work after a violation.

We also agree with SAPs who pointed out that individuals in recovery often need support to help them in their efforts to remain abstinent from drugs. They point out that people with substance abuse problems or who suffer from addiction are prone to having problems dealing with their drug use and in changing their drug use behavior, even after rehabilitation. In short, these employees are prone to relapse into drug use. We agree with SAPs who believe that DO collections would help these employees in their struggle to stop drug use.

We also agree with SAPs comments indicating that drug treatment and education programs require DO collections during their program efforts. Therefore, most employees coming back into the workplace after testing positive or refusing a DOT test would be accustomed to having their collections observed.

Employees who fail or refuse a drug test, and who are offered the opportunity by their employer to return to work, are frequently covered by a “last chance agreement,” a “two strikes and out” policy that means that a second violation will result in the individual being fired. In the aviation industry, the statutory “permanent bar” means that employees who fail a second test will never work in a particular occupation again. Where an individual cannot resist the powerful pull of drug

dependence, and realizes that a positive result can cost him or her a job or even a career, cheating using one of the readily available techniques can prove an attractive option.

We agree with the point that tests requiring DO collections make up only a small percentage of all DOT drug tests, and hence do not affect the vast majority of workers who take and pass DOT drug tests. We want to correct the misunderstanding of some commenters, who appeared to believe that all DOT tests would be directly observed under the new rules. To the contrary, people taking pre-employment, random, reasonable suspicion, and post-accident tests are not subject to DO, unless their actions trigger a suspicion that they are trying to cheat. The only workers who are affected by DO testing are those who by their conduct at the collection site or by the results of their tests have demonstrated that they are willing to endanger public safety through violating Federal law prohibiting illegal drug use. As a joint comment from two employer associations noted, the propensity to avoid accountability for drug use is particularly marked among individuals who refuse to take a drug test.

Comments Opposing Mandatory Direct Observation Testing on Return-to-Duty and Follow-Up Tests

Sixteen commenters, including several unions and a number of individuals, opposed DO in general. They said it was too intrusive, violated employees' privacy, and would work a particular hardship on people who had anxiety disorders that made it difficult for them to urinate when someone was watching. A number of union commenters also said that they believed that expanding the scope of mandatory DO testing to all follow-up and return-to-duty tests would exceed the Department's constitutional authority as outlined in the 1989 Supreme Court case (*Skinner v. Railway Labor Executives' Association*, 489 U.S. 602 (1989)) that upheld the constitutionality of Federal Railroad Administration (FRA) drug testing requirements applying to the rail industry. In addition, some of these comments cited the provision of the Omnibus Transportation Employee Testing Act of 1991 directing the Department to “promote, to the maximum extent practicable, individual privacy in the collection of specimens” (see 49 U.S.C. 31306(c)(1) and parallel sections).

Three unions suggested that DO testing was not needed for return-to-duty and follow-up tests because employees who had tested positive had, in effect, shown themselves to be

willing to submit to testing without cheating. The unions reasoned that these employees were not the sort of people who had the motivation or propensity to cheat on tests. Moreover, one of the unions said, employees it represented must go through a detailed SAP evaluation process as well as vetting by DOT before returning to duty, so are likely to be drug-free.

One of the most frequent comments made by commenters opposing the mandatory use of DO for return-to-duty and follow-up tests was that there was insufficient evidence of the need to take this step. Sixteen comments, mostly from unions and some employer groups, took this view. One union said that the low overall violation rate and the small number of recorded cases of adulteration and substitution showed that DO collections were not needed. In addition, the commenter said, individuals had shown a SAP that they were successfully rehabilitated by the time they got to the follow-up test stage of the process. Four other unions said that there was no evidence demonstrating a higher level of adulterated or substituted tests in the return-to-duty and follow-up contexts, and there was no documentation that transportation employees actually used prosthetic and other cheating devices, or that DOT agency personnel had not seen evidence of cheating.

Eleven commenters, among which were unions, employers or employer associations, and collection sites or TPAs, urged the Department to retain the existing rule that makes the use of DO an employer option in the follow-up and return-to-duty contexts. One union said that DO should not be required for follow-up and return-to-duty tests unless there were specific findings or medical determinations backing the requirement for a given employee. Two other unions suggested that SAPs were in a good position to determine when DO was appropriate for an individual subject to return-to-duty and follow-up tests, and their findings could be a basis for such a decision. Another union suggested that the employer's designated employer representative (DER) could appropriately make this decision. On the other hand, two unions and a collection site operator said that, under existing DOT rules and guidance, DERs had too much discretion to direct that a test be conducted under DO.

Twelve commenters, mostly collection sites, expressed the concern that they would be unable to find enough people to act as observers. The rule requires observers to be the same gender as the employee being tested, they noted, and their experience was

that most or all collection site personnel were women while most employees reporting for testing were men.

Seven commenters said that making DO mandatory in follow-up and return-to-duty testing would significantly increase the total number of DO collections. One employer association said that of the approximately 4000 such tests in its industry, employers found it necessary to use DO only rarely. A large employer said it chose to use DO in only a small number of the approximately 1200 return-to-duty and follow-up tests it administered per year. Another employer association predicted that the number of DO collections would double. A union projected that there would be a dramatic increase in the number of employees subject to DO tests and the number of such tests conducted, if all follow-up and return-to-duty tests are directly observed. Some commenters said that there would be increased costs, since in many cases a second person, other than the collector, would have to be paid to observe the tests. Five commenters, including a TPA, two collection sites, an employer, and an individual, said they feared that mandatory DO in follow-up and return-to-duty testing would lead to a decrease in the availability of collection facilities. Two commenters said that the prospect of additional costs had already persuaded a few collection sites to stop doing DOT testing.

In other comments, a TPA expressed concern that mandatory DO would lead employers to fire people rather than giving them a chance to return to work, because of extra costs of DO testing. A collection site said that only medical personnel should be observers in DO collections, while another collection site organization said that employer representatives should be able to act as observers.

DOT Response

The Department agrees with commenters that DO collections are intrusive. The Department's rule has always recognized that there is a subset of cases in which this intrusion is justified in the interests of program integrity and public safety. When employees' conduct at the collection site shows the likelihood of an attempt to tamper with a specimen, when unexplained invalid test results come back from the laboratory, or when employees test positive or refuse to take a test, the Department's regulations have always recognized that there is a higher risk of cheating and a higher risk to safety. In these situations, the Department's existing rules require or

permit the use of DO testing in order to deter and/or detect attempts to cheat.

The Supreme Court's decision in *Skinner* held that the FRA's post-accident drug testing program for railroad employees was constitutional, notwithstanding the absence of individualized suspicion of drug use by employees subject to testing. A companion case (*National Treasury Employees' Union v. Von Raab*, 489 U.S. 656 (1989)) concerning the testing of Federal customs personnel and a subsequent case concerning the Federal Aviation Administration's (FAA) drug testing program (*Bluestein v. Skinner*, 908 F.2d 451 (9th Cir., 1990), cert. denied 498 U.S. 1083 (1991)) made similar findings with respect to random testing programs. All of these cases found that Federally mandated drug testing was subject to 4th amendment scrutiny but that the Federal agencies involved had successfully struck a balance between the safety needs of the government and the privacy interests of employees.

The courts in *Skinner* and *Von Raab* noted that the FRA's testing program avoided additional intrusion into employees' privacy by not using direct observation. Indeed, the FRA and Customs programs, like the current DOT program, did not use DO for all tests, as the Department of Defense program for military personnel does. Nothing in the decisions, however, suggests that the courts would regard any and all use of DO as unconstitutional on its face. In fact, *Bluestein* pertained to the FAA's drug testing program that was subject to 49 CFR Part 40 which, as noted above, has always made use of DO. In determining whether requiring, rather than merely permitting, the use of DO in return-to-duty and follow-up exceeds constitutional bounds, it is reasonable to believe that courts would continue to examine whether the Department had appropriately balanced the government's compelling safety interest with the legitimate privacy interests of employees. [See *Gonzales v. Metropolitan Transportation Authority*, 73 Fed. Appx. 986, 2003 WL 22006014 (9th Cir. August 25, 2003) (compelling interest in public safety supports random testing of employees who only very rarely perform safety-sensitive functions).] Given that the precise place where the Department strikes this balance can properly be affected by changes in society, such as the greater prevalence of cheating devices and products now compared to the 1980s, the Department believes it likely that the courts would find that the Department had acted constitutionally.

The privacy provision in the Omnibus Transportation Employee Testing Act gives discretion to the Department to determine the maximum extent to which the protection of individual privacy in the testing process is practicable. Part 40 has always contained extensive protections for individual privacy in the testing process. However, given the now-widespread availability and promotion of cheating devices and products, the purpose of which is to allow employees to conceal their illegal drug use while continuing to perform safety-sensitive functions, it is not practicable to turn a blind eye to the damage that cheating on drug tests can have on public safety. In the Department's judgment, it is essential to put into place additional countermeasures to deter and detect cheating, the likelihood of which has increased in the years since Part 40 was first adopted.

The Department gives little weight to the unions' argument that people who have tested positive are unlikely to try to cheat, simply because they either apparently did not cheat while providing a positive specimen the first time around or have been through the SAP process. (This argument does not apply at all to people who have refused a test, since they have already demonstrated their determination to circumvent the testing process.) Employees in safety-sensitive positions who test positive have shown a willingness to knowingly disregard public safety and violate Federal law by using illegal drugs. Employees who know that they have duties that impact public safety and then engage in illegal drug use have, by their actions, demonstrated a lack of integrity that could readily manifest itself in an attempt to cheat on return-to-duty and follow-up tests.

In this context, we note that DOT drug program statistics show that the violation (*i.e.*, positives and refusals to test) rates for return-to-duty and follow-up tests, in every regulated industry, are higher than the random testing violation rates. While a number of commenters asserted that employees who have previously violated the rules were seen by a SAP, participated in a program, and returned to duty were less likely to be prone to the temptation of continuing to use drugs or of adulterating or substituting their specimen on return-to-duty/follow-up tests, the Management Information System (MIS) data submitted by all transportation modes indicates that the violation rate for return-to-duty and follow-up testing is two to four times higher than that of random testing.

This situation is starkly illustrated in the aviation and rail industries, those most frequently represented in comments opposing DO in return-to-duty and follow-up testing. This data comes from the Department's MIS reports for 2007:

	Random (percent)	Return-to- duty (percent)	Follow-up (percent)
Aviation	.60	2.12	1.86
Rail52	1.2	1.5

Put another way, the violation rate on return-to-duty tests is almost four times as high as the random violation rate in the aviation industry. The violation rate on follow-up tests is over three times the random violation rate. In the rail industry, the return-to-duty violation rate is over twice the random violation rate, while the follow-up violation rate is nearly three times the random violation rate. In addition, when employees in these two industries tested positive on their follow-up tests, the most prevalent drugs identified were—in order—cocaine, marijuana, and amphetamines/methphetamines.

This information supports SAP commenters' views of the motivation of previous violators to cheat. As SAP commenters pointed out, people who return to illegal drug use and realize that their jobs are at stake have strong motivation to take all necessary steps, including cheating, to avoid another positive result. The motive to cheat exists, widely advertised cheating devices and substances provide the means, and—in the absence of DO collections—current procedures for non-observed collections provide the opportunity. The Department stands by its view that return-to-duty and follow-up tests involve a heightened risk of cheating, compared to other testing occasions.

As noted above in the discussion of section 40.67(i), the Department believes it is illogical to conclude that a lack of drug test result data showing use of prosthetic and other devices supports a conclusion that there is no need for DO tests in follow-up and return-to-duty tests. Cheating attempts that evade detection, by definition, are not captured in program statistics. They are likely to be counted as normal negative test results, and not as adulterated or substituted tests. In any case, through experience in inspections, investigations, and during the course of its duties in assisting the public with complying with Part 40, the Department is aware of many instances of cheating. The FAA and the Federal Transit

Administration, for example, have found hidden above ceiling tiles empty urine containers and plastic baggies brought into collection sites. Collectors have reported finding collection containers, baggies, bottles and plastic tubing hidden above ceiling tiles and in trash containers. MROs and collectors have told us about commercial vehicle drivers who used prosthetic cheating devices and accidentally revealed them to physicians and collectors shortly after providing their specimens. There are many more specific instances of cheating that we have become aware of over time.

While this information is anecdotal rather than statistical, it is the Department's view that when well-publicized and advertised means of cheating exist, and we know these means are being used to thwart our testing program, it is clear that the Department's program is not immune. Thus, it is reasonable for the Department to take steps to deter and detect the use of cheating devices.

At the time the Department initiated its drug testing program in the late 1980s, it was common for unions and other opponents of testing (including those whose challenges to the program were rejected by the courts in cases like *Skinner*, *Bluestein*, and *Von Raab*) to argue that the Department had no basis for its testing program because the Department had not proven by statistics or otherwise that there was really a drug abuse problem in the transportation industries. The Department replied that, when public safety was at stake, the Department could not take the risk of assuming that transportation workers were immune from a society-wide problem. Likewise, the Department cannot, in keeping with its public safety responsibilities, assume that means of cheating made widely available are somehow never used by transportation workers, especially when our experience demonstrates otherwise.

The Department does not intend to depend solely on DO testing to combat the problem of cheating. The June 25 final rule made specimen validity testing (SVT) mandatory for all DOT specimens. The Department has provided additional guidance to collection sites on maintaining the appropriate safeguards against cheating, mailing to over 24,000 collection sites "DOT's 10 Steps to Collection Site Security and Integrity" posters. The Department has explicitly supported legislation to strengthen program integrity, such as criminalizing the sale of cheating products and providing DOT agencies with civil penalty authority to sanction collection sites and other

service agents who do not carry out the rules properly. While these steps are important, they do not replace DO testing as a means of deterring and detecting cheating at the collection site when there is a heightened risk of cheating.

Some comments said that large employers or groups of employers choose to conduct DO testing on only a few follow-up and return-to-duty tests. The employer option in previous versions of Part 40 was intended to give employers the chance to make careful, case-by-case, determinations of whether DO was appropriate for particular employees undergoing these post-violation tests, using their discretion wisely to protect against cheating that undermines the deterrent effect of the testing program (We note with interest that some union commenters suggested that, under present rules, it would be appropriate for an employer to require DO in follow-up and return-to-duty testing based on the findings of a SAP or a designated employer representative.) To the extent that employers are not taking responsibility for doing so, and are instead using the option to avoid using DO in all or most return-to-duty and follow-up tests (e.g., for reasons of labor-management agreements, fear of upsetting employees, concern about costs), their behavior provides additional reason for the Department to mandate DO for these types of tests.

For almost 20 years, the rules have required same-gender observers for DO collections. This requirement has not changed. If some collection sites are staffed mostly by women at the present time, while employees being tested are mostly men, the evident course of action for these sites to follow would be to hire additional men, at least on an on-call basis, to handle DO duties. Return-to-duty and follow-up tests are conducted at a day and time set by the employer, so the employer has ample time to notify the collection site in advance that a same-gender observer will be needed for a DO collection. As a major drug and alcohol testing industry association responsible for training many collectors noted in their docket comment, collectors and collection facilities must have the ability to perform DO collections in order to be in compliance with 49 CFR part 40. Collection sites and employers have had to be ready with same gender observers for two decades.

It should be noted that observers do not need to be trained collectors. They need only be able to carry out basic instructions for the observation process. Being male would be a bona fide

occupational qualification for such a position, such that collection sites could specifically seek men to play this role without running afoul of equal employment opportunity laws because most employees requiring observation are men. We do not believe that people acting as observers need to be medically trained, as they are not performing any specifically medical tasks (even trained collectors do not need to be medical professionals). DOT has produced an instruction sheet about DO procedures and made it available to all collectors and collection sites, as well as collector and MRO training organizations.

The Department also believes that, while there would be some increase in the number of DO tests, the increase would not be as dramatic as some commenters asserted. Therefore, the costs to collection sites and employers would not increase significantly.

One major drug and alcohol testing association specializing in collection activities, in their docket comments, estimated that the Department's new rule would effect less than 2% of employees. Our MIS data for 2006 shows that return-to-duty and follow-up made up 2% of all DOT tests. HHS Data for 2006 indicated that there were approximately 7.5 million tests conducted by HHS certified laboratories, of which we estimate that 7.32 million were DOT tests. That would mean that there could be approximately 146,400 return-to-duty and follow-up DOT tests annually. This figure includes those return-to-duty and follow-up tests already being conducted under DO by employer request.

The Department estimates that there are more than 24,000 collection sites throughout the United States. Even if there had been no DO collections for return-to-duty and follow-up testing, this would average only an increase of 6 DO collections per site per year. This is certainly a manageable number. As one testing industry commenter noted, if a collection site facility is currently required to conduct DO collections at any time to be compliant with part 40, "it should not matter whether they perform 1000 DO collections or 1020 (2% more)."

The Department recognizes that some collection sites may have to collect more than that, but then there will be others who will collect fewer than the average, just as some employers will be responsible for more than an average number of employees in return-to-duty and follow-up programs and others fewer than average.

The Department believes that a wide variety of factors affect an employer's decision about whether to retain an

employee who has violated the rules, and we consequently doubt that requiring DO in follow-up and return-to-duty tests will cause a major shift in employers' decisions about retention. In any case, the Department's interest is in safety, and we have always left personnel decisions to employers.

The Department's experience is that there is a good deal of turnover in the collection site business, as some sites open and others close. Having to perform additional DO tests could lead some sites to leave the business; where there is a market demand for services, others are likely to take their place. Finally, we believe commenters did not correctly understand DOT guidance concerning the role of employers and DERs in directing collection sites to conduct tests under DO. Employers and their DERs do not have unfettered discretion to direct collectors to use DO; they can only do so where the Department's rules require DO to be used. The Department will review its guidance documents to determine if any further clarification of this point should be made.

Use of Alternative Specimens

Fourteen commenters said that, rather than making DO mandatory in follow-up and return-to-duty tests, the Department should take other, less intrusive, actions to reduce the likelihood of cheating. One testing industry association, a collection site, an employer, and a few individuals recommended that the Department adopt hair or saliva testing as an alternative to urine testing, believing that these methods were less vulnerable to cheating. Other suggestions included tighter supervision of the collection process and better training of collection personnel and support of anti-cheating legislative proposals in Congress.

DOT Response

The Department is not opposed to the use of alternative, less intrusive, testing methods as a means of accomplishing the safety purposes of the program while preventing individuals from cheating. Under the Omnibus Transportation Employee Testing Act of 1991, however, the Department is authorized to use only testing methods that have been approved by the Department of Health and Human Services (HHS). To date, HHS has not approved any specimen testing except urine. To counteract serious concerns about potential cheating in urine testing, DOT must therefore rely for now on DO collections in the situations spelled out in Part 40; this is the tool we have available at this time to ensure that

cheating does not undermine the safety objectives of the Department's program.

However, we know that HHS is in the process of working toward the approval of updates to the Mandatory Guidelines for urine testing which also supports use of some alternative testing methodologies. Based upon our discussions with HHS, oral fluids and sweat specimen testing are areas of promise which will receive maximum focus in HHS's next approval process. When they are approved by HHS, these methodologies will be forensically and scientifically suitable to be used in the DOT testing programs. Both oral fluid and sweat specimen testing are considerably less intrusive than DO of urine collections. Because of their drug use detection timetables, after approval by HHS oral fluids would be very suitable for return-to-duty testing and sweat specimens would be very suitable for follow-up testing.

When HHS approves these specimens for testing, the Department intends to propose to amend Part 40 to provide for their use in appropriate testing situations. By doing so, the Department will provide a less intrusive alternative to DO urine testing in the return-to-duty and/or follow-up situations.

HHS is also considering the use of hair testing. There are a number of significant scientific and policy questions raised in public comments and Federal agency internal reviews of proposed revisions to the Mandatory Guidelines that must be answered before HHS and DOT could adopt the use of hair testing in the agencies' programs. The claimed 90-day detection window for hair testing also makes its use problematic in RTD testing and for FU tests as well, depending on when they occur. Nevertheless, at such time as HHS approves hair testing, we are open to considering its use as part of the DOT testing program.

Under authority separate from and predating the Omnibus Act, the FRA has long used blood testing and urine testing [as well as tissue and vitreous humor from cadavers] in its special post-accident testing. While blood testing is scientifically and forensically sound, its collection by needle is considered very intrusive. It also requires the use of medically-trained personnel as collectors. Importantly, blood affords a very brief window of detection. Consequently, while it can be used by the FRA appropriately in their special post-accident testing as a means of determining accident causative factors, it would not be a suitable methodology for return-to-duty and follow-up testing.

Other Agencies' Rules

While the drug testing rules of other Federal agencies do not determine the way the Department responds to comments on section 40.67(b), it is instructive to note that other agencies make significant use of DO in their testing programs. The Department of Defense, of course, has always used DO for all drug tests of military personnel, who generally are regarded, however, as having a lower expectation of privacy than civilian workers.

In new final rules that go into effect in March 2009 (73 FR 16966; March 31, 2008), the Nuclear Regulatory Commission (NRC) will also afford less privacy for its DO collections for return-to-duty and follow-up tests for nuclear industry personnel, as well as tests in which collection site behavior or laboratory results indicate an attempt to cheat. The NRC regulation requires an anti-prosthetic procedure as part of all its DO tests, in which an individual must raise and lower his or her clothing from waist to knee not only before providing the specimen (as in the DOT procedure) but also during urination. NRC's rationale for this action was the following:

More detailed procedures are necessary because devices and techniques to subvert the testing process have been developed since [the NRC rule was originally issued] that are difficult to detect in many collection circumstances, including direct observation, such as a false penis or other realistic urine delivery device containing a substitute urine specimen and heating element that may be used to replicate urination. Therefore, the agency has made these changes to increase the likelihood of detecting attempts to subvert the testing process and increase the effectiveness of directly observed collections in assuring that a valid specimen is obtained from the donor. 73 FR 17071; March 31, 2008.

The HHS intends, in its upcoming Mandatory Guidelines for the Federal employee drug testing program, to require DO collections in all follow-up and return-to-duty tests. The HHS and NRC procedures are based on the same rationale as the DOT June 25 final rule: types of testing that present a heightened risk for cheating, given the ready availability of cheating products, call for appropriate countermeasures.

The Department's Decision

Having considered the comments, the Department remains convinced that conducting all return-to-duty and follow-up tests under DO is the most prudent course from the viewpoint of safety. It is the method we have available today to deter and detect attempts to cheat, pending the

availability of less intrusive alternative specimen testing methods.

Under 40.67(b), there are no individuals who will be directly observed who have not already been subject to being directly observed under previous versions of Federal safety requirements by refusing to test, using illegal drugs, or otherwise breaching the rules. By this conduct, each of these individuals has shown a willingness to endanger public safety. Individuals in this category have a greater than average likelihood of using illegal drugs in the future and a higher than average motivation to cheat on a test. Under these circumstances, the Department is justified in regarding these individuals as having a reduced legitimate expectation of privacy, compared to covered employees in general. Given the increased availability of cheating products, compared to twenty years ago when Part 40 was first issued, the Department can properly adjust the balance between safety and privacy by making DO collections mandatory, rather than optional, in follow-up and return-to-duty testing.

The Department realizes that there may need to be some adjustments necessary for employers, collection sites and others in order to begin implementing this requirement. However, by the time the rule goes into effect on November 1, affected parties will have had four months to address implementation issues, including labor-management relations, providing for the availability of same-gender observers etc. Consequently, we do not believe that any further delay in the effective date of this provision is warranted. We emphasize that conducting all future return-to-duty and follow-up tests under DO is a requirement of Federal law (including for employees whose initial violations of the rules occurred or whose series of follow-up tests began before November 1).

For the reasons set forth in this notice, section 40.67(b), as issued in the Department's June 25, 2008, final rule will go into effect, without change, on November 1, 2008.

Issued this 16th day of October, 2008, at Washington, DC.

Jim L. Swart,

Director, Office of Drug and Alcohol Policy Compliance.

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