DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST–99–6578]

RIN 2105–AC49

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: The Department of Transportation is revising its drug and alcohol testing procedures regulation. The purposes of the revision are to make the organization and language of the regulation clearer, to incorporate guidance and interpretations of the rule into its text, and to update the rule to include new provisions responding to changes in technology, the testing industry, and the Department's program.

EFFECTIVE DATES: The amendments to the current 49 CFR part 40 are effective January 18, 2001. The revised 49 CFR Part 40 is effective August 1, 2001.

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, Washington DC, 20590, 202–366–9310 (voice), 202–366–9313 (fax), or *bob.ashby@ost.dot.gov* (e-mail); Mary Bernstein, Director, Office of Drug and Alcohol Policy and Compliance (ODAPC), 400 7th Street, SW., Room 10403, Washington DC, 20590, 202–366–3784 (voice), 202–366–3897 (fax), or *mary.bernstein@ost.dot.gov* (e-mail); or Jim L. Swart, Drug and Alcohol Policy Advisor, ODAPC , same address and phone numbers as above, *jim.swart@ost.dot.gov* (e-mail).

SUPPLEMENTARY INFORMATION:

Background

The Department of Transportation first published its drug testing procedures regulation (49 CFR part 40) on November 21, 1988 (53 FR 47002), as an interim final rule. We based the rule on the Department of Health and Human Services (HHS) guidelines for Federal agency employee drug testing, with some changes to fit the transportation workplace. The Department published a final rule responding to comments on the interim rule a year later (54 FR 49854; December 1, 1989).

The Department added alcohol testing procedures to Part 40 in a February 1994 final rule. This rule also made other changes to Part 40, including requirements for split samples in four operating administration rules. Since that time, the Department has amended specific provisions of Part 40 on various occasions (*e.g.,* with respect to non-evidential alcohol screening devices and ''shy bladder'' procedures).

In the years since Part 40 was first published, the Department issued a large volume of guidance and over 100 written interpretations, as well as a significant amount of informal advice. Most of this material has not previously been incorporated into the rule text. There have been changes in testing technology, the structure of the drug and alcohol testing business, and the functioning of the Department's drug and alcohol testing programs that make it desirable to update our regulatory provisions. Because the rule was originally based on that of another agency (*i.e.,* HHS), there are some provisions that never were a close fit for the Department's programs. Moreover, the rule's organization and language do not meet the objectives of the Clinton Administration's current ''Plain Language'' policies. Under section 610 of the Regulatory Flexibility Act, agencies are directed to review existing rules from time to time with an eye to their effects on small businesses and other small entities.

For all these reasons, the Department decided to review Part 40. As a first step, we issued an advance notice of proposed rulemaking (ANPRM) on April 29, 1996 (61 FR 18713), asking for suggestions for change in the rule. We received 30 comments in response to this ANPRM. We then issued a notice of proposed rulemaking (NPRM) on December 9, 1999 (64 FR 69076). This NPRM proposed a comprehensive revision to Part 40. In response to the NPRM, we received letters from over 400 commenters, making around 4000 individual suggestions concerning the rule. We also held three public listening sessions, at which numerous interested parties commented further on the Department's proposals, and we held an internet forum. The final rule responds to all the comments and makes significant alterations to the existing rules governing the Department's drug and alcohol testing programs.

Structure of the Rule

Perhaps the first thing readers will notice about this final rule is that we have thoroughly restructured Part 40, with subparts organized by subject matter area. Like the NPRM, and in contrast to the existing rule, the text is divided into many more sections, with fewer paragraphs each on average, to make it easier to find regulatory provisions. The rule uses a question-answer format, with language specifically directing particular parties to take particular actions (e.g., ''As an employer, you must * * *''). We have also tried to express the requirements of the rule in plain language. Commenters were very complimentary about the reorganization of the rule, generally praising it as much clearer and easier to follow than the existing rule. The Department received a plain language award, known as the ''No Gobbledygook Award,'' from Vice President Gore's National Partnership for Reinventing Government in recognition of the improved clarity of the regulation. We have retained the NPRM's format and organization, which we believe will help drug and alcohol testing program participants understand and effectively carry out this rule.

What matters most in a rulemaking is not the number of letters favoring or opposing a particular proposal. Our central concern is with the substance of the comments. In discussing comments on this rule and our response to them, we will focus on the substance of positions that commenters expressed, and on why we did or did not make changes in response to various comments. In writing the preamble, we have avoided counting up the number of comments supporting a given position except in the most general way, believing that doing so would distract from the discussion of substantive issues.

Effective Dates

The Department has decided to establish an August 1, 2001, effective date for the revised Part 40. We recognize that there is always some difficulty for everyone involved in the transition between an existing rule and a new rule. We hope that this delayed effective date will ease the transition. During the period between publication and August 1, program participants will have the opportunity to learn about new provisions before having to implement them. During this period, the Department expects to develop and issue guidance (*e.g.*, a revised medical review officer (MRO) manual) and make presentations at a significant number of conferences and training sessions. In addition, August 1 is the date on which use of the new Federal Drug Testing Custody and Control Form (CCF), to which the text of the revised Part 40 refers, becomes mandatory.

However, we believe it is important to begin implementing some new provisions sooner, since they enhance the fairness and integrity of the process. To do so, we must amend the *existing*

Part 40 to include these provisions, so that they are in effect during the period before the August 1 effective date of the entire new version of the regulation. Come August 1, the existing Part 40 (including the amendments we are issuing today) will be replaced, in its entirety, by the new Part 40. Since the substance of today's amendments will be the same in both versions of the document, there will be no change in how we implement them after August 1.

The provisions requiring MRO review and split specimen testing following adulteration and substitution findings will go into effect in 30 days. The majority of laboratories already perform validity testing on a voluntary basis. Making the MRO review and split specimen procedures effective in 30 days will make these additional protections available in connection with this existing validity testing. At the same time, a provision explicitly authorizing the continuation of this existing practice under the new rule will go into effect. To the extent that the Department's September 1998 guidance memorandum concerning adulterated, substituted, dilute, and unsuitable tests is inconsistent with any provisions of these amendments, we regard that guidance as having been superseded on the effective date of the amendments.

HHS is currently working mandatory requirements for validity testing. HHS is projecting completion of this project by August 1, 2001. We believe that, to avoid any potential uncertainty about the standards and procedures for mandatory validity testing, DOT should put its mandate for validity testing into effect simultaneously with the new HHS requirements. Consequently, in the event HHS has not issued its new requirements by that date, we will publish a subsequent **Federal Register** notice postponing the Auust 1, 2001, effective date for mandatory validity testing.

Another provision that we are including in the amendments to the existing Part 40, and that will go into effect in 30 days, is the public interest exclusion system. These provisions are very important to ensuring accountability in the provision of drug and alcohol testing. In addition, we are making the provisions of § 40.5 effective in 30 days as § 40.203, since the Department expects to be issuing guidance materials on the new Part 40 before August 1, 2001.

For readers' convenience, here is a table of the relationship between the section numbers in the amendments to current Part 40 that go into effect in 30 days and the section numbers of the corresponding sections of the new, revised Part 40 that goes into effect on August 1, 2001:

Amended current part 40	New revised part 40
40.201	40.3
40.203	40.5
40.205	40.89
40.206	40.91
40.209	40.93
40.211	40.95
40.213	40.99
40.215	40.145
40.217	40.179
40.219	40.181
40.221	40.183
40.223	40.187
40.225	40.191
Subpart F (same section numbers).	Subpart R

Principal Policy Issues

In addition to often very detailed paragraph-by-paragraph comments on the text of the NPRM, commenters focused on several major policy issues. These included employee stand-down, validity testing, the public interest exclusion mechanism, the return-to-duty process, transmission of test results and other information through consortia and third-party administrators, reporting and storing information through electronic means, and reporting violations to DOT agencies. Issues also arose concerning confidentiality of information, conflicts of interest among service providers, training, and the collection process. In this preamble, we will discuss these policy issues first. After that, we will proceed to a section-by-section discussion of the rule, including the Department's responses to specific comments.

Stand-Down

Stand-down refers to an employer practice of temporarily removing an employee from performance of safety-sensitive duties upon learning that the individual had a confirmed laboratory positive drug test, but before the MRO has completed the verification process. The existing regulation prohibits stand-down. MROs are not permitted to inform employers about the existence of a confirmed laboratory positive test pending verification, and employers are not allowed to take any action concerning an employee until they receive the MRO's notification of a verified positive test.

The preamble to the NPRM noted the reasons for the current policy: stand-down undercuts the rationale for MRO review, can compromise the confidentiality of test results, and may result in unfair stigmatization of an employee as a drug user. While the rationale for stand-down is that it enhances safety, the Department has no evidence that the current policy has compromised safety. For example, we are not aware of any case in which an employee has had a drug-related accident while verification of a confirmed positive drug test was pending.

The preamble also noted that some employers advocated the use of stand-down as a measure to enhance safety and reduce liability. They wanted to use this approach to eliminate, as far as possible, any risk that someone who had tested positive would be involved in an accident before the MRO could complete the verification process. We noted that, essentially for this reason, the Department's own internal drug testing program stood down some employees (*e.g.*, air traffic controllers) in some circumstances following a report of a confirmed positive laboratory test.

The NPRM regulatory text proposed two alternatives, one of which prohibited, and the other of which permitted, stand-down. The alternative that permitted stand-down included requirements to help safeguard employees' interests in confidentiality and fairness.

Comments

Comments were sharply, and fairly evenly, divided on this issue. Some commenters, mostly employers and some service agents, supported stand-down. A few of these comments went further and urged that stand-down be made mandatory, while a greater number said that it should be discretionary with each employer. A smaller number of commenters, including all unions and other employee organizations as well as some employers and service agents, opposed permitting stand-down.

The most important argument cited by stand-down supporters was safety. Safety is a more important objective than confidentiality, many of them said. Even if there have not been documented cases of safety problems occurring in the absence of stand-down, no employer wants to be the first to face such a situation. Many employers may feel it so important to stand down employees on safety grounds that they would have an incentive to violate this prohibition. Avoiding unnecessary liability is also a consideration: It would be unwise, commenters said, to force a company to permit an employee it knew had a confirmed positive laboratory test to continue driving a commercial truck or flying a plane during the verification process.

Supporters also noted that, in most cases, there were very low rates of confirmed laboratory positive tests being verified negative (indeed, some drugs, like PCP, have no legitimate medical uses that would support a negative verification). Therefore, they said, stand-down would not adversely affect more than the small number of drivers with confirmed positive laboratory results that an MRO later verified negative. Other commenters said that adverse consequences for employees could be minimized by employers choosing to keep employees in non-safety-sensitive positions until verification or ensuring that employees whose tests were ultimately verified negative did not suffer any loss of pay or other adverse consequences.

Opponents of stand-down said that the practice embodied a ''guilty until proved innocent'' approach that was manifestly unfair and ignored the purpose of having MRO review of positive tests. Confidentiality provisions would likely be inadequate. In practice, the ''word'' would get out that the employee had a confirmed laboratory test result and the employee—even if the MRO ultimately verified the test as negative—would be stigmatized in the workplace as a drug user. This would upset the regulatory balance between safety interests and the protection of employees from unfair consequences of the process. One motor carrier association said that this would be a particular problem in its industry. In large carriers, an employee cannot be taken out of service without involvement by multiple management employees. For unionized carriers in which assignments are made by seniority, it would be impossible to take a driver out of service without other drivers knowing it.

Some commenters contested the safety rationale of stand-down by pointing out that a positive drug test does not indicate impairment. Other commenters said that the risk to the public from the current ''no stand-down'' policy was minimal, given that there were no known instances of accidents resulting from the absence of stand-down. Opponents also cited pay, privacy, and personnel consequences, as well as potential Americans with Disabilities Act and other issues potentially comploicating implementation of stand-down.

An associated issue concerns pay status. If a company stands down an employee, should the company be required to pay the employee during this period, pending verification? Several commenters directly addressed this issue. About half of them, including a union and some employers and their associations, favored paying employees while they were in a stand-down status. The remainder said either that the regulation should be silent on the issue, with labor-management negotiations deciding the matter in each case, or that employees should not be paid while in stand-down status.

While a number of comments addressed confidentiality and privacy issues, they provided little detail in the way of suggestions for how best to accomplish these objectives in a stand-down situation. Likewise, while a few commenters noted that confidentiality might be a more difficult issue in small companies, they did not provide any suggestions for how to address the issue. There was a suggestion that, to deal with the situation of owner-operators in the motor carrier industry, service agents be empowered to stand down these individuals.

DOT Response

At the time of the NPRM, the Department recognized enough merit on both sides of this argument to propose alternative provisions. Having reviewed the comments, we remain convinced that advocates of both basic positions on the issue make some strong points. The Department is also aware that potential future changes in drug testing technology, such as the advent of HHS-approved on-site testing and alternative testing methods, may alter the response the Department's procedures take concerning stand-down in the future. Consequently, the Department is taking a middle-ground position on this difficult issue.

The general rule will remain that stand-down is prohibited. The reasons for this general rule are the reasons articulated in the existing rule, the NPRM, and the comments from stand-down opponents. However, we believe it is necessary to respond to the genuine and plausible safety concerns of commenters favoring stand-down, the fact that safety is the Department's highest priority, and the fact that the Department's internal program uses a form of stand-down. Therefore, the Department will establish a waiver mechanism that permits employers, on a case-by-case basis, to request DOT agency approval for a specific, well-founded stand-down plan that effectively protect the interests of employees.

This approach makes the Department's approach to its internal and external programs consistent with one another. When the Department, in its role as an employer, wanted to use a stand-down approach, it sought and received a waiver from HHS, whose drug testing guidelines also generally prohibit stand-down. Under the final rule, employers in the external program who wish to employ stand-down can, in an analogous way, seek a waiver from the Department of Transportation.

We realize that some employers have employees that are regulated by more than one DOT agency. To avoid unnecessary administrative burdens in the waiver process, such an employer would have to submit only one waiver request, to the DOT agency that regulated the largest number of its employees. The various DOT agencies involved would coordinate internally before the lead agency responded to the employer.

The Department intends to grant waivers only to employers who present a sound factual basis for their request and will have in place a number of provisions to protect employees' legitimate interests. The final rule (§ 40.21) lists several types of information that the employer would submit to the DOT agency in support of its request. This information is intended to give the DOT agency a picture of the employer's organization and safety situation. For example, the size or structure of the organization may affect the ability of an employer to carry out confidentiality requirements for the grant of a waiver. An organization that has an in-house MRO may be in a better position to control access to testing information than one that does not. An organization that stands employees down for reasons other than substance abuse testing may be in a better position to safeguard confidentiality than one that does not. Organizations' drug and alcohol testing history may be a relevant factor in determining whether stand-down is useful in a particular company.

None of these kinds of information is intended to establish a litmus test for granting a waiver. DOT agencies will make a case-by-case decision about the merits of a stand-down petition with respect to each company that applies for one. DOT agencies will respond to each petition in writing, with reasons for the decision. DOT agencies are intended to have wide discretion in making these judgments. For example, two companies might present stand-down policies that are nearly identical on paper. However, contextual factors in one company may make its confidentiality assurances credible as a practical matter, while in the other case may suggest that confidentiality could not practically be maintained, despite the company's good faith efforts. DOT agencies could make different decisions in the two cases. We also point out that petitions for waivers

will be considered on a company-by-company basis. DOT agencies will not, for example, consider a petition from a trade association or C/TPA on behalf of an industry or segment of an industry.

As a condition for receiving a waiver, the rule requires the employer to submit its proposed written stand-down policy. These requirements pertain to confidentiality and protection of legitimate employee interests and are described in greater detail in the discussion of § 40.21 below. One of these requirements is that an employer must continue to pay a worker who is in stand-down status, in the same way it would have in the absence of stand-down. This is a matter of fairness. To assume that the employee's test will be verified positive is to fall into the trap of presuming the employee guilty until proved innocent. In addition, continuing normal pay status for the employee should not be a major burden for employers, given the usually short interval before verification is completed. As a major employer association commented, most employers would not object to paying the employees for a reasonable amount of stand-down time if they believe they will gain a substantial safety benefit. An employer who articulated a safety rationale for stand-down but who objected to paying employees in the brief interim would seem to be an employer reluctant to expend resources commensurate with its expressed commitment to safety.

These conditions are intentionally stringent. The Department wants to ensure that only employers who are able to maintain a successful balance between the potential safety benefits of stand-down and the legitimate privacy interests of employees are permitted to operate a stand-down policy. A DOT agency can impose additional conditions on a waiver or, if necessary, revoke a waiver it once granted. A DOT agency could also take enforcement action against an employer that violated the terms of its waiver.

Some comments suggested that stand-down be permitted for confirmed laboratory tests for some drugs (*e.g.*, PCP) but not others (*e.g.*, opiates), based primarily on the lower or higher probabilities of verified negatives for these substances. The Department is not including such a provision as a general matter, out of concern that such a provision might lead to confusion.

Public Interest Exclusions (PIE)

The NPRM proposed that service agents—persons and organizations that provide drug and alcohol testing services to employers, such as laboratories, MROs, substance abuse professionals (SAPs), collectors, breath alcohol technicians (BATs), screening test technicians (STTs), consortia and third-party administrators (C/TPAs)—should be accountable for serious noncompliance with Part 40. The NPRM proposed a mechanism based on the Department's existing non-procurement suspension and debarment rules (49 CFR part 29). This mechanism would permit the Department, following a series of procedures designed to ensure fairness, to impose a public interest exclusion (PIE). A PIE would direct DOT-regulated employers not to use the service agent for a period of time. The Department proposed to use this mechanism only in cases of serious misconduct where the service agent has not implemented prompt corrective action following notice by a DOT agency. The preamble noted that this mechanism rested on the Department's existing authority to establish requirements for the conduct of the drug and alcohol testing process and to direct employers to use only products and services that met these standards.

Comments

The PIE proposal generated a good deal of comment. Almost a hundred written comments to the docket addressed the proposal, which was also the subject of extended discussion at the Department's three listening sessions, where the Department convened forums specifically on the subject. A strong majority of employers and all unions addressing the proposal favored it. Among service agents and their organizations, and other commenters submitting written comments, about 60 percent opposed the proposal, as written. Some service agent commenters urged postponing consideration of the provision and addressing it in a separate rulemaking.

Even the commenters who opposed the proposal said that they believed service agents should be accountable for their conduct, at least in principle. Their reasons for opposing the proposal included doubting the need for such a mechanism and the Department's authority to implement it, a belief that the proposed process was insufficiently defined and did not provide enough procedural safeguards for service agents, a concern that DOT auditors and inspectors might initiate PIE proceedings arbitrarily, a preference for other alternatives (*e.g.*, additional industry standards, certification, training programs, litigation), or support for other options mentioned in the preamble to the NPRM (*e.g.*, certification or self-certification by all service agents with a DOT decertification process).

Proponents of the proposal cited examples of misconduct by service agents for which there was no present remedy. They said that employers, especially small employers, often had to take on faith the quality of service agents, and the PIE process could help them to know which service agents to avoid. Employers also believed that it was unfair for them to be solely accountable for serious problems in the testing process. Service agents who supported the proposal said that it would enhance the overall quality of performance by service agents. Some service agents cut corners to reduce costs, putting more conscientious service agents at a competitive disadvantage, these commenters said, and then ''whined'' when the Department proposed a meaningful accountability mechanism.

Commenters had a number of thoughts on specific aspects of the proposal. Many asked for greater specificity concerning the kinds of ''offenses'' that would lead to a PIE proceeding. DOT staff pointed out, during the listening sessions and in writing, that the PIE mechanism was intended, both for policy and resource reasons, to be used only in the case of ''egregious'' misconduct. However, commenters pointed out that this statement was not made in the proposed regulatory text. They feared that differences in interpretation among inspectors and other DOT staff could lead to the inconsistent or arbitrary use of PIE proceedings. Some of these commenters desired a specific list of the actions that would lead to a PIE proceeding, while others suggested the Department should at least provide examples.

Another frequently-made comment concerned the scope of PIEs. The NPRM said that a PIE would apply to all divisions, organizational elements, and types of services provided by a service agent, unless the ODAPC Director decided to limit its scope. Affiliates and individual officers and employees could also be subject to a PIE. A number of service agents and employers objected to this aspect of the proposal, saying it was too broad. It was unfair, they said, to prohibit employers from using a service agent's other services because of a problem in one area. If a TPA has violated the rule with respect to MRO services, for example, why should a PIE prevent an employer from using the TPA for collection or SAP services? Many commenters who made this point favored an approach that came to be known, in the listening sessions, as the

''slice of PIE.'' Under this approach, a PIE would apply only to the type of service in which noncompliance had taken place. Some commenters said the ''slice'' should be even narrower, applying only to the specific employer, facility, or individual service agent staff members who had been involved in the noncompliance. A few laboratories said that laboratories should not be subject to the PIE process, since HHS already regulates laboratories through its certification process. Another commenter thought that it would be better to fine erring service agents rather than issuing a PIE.

Commenters raised two issues concerning the role of the ODAPC Director in the PIE process. A few service agents suggested that the Director would not be an objective decisionmaker, because he or she would be too sympathetic to the position of DOT staff. Others suggested that the ''firewall'' between the Director and other staff be made more explicit in the regulatory text. Several service agent commenters also asked for criteria for determining the length of a PIE, as well as a regulatory time frame for the Director's consideration of a service agent's petition to lift a PIE.

Smaller numbers of commenters suggested other procedural changes in the PIE provisions. One recommendation was that the initiating official's burden of proof be ''clear and convincing evidence'' instead of a preponderance of the evidence. Others asked for specific rules of evidence to apply to PIE proceedings. Some asked that the Department contact the service agent first, to check on alleged facts, before initiating a proceeding. A number of employers asked for periods longer than the proposed 90 days to replace a service agent that was subject to a PIE, or for the possibility of extensions of that period. Some service agents asked to delay the effective date of the PIE provision by a year or two, to give organizations time to get used to the requirements of the new final rule. A commenter asked that the rule provide for a private right of action by employers against service agents. Other commenters disagreed with the statement in the proposed rule text that the purpose of a PIE was not punishment.

DOT Response

1. Basic Rationale for the PIE Provisions

Service agents perform the bulk of drug and alcohol testing services for transportation employers. Employers, particularly small employers, necessarily rely on service agents to comply with their testing obligations. These employers often do not have the expertise in testing matters that would enable them to evaluate independently the quality, or even the regulatory compliance, of the work that service agents perform for them. Yet an employer's compliance with DOT regulations is largely dependent on its service agents' performance. If a service agent makes a serious mistake that results in the employer being out of compliance with a DOT rule, the employer alone is now accountable. The employer may be subject to civil penalties from a DOT agency. The employer can be subject to litigation resulting from personnel action it took on the basis of the service agent's noncomplying services. Most importantly, the employer's efforts to ensure the safety of its operations may be damaged, as when an employee who apparently uses drugs is returned to duty because of a service agent's noncompliance. In many cases, there are now no consequences to a service agent who creates such problems, even if the problems are serious.

The experience of DOT agencies, which are responsible for reviewing employers' compliance, is that the vast majority of employer noncompliance results from service agent errors. (Given the pervasive role of service agents in performing testing functions, this is probably not a disproportionate effect.) FAA staff informally estimate, for example, that more than nine out of ten deficiencies their inspectors discover result from service agent errors. In addition, the Department's drug and alcohol testing office staff, from time to time, encounter serious noncompliance with DOT rules by service agents, for which there is no present remedy. Here are a few examples of actual cases we have encountered:

- An MRO verified many tests positive without conducting verification interviews. As a result, the tests had to be cancelled, and the employer had to return the employees to duty, incurring extra safety risks and costs.
- Another MRO, who had counterfeit medical credentials, verified several tests positive, bringing into question the integrity of the verification process.
- In defiance of the clear language of Part 40, a letter from the Department, and a finding by a court, a laboratory refused to provide an employee information to which she was entitled.
- A service agent made false claims that its personnel were certified by DOT. DOT wrote them a letter telling them to stop. Years later, the same service agent's letterhead continues to make the same claims.
- A consortium and a laboratory were engaged in a billing dispute with one another. As a result, numerous pre-employment results were not transmitted to employers for a number of months. No one informed the employers of the problem, and some of the employers, in the apparent belief that ''no news is good news,'' placed some of the workers—including one who tested positive—in safety-sensitive positions.
- A major employer used a service agent for SAP services. The SAPs provided by the service agent established a long-standing pattern of returning virtually all employees who have tested positive to work quickly, without education or treatment.
- Personnel of a major laboratory engaged in misconduct apparently involving the backdating and attempted destruction of documents relevant to litigation concerning a drug test result.

Attempting to deal with service agent problems one employer at a time is both inefficient and potentially unfair. It is inefficient because service agents work for many employers. It is potentially unfair because employers may be unwitting victims of service agent misconduct. Conducting civil penalty proceedings against several employers because of the actions of one service agent, moreover, does little if anything to correct the conduct of the service agent or protect other employers from the consequences of its noncompliance. In addition, service agents often work for employers in more than one transportation industry. For example, if FRA takes action with respect to a railroad whose noncompliance is caused by service agent errors, this does nothing to protect a motor carrier who uses the same service agent.

The Department believes that, in this situation, an accountability mechanism that protects the public interest, employers, and employees is appropriate and necessary. A few commenters appear to have misunderstood the nature of the PIE proposal. It is not an assertion of new regulatory authority over service agents. It makes use of the Department's long-standing authority to direct transportation employers not to use products and services that do not meet Federal standards. Employers may not use laboratories that are not HHS-certified. They may not use evidential breath testing devices (EBTs) that are not on the National Highway Traffic Safety Administration (NHTSA) conforming products list (CPL). They may not use SAPs and MROs who fail to meet regulatory qualifications. There is no difference in legal principle

between these well-established prohibitions and a requirement not to use a service agent who has been found to have seriously noncomplied with Part 40. A PIE is simply one additional directive to transportation employers to ensure that the employers use only service providers that meet regulatory requirements.

Procedurally, the PIE process is modeled on a well-established procedure for handling non-procurement suspensions and debarments. While not identical to the non-procurement suspension and debarment rules of the Department (49 CFR part 29), the PIE process draws on Part 29 for many of its details. Modeling PIE on an existing program that affords due process to participants ensures that PIE will be an effective and fair approach to serious noncompliance in the drug and alcohol testing program.

2. Legal Authority

The Department looked carefully at the issue of legal authority before proposing the PIE process in the NPRM. As noted in the preamble to that document, there is ample legal authority to implement this proposal. First, there is specific statutory authority for rulemaking in this area. Section 322 of the DOT Act provides general rulemaking authority to the Secretary of Transportation. It states that ''[t]he Secretary of Transportation may prescribe regulations to carry out the duties and powers of the Secretary.'' Further, the 1991 Omnibus Act authorizes the Secretary of Transportation to continue in effect, amend, or further supplement regulations governing the use of alcohol or a controlled substance. See 49 U.S.C. 31306(i), 49 U.S.C. 20140(f), 49 U.S.C. 5331(f)(3), and 49 U.S.C. 45106(c). Upon review of the Act, it is clear that Congress—while not explicitly mentioning a particular mechanism to ensure compliance—intended the Secretary to use his or her discretion to devise appropriate regulatory methods to carry out the Department's drug and alcohol testing responsibilities.

Moreover, under well-settled case law, specific statutory authority is not needed in order for an agency to have authority to impose a reasonable requirement. There are many court decisions that support this point, particularly cases following *Chevron* v. *Natural Resources Defense Council*, 467 U.S. 837 (1984). *Chevron* stands for the proposition that courts will defer to ''permissible'' agency interpretations where the statute is ''silent or ambiguous''. In *Chevron*, the leading case on the regulatory and interpretive authority of agencies, the Supreme Court articulated the following standard:

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

Numerous cases have reaffirmed this standard. When courts have applied the *Chevron* analysis to strike down an agency regulation or interpretation, they have not done so on the basis that a statute did not speak to the issue at hand. Rather, they did so because something in the statute specifically precluded the action the agency had taken. It is clear that nothing in the Department's statutes precludes the Department from instituting a procedure like PIE.

To the contrary, the most important statute authorizing the DOT drug and alcohol testing program, the Omnibus Transportation Employee Testing Act of 1991, confirms the Department's broad authority to carry out its drug and alcohol testing responsibilities. Congress intended that the Secretary use his or her discretion and issue supplementing regulations when necessary to carry out the Department's drug and alcohol testing responsibilities.

The DOT agency drug testing regulations and Part 40 were originally adopted in 1988–89 without any specific statutory authority. These rules were based on the DOT agencies' general safety rulemaking authority and the Department's general rulemaking authority. These DOT agency safety statutes are silent with respect to drug and alcohol testing. They do not describe drugs to be tested, types of tests, random testing rates, laboratories, medical review officers, return-to-duty procedures, testing equipment or personnel, or any of the other subjects addressed by DOT agency substance testing rules and Part 40. Before the Omnibus Act, these statutes provided the only authority for the DOT agency drug testing rules, and they still provide the only authority for the RSPA and Coast Guard rules. There was never any question—aside from the original transit rule—about the authority of the DOT agencies to issue these rules. When plaintiffs challenged these rules, they and the courts focused on the constitutional issues, mentioning the agency's authority for the rules only in passing, since it was so clear.

Under *Chevron*, when the intent of Congress is clear, as is the case here, no further inquiry is necessary. This makes it unnecessary for any reviewing court to move on to the second prong of *Chevron*. If a court did examine the PIE provision under the second prong however, there is little doubt that the Department's action is based on a permissible construction of the statute. The Department 's decision to facilitate employer compliance and protect employers and employees from the consequences of services that are inconsistent with regulatory requirements is reasonable. Each of the requirements of Part 40 is important to ensure the accuracy, integrity, privacy and fairness of the testing process as well as the safety of the public. If a service agent fails or refuses to meet these requirements, then these important interests are adversely affected.

As the testing program and the role of service agents have evolved over ten years, the Department has learned that additional measures are needed to ensure the proper provision of testing services to employers. In every respect, the proposed PIE process comes squarely within the range of agency actions which courts, applying *Chevron*, have approved.

3. *Alternatives*

The Department believes that efforts by industry groups to establish certification programs, training programs, and industry standards are laudable and helpful. Such efforts, however, do not address the issue of accountability for service agents whose noncompliance is serious. These programs cannot respond, in a legally binding way, with real consequences, to protect employers and employees from the misconduct of a party who makes serious errors or chooses to noncomply to gain an economic advantage.

An accountability mechanism like that proposed in the NPRM would effectively complement voluntary industry efforts. By attaching tangible consequences to serious noncompliance, an accountability mechanism would assist industry groups in getting service agents to take certification, training, and industry standards programs seriously.

Some commenters favored one or more of the options discussed in the NPRM preamble, such as certification or self-certification followed by a DOT decertification procedure or a contract-based mechanism. With respect to the contract mechanism, comment was, however, very divided, with many commenters (in response to the PIE proposals or proposed § 40.11) saying that the contract clause requirement was too burdensome or ineffective (*i.e.*, with respect to parties who typically do not have written contracts). The Department does not have the resources to operate a Department-wide active certification program (especially with respect to the motor carrier industry). Maintaining a data base for a self-certification program would be difficult for the Department, and there are significant issues concerning keeping such a data base up to date. For these reasons, we do not believe that these options are preferable to the PIE provisions the NPRM proposed.

A few commenters supported reliance on the legal system (i.e., court litigation) as a tool for employers to use to address problems caused by service agent noncompliance. Nothing prevents employers from resorting to private litigation now or in the future. By nature, however, such private litigation focuses on vindicating the private interests of the employer involved, not in more broadly protecting testing program participants and the public interest. For this reason, we do not view private litigation as a substitute for the PIE provisions.

4. How Does a PIE Proceeding Begin?

Many service agent commenters asked for greater clarity and specificity concerning what ''offenses'' would be sufficient to warrant starting a PIE proceeding. They expressed the concern that the NPRM proposal would give DOT officials, including auditors and inspectors, too much discretion to start PIE proceedings based on minor problems, despite the Department's statements that PIEs were intended to be used in cases of ''egregious'' noncompliance.

As DOT officials said during the listening sessions in PIE roundtables, we do not think it is a good idea to have a definitive list of offenses that would trigger a proceeding. The Department's experience with this program suggests that new situations will always arise. We cannot possibly specify them all at this time. A list that appeared definitive could lead to arguments that the Department was precluded from starting a PIE proceeding because the underlying conduct was not on a regulatory list.

Nevertheless, the Department does believe it would make our intent and policy clearer to state in the regulatory text that this process is intended to be used only for serious noncompliance. We provide several examples of the kind of noncompliance that would, as a policy matter, have a level of seriousness sufficient to warrant starting a PIE proceeding. This regulatory text provision also states that the list is not exclusive or exhaustive: we retain the discretion to start PIE proceedings in situations not on the list and we are not required to start a PIE proceeding every time something on the list comes up.

We also make clear that not everyone with a DOT ID card is authorized to start a PIE proceeding. Only certain officials, such as DOT agency drug and alcohol program managers, are authorized to do so. They may rely on credible information from any source, including but not limited to DOT auditors and inspectors, as the basis for starting a proceeding. As several commenters requested, the final rule text provides that the initiating official must contact the service agent to get its side of the story and any facts it can provide before taking further action, such as issuing a correction notice or a notice of proposed exclusion (NOPE).

One issue on which commenters spoke concerns the relationship of the PIE process and the HHS certification process for laboratories. With respect to matters on which HHS takes certification action against a laboratory, the Department would defer to the HHS action. That is, as a policy matter, the Department would not start a PIE action is HHS had already taken a certification action against a laboratory on the same matter. We do not believe it would be an economical use of resources to have two Federal proceedings in progress with respect to the same laboratory, on the same issues, at the same time. However, if DHHS decided that it was not appropriate to begin certification action (*e.g.,* because the laboratory's conduct did not trigger the HHS ''imminent harm'' standard), DOT could consider whether to begin a PIE proceeding.

One of the concerns that some commenters expressed was that the very existence of a PIE proceeding, regardless of its ultimate outcome, could have adverse economic effects on a service agent. They asked that such proceedings be kept confidential. The Department does not believe that it is possible to keep a PIE proceeding, or the events leading up to it (*e.g.,* a factual inquiry, a correction notice) secret. For example, in seeking to establish whether there is a factual basis for a PIE proceeding, DOT personnel might well have to ask questions of a number of employers about the service agent's activities. On the other hand, the Department will not affirmatively seek to make pending proceedings public knowledge, prior to the issuance of a NOPE. For example, we do not intend to issue a press release or make other kinds of public announcements at the time that we send a correction notice to a service agent. The issuance of a NOPE and the Director's decision, however, are matters of public record.

5. Scope of PIE Proceedings

Section 40.379 of the NPRM proposed that a PIE would apply to all the divisions, organizational elements, and types of services provided by the service agent involved, unless the Director limited the scope of the proceeding. Under some circumstances, affiliates and individuals could also be subject to a PIE. Many service agent commenters thought the scope of a PIE should be narrower, limited to a particular type of activity, affected employer, etc.

The intent of the PIE proposal is to protect the public from the misconduct of an organization. Allowing the organization to segment its activities, and contend that the public should be protected only from some of what it does, is contrary to this objective. Nevertheless, the Department believes that it is appropriate to decide, on a case-by-case basis, whether a compliance problem is limited to one facet of a service agent's activities or pervades the service agent's organization. The Department is therefore making a procedural change from the NPRM. Instead of saying that a PIE would apply to everything a service agent does, the final rule makes the scope of the PIE an issue in the proceeding.

That is, the initiating official would propose a scope for the proposed PIE, depending on that official's view of how pervasive the noncompliance was in the service agent's organization. It might be one activity or organizational element; it might be more than one; it might be the totality of the service agent's activities. The service agent could contest the initiating official's scope proposal, and the Director would make an explicit decision about scope. This is not quite the ''slice of pie'' proposal advanced by some service agents, since the Department would not necessarily be limited by rule to applying a PIE only to the type of activity or organizational element directly involved in the noncompliance. But the initiating official would have the burden of persuading the Director that the

proposed scope of the PIE was appropriate in light of the facts of the case. The final rule text provides several examples to illustrate the way this scope procedure is intended to work.

6. Procedural Issues

Like the NPRM, the final rule requires initiating officials to send a correction notice to a service agent before starting a PIE proceeding. This notice gives the service agent 60 days to fix a problem or change its procedures before a more adversarial process begins. We have added greater specificity concerning the NOPE that begins a PIE proceeding (*e.g.,* specifically requiring information on the proposed scope and duration of the PIE).

We believe that the ODAPC Director is the appropriate person to make decisions in PIE cases. The ODAPC Director is someone who is knowledgeable about the DOT program and regulations but who is not directly involved in their enforcement by the DOT agencies. We disagree with contentions that the Director is inherently biased in potential PIE matters. It is the Director's job to consider such matters fairly and in accordance with the Department's rules, and nothing in the comments persuades us that the Director will be unable to do the job right.

To reassure participants further about the objectivity of the process, we have added language to the final rule specifically prohibiting the ODAPC Director from playing any role in the initiation of a PIE and establishing a ''firewall'' between the initiating official and the Director. This firewall would prohibit any *ex parte* contacts between the two. In any situation in which it would be inappropriate for the Director to act as the decisionmaker (*e.g.,* the Director had recent professional ties to the service agent who was the subject of the PIE proceeding, the Director has had substantial involvement in a matter before it becomes the subject of a PIE proceeding), the rule the Director would designate another person to decide the case. In addition, the final rule lists the elements of the Director's decision, including not only the basic decision about whether to issue a PIE but also decisions about disputed matters of material fact, the scope of a PIE, and the duration of a PIE.

The standard of proof in a PIE proceeding will remain ''the preponderance of the evidence.'' There is no policy or legal basis apparent for raising this burden to the higher ''clear and convincing evidence'' level. Contrary to a few comments, there is no ''presumption of guilt'' on the part of a service agent in a PIE proceeding. The initiating official bears the burden of proof. Administrative proceedings in many kinds of matters, including suspension and debarment proceedings under Part 29, are conducted informally, without formal rules of evidence of the kind used in the court system, with evidence accepted on a general relevance standard. The final rule makes clear that PIE proceedings will be conducted in this way.

The Department takes no position on whether Part 40 creates a private right of action, deferring to the courts or to DOT agency regulations on this issue. While the Department recognizes that a PIE will have adverse consequences for a service agent, we continue to believe that the purpose of a PIE is to protect the public interest, not punishment. This language, which is derived from Part 29, is an accurate statement of the intent of the PIE provision and we are retaining it. A few commenters asked for a time frame for PIE decisions by the Department. We have responded by saying that the Director will generally make a decision within 60 days of the completion of the record in the case, though the Director can extend this period for good cause.

Some commenters requested additional clarification of the standards for determining the duration of a PIE. In response, we have added a new section listing examples of the kinds of factors that the Director will consider in determining the appropriateness, scope, and duration of a PIE. Since the proposed duration of a PIE is one of the elements of a proceeding that service agents can contest, service agents and initiating officials will have the opportunity to refer to these factors in their arguments about duration. In general, we say in the final regulatory text that a PIE stays in effect for one to five years. In deciding on the duration of a PIE, the Director will take into account the seriousness of the noncompliance and other factors listed in the rule. Nine months after the Director issues a PIE, the service agent can apply to the Director in writing to terminate or reduce a PIE. The rule spells out the grounds for such a request.

As noted in the **Effective Dates** section of the preamble, the Department is making the PIE provisions of the rule 30 days from the date of publication. The effect of this action is to make PIE proceedings available to the Department with respect to noncompliance with the existing Part 40 rule between the publication date of this revision and the August 1 effective date of the complete revised Part 40. We are doing so in order to emphasize to service agents that they are accountable for their actions. In some recent instances (*e.g.,* the apparent laboratory evidence tampering incident referred to in ''Basic Rationale for PIE Provisions'' above), the Department would have had grounds for considering the use of PIE proceedings, had they been available to us.

Return-to-Duty Process

The NPRM raised a number of issues surrounding the return-to-duty process. We proposed to consolidate this material in Part 40. One issue concerned the minimum number of follow-up tests that SAPs should prescribe. Should there be an increase over the current rule's requirement of six tests over the first 12 months following an employee's return to duty (*e.g.,* to 12 tests over one or two years)? Another issue was ''aftercare.'' That is, SAPs often make recommendations for continuing assistance after the employee returns to work. The NPRM proposed that employers would have to monitor employees' compliance with these recommendations. A third issue was whether SAPs should routinely receive drug test quantitations.

Comments

Comments from a mixture of employers, employees, and service agents directly addressed the question of whether the Department should increase the minimum number of follow-up tests. A substantial majority of these commenters opposed any change in the current requirement of a minimum of six tests over the first year following the employee's return to duty, and a few of these suggested reducing that minimum. These commenters did not oppose retaining the SAP's discretion to prescribe a higher number of tests or testing that went beyond the first year. Some additional commenters said that number of tests should be determined at the SAP's discretion, or in negotiation between the SAP and employer. On the other hand, a few commenters favored increasing the minimum to 12 tests.

With respect to aftercare, several motor carriers and motor carrier associations opposed the proposal for employers to monitor employee compliance with SAP recommendations. They said it would be too burdensome and went beyond their expertise, which centered on running trucks, not aftercare. A few service agents supported the proposed change. There was also concern expressed, principally in discussions at the listening sessions, that some SAPs were reluctant to recommend assistance

even after employees tested positive, whether out of over-reliance on employee's excuses, claims that the testing process was flawed, or the SAP's personal opinions about the justification for or utility of the testing process. Some commenters asserted that the very fact of a violation showed that an individual was in need of some education or treatment, so it was inconsistent with the purpose of the rules to permit SAPs to find that an individual was not in need of assistance.

Commenters were divided on the issue of whether SAPs should routinely receive reports of the quantitation of drugs in the specimens of individuals who tested positive. Those who favored this approach, including most of the employers who spoke to this issue and some of the SAPs, said that it would be useful to know the levels of drugs in the employees' specimens. This would be helpful to SAPs as they try to evaluate an employee's situation and determine what sort of treatment was appropriate. The majority of commenters opposed providing this information on a routine basis, saying that the quantitation of drugs in a specimen was usually irrelevant to evaluation and treatment and could sometimes be diagnostically misleading. Testing was never intended to diagnose addiction, and urine test quantitations rarely provide a good basis for evaluating an employee's drug problems. A laboratory added that requiring laboratories to report this information to SAPs would be burdensome.

DOT Response

With respect to follow-up tests, the Department has decided that it is not necessary to increase the minimum number. We believe that follow-up tests are very important. They are the best tool we have to make sure that an individual who has returned to duty after a violation remains in compliance while experiencing the actual stresses and temptations of the work environment. However, requiring a greater number of tests could be unnecessarily burdensome in those cases in which SAPs are satisfied that six tests are sufficient. We will keep in place the basic provisions of the existing rule: a minimum of six such tests in the first year of safety-sensitive work following the employee's return to duty. SAPs will continue to have discretion to require a greater number of tests over a period of up to 60 months, as in the current rule.

The Department has become convinced that there is no basis for a SAP ever determining that an individual who has tested positive or otherwise violated the drug and alcohol rules does not need education or treatment as well as follow up testing. For someone who performs safety-sensitive transportation functions, the very fact of a violation indicates a disregard of safety that must be addressed, corrected, and monitored in order to ensure safe performance of those functions in the future. Therefore, the final rule will require the SAP to mandate some level of assistance in every case, as well as to prescribe at least the minimum number of follow-up tests for each employee who returns to duty following any violation of the rules. We also clarify that the SAP must present a copy of his or her written follow-up testing plan to the designated employer representative (DER). The rule text also cautions SAPs against basing any decisions, even in part, on employee claims of flaws in the testing process or any private opinions of the SAP about the validity or utility of the testing process.

In response to comments, the regulation clarifies that the follow-up testing requirement follows the employee from one job to another and persists through a break in service. That is, if after returning to duty with an employer, the employee changes jobs before completing all required follow-up tests, the employee is responsible for completing the follow-up tests with his or her new employer. Likewise, if the employee returns to work, is laid off for several months, and then comes back to work with the same employer, the employee must complete the series of follow-up tests ordered by the SAP.

With respect to employer monitoring of aftercare, the Department is persuaded by the objections of employer commenters that we should not require employers to take on this task. SAPs have the obligation to make recommendations for aftercare where they believe such assistance is needed to maintain sobriety or abstinence from illegal drugs. These recommendations should carry a good deal of weight, because they in effect declare that employee compliance with them is important to ensure safe performance of safety-sensitive functions. The rule states the employee's obligation to comply with these recommendations.

Rather than requiring employer monitoring, however, the rule provides the employer discretion to take a variety of steps. These could include putting compliance with SAP recommendations into return-to-duty agreements, disciplining employees for noncompliance, and using the services of SAPs or employee assistance programs (EAPs) to assist and monitor employees' aftercare activities. The rule notes that employers can choose to monitor these activities, and that employees who fail to carry out the recommendations can be subject to sanctions from their employers. We note that this discussion concerns employer discretion with respect to aftercare (*e.g.,* treatment and education) activities only. Employers do not have discretion with respect to follow-up tests. Employers must carry out the follow-up test instructions they receive from SAPs.

The Department believes that the commenters who opposed routinely providing drug test quantitations to SAPs have the better of the argument. SAPs take a variety of factors—including a face-to-face interview with the employee—into account when determining what assistance the employee needs. The amount of a particular drug in an employee's specimen at a particular time does not determine what sort of treatment is most appropriate for the individual. Consequently, we will not provide for quantitations to be given to SAPs on a routine basis. We do provide, however, that SAPs can consult with MROs (who must cooperate with SAPs) and receive information that the MRO has gathered as part of the verification process. Through this process, SAPs can get additional information that may be of use to them in the evaluation process.

We want to emphasize that neither the rule nor the Department requires employers to fire employees who violate the Department's drug and alcohol testing rules. There is no national policy, and certainly no policy articulated by the Federal government, that commands this result. We would not have this detailed return-to-duty procedure if we believed that no one should be returned to duty after a violation.

As has been true from the beginning, all the Department requires is that an employee who violates the rule not perform safety-sensitive functions until and unless he or she successfully completes the return-to-duty process. Decisions about discipline and termination are left to the discretion of the employer or labor-management negotiations. Where employer policy, or labor-management negotiations, have delegated personnel decisions of this kind to an arbitrator, the Department intends that the arbitrator's decision determines the personnel action that the employer takes. The Supreme Court has recently affirmed these principles. *Eastern Associated Coal Corporation* v. *United Mine Workers of America, District 17, et. al,* 531 U.S. ____ (2000).

Of course, an arbitrator cannot order an employer to return an employee to

the performance of safety-sensitive functions until the employee has successfully completed the return-to-duty process. Nor can an arbitrator or an employer change the laboratory's findings about a specimen or an MRO's decision about whether there is a legitimate medical explanation for a test result.

Collector Training

Competent performance of drug and alcohol testing functions by collectors, BATs and STTs, MROs, SAPs and others involved in the testing process is obviously very important to the integrity and fairness of the Department's program. The Department's NPRM asked questions and offered proposals for the training and qualifications of these personnel. This discussion focuses on collector training, which was the subject of more comment than training for other personnel. Training and qualifications for other personnel are discussed in the section-by-section portion of the preamble.

Comments

Training for collectors in the drug testing program was the subject of comment from a wide variety of parties, including service agents, employers, and unions. Commenters differed on most of the subjects under discussion, including the basic point of the extent of current problems in the collection area. Most commenters on the subject believed that collections were the weakest point of the testing process, though some argued that there was a low rate of collection errors in their experience. Some commenters said that it would reduce collection errors if the Federal Custody and Control Form (CCF) were simplified.

Some commenters favored a formal instruction course for collectors, like the Department's BAT course. Most of these and some other commenters opposed the notions of self-instruction and self-certification for collectors, saying that they were meaningless. They believed that there should be some sort of formal training, with an examination or other means of ensuring that a collector deserved to be certified. Some commenters also supported a ''train-the-trainer'' course requirement to certify trainers.

Other commenters, however, opposed any formal training requirements for collectors, saying it was expensive, burdensome, and might make it harder to find collectors, especially in less densely populated areas. A maritime employer group asked for some exceptions to training requirements for people who were not regularly collectors but might occasionally have to conduct a collection, as in a post-accident situation.

Commenters who thought the NPRM's training proposals were too extensive often objected to requirements for classroom training or other training modes involving a live instructor or monitor. They said the requirements should be more flexible, and provide for training through such approaches as videos, internet-based courses, or instruction and monitoring through telephone or interactive computer methods.

A number of commenters objected to the term ''sufficiently knowledgeable,'' which the NPRM used to describe the personnel who trained collectors. The commenters said the term was too vague. Some of these commenters asked that the rule include more specific qualifications for trainers. Some commenters also objected to the proposal that trainees be required to complete five error-free mock collections, saying that the requirement was either too burdensome (some suggested the number of mock collections be reduced) or insufficient. Some commenters also took issue with the requirement that a collector who made a ''fatal flaw'' mistake should have to be retrained, particularly since they felt it might threaten the validity of subsequent collections the collector conducted prior to the retraining. Others thought it would be better to have a slower trigger for the retraining requirement (*e.g.,* two fatal flaws in two years).

DOT Response

The Department believes that making collector training more effective will be an important step in reducing errors in the drug testing process. The collection of urine specimens is the step in the process with the greatest potential for administrative error, and our own experience confirms the comments of persons who said that collections are a fertile source of mistakes. When our inspectors and program personnel visit collection sites in the field, they commonly find a wide variety of mistakes and misunderstandings in the collection process. We also agree that self-certification is inadequate. For these reasons, we will require additional training of collectors, compared to the present rule. We believe that this training should be provided in as flexible a manner as possible. Section 40.33 contains the Department's resolution of collector training issues.

Part 40 contains much information about how collections must be conducted. It is essential that collectors become knowledgeable about the relevant portions of the new Part 40, DOT collections guidance and relevant DOT agency rule provisions, and we will require them to do so. We also believe that more formal training is needed to ensure that collectors understand and can carry out the requirements of this part. We believe that, as commenters noted, the training can be provided in a number of ways (*e.g.,* classroom sessions, videos, internet courses). We are not prescribing a particular curriculum as we have for alcohol testing personnel, and we will not require that collectors be ''certified.'' By taking this approach, we achieve the objective of additional training while allowing flexibility and minimizing costs. In-person involvement of a trainer is not required for this part of the training process.

To demonstrate that they can practically apply what they have learned, collectors must conduct five consecutive error-free mock collections. We believe this is an extremely important requirement, because collectors must deal with real people and real specimens in their job, not just regulatory text or computer simulations. By mock collections, we mean collections that are not real collections of employees subject to testing under DOT regulations. The five collections must include both uneventful and ''problem'' testing scenarios. Another person must monitor and evaluate the mock collections to ensure that they are error-free. This part of the process does involve the in-person participation of someone to monitor and evaluate the trainee's performance (unless some technology is used that permits the real-time, step-by-step observation and evaluation of the trainee's performance without a person in the same room with the trainee).

The monitor must be someone who has demonstrated necessary knowledge, skills, and experience (1) by regularly conducting DOT drug test collections for a period of at least a year, (2) by having conducted collector training under this part for a year, or (3) by successfully having completed a ''train-the-trainer'' course. The Department sets out these alternatives for qualifying as a trainer in response to comments that said ''sufficiently knowledgeable'' was too vague.

All new collectors must meet these training requirements. In addition, current collectors must meet the requirement within 2½ years after the effective date of this rule (December 2003). This will provide adequate time for current collectors to get the

necessary qualification training, if they have not already done so.

Collectors would have to get refresher training every five years. We believe that, just as other professionals in the drug and alcohol testing business need continuing education, it is important for collectors to brush up on the rules and techniques of their part of the drug testing process, in order to ensure that they perform at the highest level. This training would also focus on any changes in collection technology that had come into use in the meantime.

One of the most important occasions for training is following a mistake that actually results in a test being cancelled. This requirement does not apply every time there is a cancelled test, only when the cancellation is the result of the collector's error. The training would focus on the subject matter that was involved with the error, and would also involve three monitored error-free mock collections. This training would have to take place within 30 days of the collector's being notified of the error. The reason for this training is obvious: if someone makes a mistake once, we want to make sure he or she does not make a similar mistake again.

Commenters noted that it might be very burdensome for employers, or even some service agents, to keep training records for each of their possible many and widespread collectors. To avoid this problem, we are requiring that collectors (like other service providers) keep their own training records, which would have to be made available to employers, other service agents (*e.g.,* C/TPAs) involved with the collector's provision of services, and DOT. In addition, we specify in § 40.209 that a test is not invalidated because a collector has not fulfilled a training requirement. For example, suppose someone collects a specimen correctly but has not completed required training or retraining. The test would not be cancelled because the training requirement was not met, though the collector, other service agents, and employer involved might be found in noncompliance as the result of the failure to meet training requirements.

Transmission of Information Through Consortia and Third-Party Administrators

When the Department began the drug testing program in 1988–89, we had in mind a perhaps simplistic model of how the program would work. We imagined that most employers would have an in-house testing program that would perform most of the tasks the rules required, except that employers would contract directly with laboratories for specimen testing services and perhaps with MROs for medical review services. We thought that owner-operators and other very small employers might well band together in consortia to gain economies of scale in purchasing testing-related services.

The program has developed in quite different directions, to the point where most employers' drug and alcohol testing programs are outsourced, often operated by C/TPAs. These organizations often bundle their services to employers. Only a minority of employers, usually large ones, operate their own programs.

One of the Department's tasks in revising Part 40 is to make appropriate adaptations to the altered shape of the drug and alcohol testing business. We have no desire to stand as King Canute before the marketplace sea. Nor do we wish to surrender to purely economic considerations features of the program we regard as critical to its integrity. The goal of finding an appropriate balance has influenced our efforts in a number of areas as part of this rulemaking, including the functions of MROs and SAPs and the issue of how test results are reported to employers.

In the NPRM, the Department proposed keeping sharp lines of demarcation between different participants in the program. Specifically, we proposed putting into regulatory text the interpretation we have maintained under the existing rule with respect to the transmission of drug test results from MROs to employers. That is, MROs must report the results directly to employers. C/TPAs could not act as intermediaries in this process. This position was based on the premise that indirect reporting was likely to be slower, and more prone to error and compromise of confidentiality, than direct reporting.

Comments

The bulk of comments on this issue came from TPAs, who asserted that they should be permitted to act as intermediaries in the transmission of drug testing results. There were also comments from employers and unions, most of which supported the TPAs' position. During discussions of this issue in the listening sessions, DOT staff asked TPAs to address the question of how it was as or more efficient and effective to move a result from Point A (the MRO) to point B (the employer) through Point C (a TPA), rather than sending it directly from Point A to Point B. Many of the C/TPA comments did address this question.

A common response was that many MROs do not have the staff or electronic capability to receive, process, and transmit results to clients. Indeed, many smaller doctors' offices would find it burdensome to handle all the paperwork. It is more efficient division of labor to have doctors concentrating on medical review and TPAs on information distribution, some said. TPAs, commenters said, are set up to act as electronic transfer points for data, allowing for the more efficient and timely delivery of results. Requiring the MRO to transmit the results directly would increase rather than decrease processing time and add costs.

Commenters favoring change in this proposal also said that TPAs know the rules and regulations well, since this is their full-time business. Small employers find it easier to call one place—the TPA—for all drug program information rather than having to deal with a variety of sources. Some of these commenters noted that, in the Coast Guard program, TPAs had played this role successfully for some time. They said there was no evidence of any detriment to public safety in this case, or in other cases where TPAs (contrary to existing rules) have transmitted results.

Some MROs and TPAs disagreed with this point of view, citing concerns about delays, administrative errors, and risks to confidentiality. Commenters said that many MROs are fully capable of transmitting results information directly to employers, and that if an employer found that it was not receiving results in a timely fashion, it could change MROs. In addition, direct MRO transmission may provide greater value to employers, because MROs can answer questions about the result and help the employer resolve procedural issues.

Comment on this issue focused on MRO transmission of verified drug testing results to employers. However, many commenters mentioned other areas in which similar issues arise, such as laboratory transmission of results to MROs, transmission of SAP reports to employers, and transmission of alcohol test results from BATs to employers.

A related, but distinct, issue concerned who could appropriately play the role of the designated employer representative (DER). Some commenters said that C/TPAs should be able to act for employers as DERs, at least in small companies. Some of these comments alleged that the role of the DER was a complex, multifaceted one, and that it would be very costly, particularly for small companies, to hire a DER.

DOT Response

The Department is persuaded by the comments on this subject that C/TPAs

have the ability to transmit verified drug test results to employers as or more efficiently than MROs who transmit the information directly. While we understand, and to an extent share, concerns about potential delays, errors, and breaches of confidentiality when intermediaries are used, we do not have any evidence in the record that these problems actually occur in any significant way. The Coast Guard experience, as reported by commenters (including some employer and union commenters) and verified by Coast Guard staff, suggests that the parties concerned in that industry are satisfied with this approach.

Consequently, the final rule (see —40.345) gives employers the choice of receiving drug test results directly from the MRO or via a C/TPA. We emphasize that it is up to the employer—not the C/TPA—to make this choice. The employer can make this choice for any or all of the items listed in Appendix F (e.g., an employer may choose to receive some items via the TPA and others directly from an MRO). The rule authorizes C/TPAs to act as intermediaries in the transmittal of information to employers only with respect to the specific provisions of the rule listed in Appendix F. C/TPAs are prohibited from acting as an intermediary in transmitting information not listed in Appendix F.

For example, C/TPAs are not allowed to act as an intermediary who transmits laboratory test results to MROs , SAP reports to employers, or medical information from MROs to employers. In the case of the laboratory reports, we believe that the direct link between laboratories and MROs is critical to the timely and independent medical review of those results. (Certainly laboratories have the electronic capability to readily transmit results directly to MROs in a timely and accurate fashion.) With respect to SAP reports, we are concerned that using an intermediary creates the opportunity and temptation to alter the SAP's recommendations (a problem that DOT staff have noted in the current program). With respect to medical information, we believe this is confidential medical data that should not pass through an additional hand on its way from the MRO to the employer.

The discussion of this issue among commenters focused mainly, though not exclusively, on drug test information. A few commenters mentioned that similar considerations should apply to alcohol testing information. With respect to ''negative'' alcohol test results (i.e., results of less than 0.02), we agree. The same rationale that supports permitting drug testing information to be conveyed by C/TPAs applies to this information. However, we draw a distinction with respect to alcohol testing results of 0.02 or higher. These results—unlike positive drug test results or negative drug or alcohol test results—mean that an employee is, to some extent, impaired by alcohol. As a safety matter, the employer must immediately remove the employee from performance of safety-sensitive functions. This is a situation where time is of the essence, and we therefore will continue to require BATs to transmit these results directly to employers. C/TPAs are not authorized to act as an intermediary in this situation.

We believe that it is essential that someone employed by the actual transportation employer act as the DER. The DER's function is to receive information about certain kinds of test results and take required action, such as removing an employee from the performance of safety-sensitive functions. Someone who is an employee of a C/TPA, rather than of the actual transportation employer, is less well situated to perform these functions, especially since a C/TPA representative generally does not have line authority over a transportation employer's employees.

Much of the comment on this issue appears based on a significant misunderstanding of the role of a DER. A DER is not a drug and alcohol program manager. A DER does not need extensive knowledge about the DOT drug and alcohol testing program and need not spend extensive time on DER duties. The DER is simply someone who can act immediately to remove an employee from safety-sensitive functions, or take other appropriate action, upon receipt of information that the employee has violated the rules or needs to be subject to certain testing requirements. Particularly for small companies (e.g., a 3-10 driver trucking company), the DER is likely to perform this function on a collateral duty basis, fielding a rare phone call (i.e., there are not many tests per year and only a small percentage of tests result in violations) and removing an employee from safety-sensitive functions on those occasions. This is not a time-or resources-intensive activity, and it would certainly not require hiring an extra human resources staff person.

The one exception the final rule makes concerns owner-operators. Under the FMCSA rule, owner-operators are, in effect, required to get at least random testing services through a C/TPA. In an owner-operator, the driver is his or her own boss, so there is no one else in his or her own organization to direct him or her to stop performing safety-sensitive functions. In this situation, we think it is probably better to permit the C/TPA to perform what otherwise would be a DER function.

Collection Process Issues

Commenters were interested in a variety of issues in the drug testing collection process. These included dilution issues, the consequences of refusing to drink fluids and the length of the interval before the second collection attempt in ''shy bladder'' situations, retests under direct observation when a split specimen is unavailable for testing, using split specimen collections in all DOT modes, and having employees remove boots as part of the preparation for a collection.

Comments

The first issue in this category is whether, when there is a specimen that is both negative and dilute, there should be an immediate recollection under direct observation. Commenters took a number of positions on the issue. Some employers and service agents favored making retests under direct observation mandatory, on the ground that a dilute specimen effectively formed a basis for a reasonable suspicion that the employee had tried to conceal drug use. Some unions and service agents opposed such a requirement because it would intrude on employees' privacy, might well result from innocent consumption of water, and was of dubious value in deterring and detecting illegal drug use.

A plurality of commenters favored making a recollection, as well as the decision about whether to use direct observation, optional with the employer. This approach, they said, would recognize the variety of situations in which a dilute specimen may occur. It could be done in consultation with MROs, to ensure that there was some medical input into the employer's decision.

The second, related issue is whether an employer should be able to disregard a negative dilute result. For example, suppose an employer receives such a result on an applicant's pre-employment test. Should the employer be able to require the applicant to take another test to get a ''real negative'' before beginning safety-sensitive work? Most employers, and some service agents, who commented on this issue favored this approach, especially in pre-employment testing. They did so in the belief that a negative dilute result was, at best, questionable. Even if it did not result from a deliberate attempt to cheat on a test, it was not as definite a

demonstration of compliance as a negative test from a more concentrated specimen. Unions and some service agents disagreed, saying that this would unnecessarily burden employees, including many who could achieve dilute (as distinct from substituted) results naturally, by drinking a lot of water (which some commenters made a point of noting was a legal substance). This approach would involve a ''guilty until proved innocent'' approach, in this view.

Most, though not all, employers said that an employee who refuses to drink additional liquids after failing in his or her initial attempt to produce a sufficient specimen should be regarded as having refused to test. These commenters saw refusals to drink as attempts by employees who had used drugs to avoid a positive test. They also viewed it as a waste of up to three hours of time that the employee remained off the job (but presumably in paid status). Some service agents also shared this point of view. Unions and other service agents disagreed. They said that an employee could have legitimate health or other reasons for not wanting to drink additional fluids. Moreover, if an employee fails to drink fluids, and consequently fails to produce a sufficient specimen on the second try, the employee will be referred to a physician for an evaluation. If the physician does not find that a medical condition produced, or could have produced, the inability to provide a sufficient specimen, the employee will be treated as having refused the test. This consequence is sufficient, these commenters said.

When an employee has a verified positive test, the Omnibus Employee Testing Act gives the employee the right to request a test of the split specimen. The Department has long taken the position that if the employee makes a timely request to test the split specimen, and the split specimen is unavailable for testing (e.g., the split specimen was never collected, leaked away, or was lost), the test must be cancelled. While we believe this outcome is necessary as a matter of law, it raises a safety concern. In such cases, we have an apparently valid, verified positive result, indicating that the employee used illegal drugs. However, because of the accidental unavailability of the split specimen, the employee can continue to perform safety-sensitive functions.

In response to this concern, the NPRM sought comment on the idea of requiring a recollection under direct observation in these cases. This might detect drug use by the employee and result in his or her removal from the performance of safety-sensitive functions. The rationale for the direct observation aspect of the procedure reflects the belief that an employee, having recently tested positive, may have an additional incentive to cheat on the second test.

Comment was divided on this issue. Employers generally supported the proposal to require recollection under direct observation on the safety rationale mentioned above. Unions and some service agents opposed the proposal, saying that it undermined the employee's right to a test of the split specimen. Some added that the second test would not really answer the question of whether the employee has tested positive on the first test. Opponents of the proposal particularly objected to the direct observation aspect of it, on intrusiveness and violation of privacy grounds. Why, they asked, should someone suffer a directly observed test because the collector made an error?

Currently, those DOT agencies covered by the Omnibus Transportation Employee Testing Act—FRA, FAA, FTA, and FMCSA—are required to collect split specimens. RSPA and Coast Guard, whom the Act does not cover, give employers the choice of collecting single or split specimens. Commenters on this point almost unanimously favored requiring split specimens in all DOT agency programs. They said that this would be much simpler and less confusing, and likely would reduce the incidence of errors (e.g., failure to collect split specimens where required). Split specimen collections are not any more expensive than single specimens, one commenter said. One commenter questioned the Department's authority to require split specimen testing in RSPA and the Coast Guard absent legislation.

The Department has heard concerns, over the years, that some employees have concealed adulterants or other means of tampering with tests in their boots (e.g., cowboy boots). For this reason, the NPRM proposed that collectors would ask employees to remove their boots, so that collectors could check them for such items. Commenters almost unanimously panned this proposal, asserting that it was intrusive, ineffective, and inconsistent (i.e., vis a vis the rule's treatment of other footwear and clothing). Commenters raised specters ranging from confrontations between employees and collectors to exposing collectors to unpleasant foot odors.

DOT Response

With respect to the issue of negative dilute tests, the Department has decided to give employers discretion about how to handle these situations (see —40.197). There are reasonable arguments on both sides of this question, and the Department is not persuaded that that there is a single, across-the-board, right answer. The variety of circumstances among employers appears too wide to permit a unitary solution. In response to concerns about recollections being unduly burdensome on employees, the Department will require that a given employer treat all employees equally, to avoid the possibility of arbitrary selections of individuals for recollection. That is, an employer would have to treat all situations in a given category the same way (e.g., require recollections in all pre-employment test situations that had negative dilute results). This would prevent employers from singling out disfavored employees. In addition, employers would be limited to a total of two tests (the original negative dilute result and one recollection). They could not conduct additional tests if the recollection were also a negative dilute, for example. This provision limits the potential burden on employees.

If an employer chooses to conduct another test, it could not be conducted under direct observation, unless one of the other circumstances permitting or requiring direct observation occurred. We use direct observation primarily to counter the likelihood of tampering at the collection site. This makes sense in situations where we are mostly concerned about adulteration or substitution. Most dilution cases, however, arise because an individual hydrates his or her system before going to the collection site. Privacy issues aside, then, direct observation seems off point in the dilution situation. What is useful is giving an employee the shortest possible interval between notice of the test and the conduct of the test, so that the individual does not have time to overhydrate. For this reason, the rule requires employers to provide no advance notice of the recollection to employees.

The Department will not include any general provision requiring or authorizing employers to disregard the results of negative dilute tests. Given the structure of the rule, such a provision is unnecessary. Employers have the discretion to conduct one recollection following a negative dilute result. If the employer chooses not to conduct a recollection, then the negative result is the only result it has, and the employer will rely on the result just as is does in any other case. If the employer does conduct a recollection, then the result of

the recollection—not the original test—becomes the result on which the employer relies for all purposes. The original test would be cancelled in this situation, and not reported for management information system (MIS) purposes.

The bottom line in any ''shy bladder'' situation is that, if, by the end of the collection process, the employee has not produced a sufficient specimen, the employee must be evaluated by a physician. Unless the physician finds that a medical condition resulted, or could have resulted, in the inability to provide a sufficient specimen, the employee is regarded as having refused to test (see —40.193). Given this provision, we believe it is unnecessary to say that a refusal to drink fluids, standing alone, is a refusal to test.

As some commenters said, there may be legitimate reasons for an employee's decision not to drink fluids in this situation. In any case, if the employee declines to drink, subsequently does not produce a sufficient specimen, and cannot establish a medical condition explaining his or her inability to provide the specimen, a refusal to test will be established. While having employees waiting in a collection site for three hours, with or without drinking, may annoy employers and collectors, we do not believe this is a sufficient reason to terminate the shy bladder process because the employee does not choose to drink during that period.

We believe that there is a strong safety rationale for requiring a recollection under direct observation following a verified positive, adulterated, or substituted test that is cancelled because the split specimen is unavailable for testing. In this situation, we know that there were drugs or an adulterant in, or substitution of, the primary specimen, and that there was no legitimate medical explanation. Split specimens fail to reconfirm the result of the test of the primary specimen in only a tiny minority of cases. If we do not collect another specimen in this case, there is a very high probability that we will be permitting an employee who has used illegal drugs, or tried to tamper with a test, to continue performing safety-sensitive functions. That is a significant safety concern.

By recollecting another specimen, we have some possibility of detecting continuing drug use. Knowing that recollections will occur in this situation may also have some deterrent effect on employees. By recollecting another specimen under direct observation, we can limit the opportunities for tampering, for which there is a heightened incentive in this situation. We do not view this provision as penalizing an employee because a laboratory or collector erred. Rather, in the face of a laboratory or collector error, we view this provision as closing an inappropriate loophole for an employee who appears to have used illegal drugs or tried to defeat a test.

We agree with commenters that it makes much more sense for all DOT agencies to have consistent requirements concerning split specimens. Therefore, Part 40 requires all collections to be split specimen collections, and RSPA and Coast Guard will amend their rules accordingly. We will delete from Part 40 all references to single specimen collections. There is no legal authority issue here: RSPA and Coast Guard base their rules on their statutory general safety authority, which does not contain specific requirements or prohibitions concerning how drug specimens are collected. There is no legal difference between these agencies using their discretion in implementing their general safety authorities by requiring split specimen testing and using it to give employers an option between split specimen or single specimen collections.

We are persuaded by commenters that we should not go forward with the proposal to have collectors remove and inspect boots. The problems of this approach likely outweigh the benefits. Therefore, we have booted this provision out of the final rule.

Information Release Issues

MROs sometimes find themselves in a dilemma. They verify a positive test result on an employee of Employer A. They also know that the same employee works in a DOT-regulated safety-sensitive position for Employer B. Consistent with safety and confidentiality responsibilities, what should the MRO do? The NPRM sought comment on this issue. The NPRM also asked for comment on whether MROs and other parties (e.g., C/TPAs) should report positive tests and other rule violations to DOT operating agencies, so that they could take enforcement action.

Comments

There was a variety of comment on the idea of MROs sharing test information with other employers. Many employers, MROs, unions and other parties opposed allowing MROs to do so because it would breach employee confidentiality. Given the large data bases that some service agents maintain, this breach could be very wide, some commenters said. Some service agents questioned whether the proposed rule's language would have the effect of creating a duty on service agents to conduct searches of such data bases.

Other MROs and employers favored giving MROs this discretion, in order to enhance safety and help MROs who find themselves in this dilemma. Commenters cited potential liability concerns on both sides of the question. Other commenters suggested that more systematic approaches to this problem might be more productive, such as creating a national data base of persons who had violated rules or requiring employers hiring new workers to check with previous employers about past test results (as FMCSA's rule already does). Canadian commenters also mentioned a concern that information release to third parties without individual employee consent may violate Canadian law.

Commenters addressed the issue of release of information in legal proceedings. The existing rule and the NPRM focus on legal proceedings brought by an employee (e.g., an unjust termination suit). What about personal injury cases in which the employee's test result is a relevant issue, commenters asked.

Some commenters thought that having service agents report rule violations to the DOT agencies was a good idea that would enhance safety. For example, if an owner-operator fails to show up for a test and continues to drive, only the C/TPA may know of the refusal. If the C/TPA does not report the problem to FMCSA, the likelihood of the owner-operator getting away with his or her refusal is heightened. Others raised confidentiality concerns and thought that there could be problems if service agents reported incomplete or erroneous information to the DOT agencies. Some service agents also feared that if they had authority to report violations to DOT agencies, even if this were not mandatory under the rule, they would be liable for not doing so. Others thought that this would create a difficult conflict of interest situation for service agents.

DOT Response

The Department has decided to drop the proposal to permit or require MROs to pass on to third party employers information about the results of tests the employee took at the direction of another employer. The Department understands that confidentiality rules sometimes place MROs in a difficult position. Nevertheless, confidentiality is a cornerstone of the balance between safety and employee privacy that is crucial to the acceptance and constitutionality of the testing program. The Department is also concerned that

it would be very difficult to draft a provision that solved the ''doctor's dilemma'' situation without opening the floodgates to widespread searching of large data bases for information on employee testing records that could severely compromise confidentiality. We do not think our NPRM language succeeded at this task. Consequently, as under the current rule, MROs will be prohibited from passing such information on to third party employers without the employee's consent. As described in the discussion of § 40.25, we are adding a requirement to query previous employers for drug and alcohol test information in place of the proposed provision, based on an existing FMCSA provision.

Another alternative to the proposal would be to create a Federal data base that would include all test results, which authorized employers could search to learn authorized information about current or prospective employees. This is a significant issue, but not one we are able to resolve at this time. We do believe that, in order to be effective, a data base of this sort would have to be national in scope under Federal supervision, rather than a mixture of state, local, and private data bases. It would also have to successfully solve security, access, due process, and updating issues. Creation of such a data base remains a matter for further study.

The Department has decided to broaden the scope of release of information in the context of legal proceedings. We have added a provision (see § 40.323) that would permit employers to release test information in a criminal or civil court proceeding resulting from an employee's performance of safety-sensitive duties, if the court orders it. For example, in personal injury litigation following a truck or bus collision, the court could determine that a post-accident drug test result of an employee is relevant to determining whether the driver or the driver's employer was negligent. The employer would be authorized to respond to the court's order to produce the records.

There would be limits on the use of this information, however. The employer could release the information only to the decisionmaker, such as the judge in a lawsuit. It could be released only subject to a binding stipulation or protective order that the decisionmaker to whom it is released will make it available only to the parties to the proceeding, who could not disseminate it further or use it for other purposes. The Department believes that this approach provides for relevant use of test information without permitting the information to be spread about too widely. These limits also apply in situations where the information is made available in a proceeding brought by the employee (*e.g.*, a grievance, arbitration, or lawsuit concerning personnel action following a violation).

The Department has decided against requiring service agents to report apparent violations of the rules to the DOT agencies. Service agents can do so in any situation in which DOT agency rules already permit them to do so. The principal reason for this decision is that the Department's enforcement resources are limited. The DOT agencies must take great care in prioritizing the use of those resources, so that the greatest safety benefit is derived from their allocation.

Service Agent Contract Language

The NPRM proposed that every contract or agreement between an employer and a service agent would have to include an assurance of compliance with DOT rules. The purpose of this proposal was to ensure that the obligation to comply with Part 40 and other DOT rules was not only a matter of regulation, but also a key part of the contractual relationship among participants in the testing program.

Comments

Some employers and unions favored the proposed requirement, saying that it would help them ensure that services were provided properly. They said it would create universally understood contract remedies if service agents failed to provide appropriate services. Most of the commenters on this proposal were service agents, and they almost unanimously opposed the proposal. They said it would add substantially to the paperwork burden of the rule and would add costs (*e.g.*, for attorney involvement in the contracting process). Moreover, opponents said, there are many times in which employers do not have written contracts with some service agents (*e.g.*, collection sites remote from the employer's principal place of business), so there is no contract in which to incorporate such a clause. Requiring written contracts where none now exist would also be unnecessarily burdensome, they said. A mandatory contract clause could also lead to litigation, some commenters feared.

DOT Response

The purpose of the proposed requirement was to ensure that compliance by service agents with this and other DOT rules was an enforceable contractual responsibility. The Department now believes that this purpose can be achieved by other means. We have replaced the proposed written contract clause requirement with a regulatory statement (see § 40.11(c)). It provides that all agreements and arrangements, written or unwritten, between employers and service agents are deemed, as a matter of law, to require compliance with all applicable provisions of this part and DOT agency drug and alcohol testing regulations. The rule declares that compliance with these provisions is a material term of all such agreements and arrangements. Combined with the PIE provisions of Subpart R, this provision ensures that when a service agent is in noncompliance, DOT (through a PIE) or an employer (through a contract action) can respond effectively to service agent noncompliance. These provisions will achieve the Department's objective without incurring the paperwork burden and other problems cited by commenters with the NPRM provision. We also did not want to create potential compliance problems for service agents and employers based on the lack of a written agreement.

Electronic Technology Applications

The NPRM asked for comment on how best to incorporate electronic technology into the drug and alcohol testing process to a greater extent.

Comments

A substantial majority of all commenters on this issue strongly supported the wider use of electronic technology throughout the DOT drug and alcohol testing program. The suggested applications included such things as electronic signatures by various participants, an electronic CCF, and electronic storage and transmission of data. One of the goals mentioned in some comments was the ''paperless lab.'' Supporters emphasized the greater speed and efficiency of these applications, contrasted to a paper-based system. Some commenters noted that electronic applications of this kind were already in wide use in the private, non-regulated sector of drug and alcohol testing, and that the Food and Drug Administration had approved the use of electronic signatures in some contexts.

Commenters mentioned that, in order to do the job right, electronic applications had to ensure the integrity and security of information, but many commenters also said that appropriate technological tools for this purpose already existed. Some commenters sounded cautionary notes, particularly with respect to the Department being assured of the effectiveness of system safeguards and the forensic acceptability

of electronic records and signatures before authorizing additional use of electronic applications in the program.

DOT Response

The Department believes that the increased use of electronic methods in the program is both inevitable and beneficial. At the same time, we want to make sure that there are good, consistent minimum standards for the use of this technology, so that the integrity and confidentiality requirements of the program continue to be met. For this reason, the Department, in cooperation with HHS and the Office and Management and Budget (OMB), intend to form an advisory committee under the Federal Advisory Committee Act. Many of the interested parties began meeting this past summer to discuss the issues under the auspices of an OMB information technology initiative.

This committee would be charged with making recommendations to DOT and HHS concerning changes in our regulations we could make to accommodate electronic technology. The committee would also make recommendations about consistent minimum standards for the technology used in Federal drug and alcohol testing programs. The Department anticipates that, following the receipt of the committee's recommendations, DOT and HHS will propose changes to Part 40 and the HHS Guidelines that will result in authorizing the more widespread use of electronic technology in the program.

Meanwhile, the Department will make some modest changes to its requirements. For example, we will permit greater use of faxes and scanned computer images for reporting test results. Additionally, we are permitting laboratories to send electronic results reports to the MROs, provided that the laboratory and the MRO ensure that the information is accurate and can be transmitted in such a manner as to prevent unauthorized access or release of this information while it is transmitted or stored. The Department, at this point, is not requiring specific transmission or security standards, but as these are developed in the future, we will provide them as guidance for laboratories and MROs. Even when the Department has changed its regulations to permit greater use of electronic methods, we expect to retain the option to use a paper-based system, however. This is because many of the participants in our program, such as small transportation employers, may not be equipped to participate in a fully electronic system.

MRO/Laboratory Conflicts of Interest

The Department has long believed that the MRO has a uniquely important responsibility for maintaining the integrity of the Department's drug testing system. For that reason, since the beginning of the Department's program, we have been concerned about the potential of conflicts of interest between MROs and other participants in the system, particularly the laboratory. For example, if an MRO is reviewing results of a laboratory with which the MRO has a financial relationship, it could happen, or appear to happen, that the MRO would be less likely to bring problems in the laboratory's test results to light. In the NPRM, the Department asked commenters for their thoughts on conflicts of interest, particularly whether the Department should state with greater specificity the kinds of relationship that involve conflicts or the appearance of conflicts.

Comments

Some commenters questioned the NPRM's focus on the MRO-laboratory relationship, saying there were other relationships among participants that could be as or more troubling (*e.g.*, laboratory-collection site relationships). Commenters also differed about what the rule should say about laboratory-MRO relationships. Some commenters favored a strict separation of roles, while others said that the program would be more efficient and less costly if MROs and laboratories could collaborate more closely. Some commenters, in response to a preamble question, supported adding more specific guidance to the rule on what sorts of relationships were considered inappropriate.

A large majority of comments on this issue said it was important for the rule text to list the kinds of relationships that the Department regarded as creating conflicts of interest between MROs and laboratories. The comments acknowledged the significance of maintaining laboratory/MRO relationships that were free of such conflicts, in order to maintain the integrity of the program. In the absence of specificity, however, a general provision prohibiting conflicts or requiring a certification that there were none would be ineffective, they said. Commenters generally agreed with the list of conflicts listed in the NPRM preamble, as a means of ensuring the necessary separation of functions among participants. Commenters who dissented from this position usually argued that to prohibit close MRO/laboratory relationships would interfere with the integrated organizational arrangements that were most efficient in providing services to customers economically (*e.g.*, one-stop shopping or ''turnkey'' programs).

DOT Response

We agree that other relationships in the program might create conflict of interest issues. However, we continue to believe that the focus on the MRO-laboratory relationship is appropriate. In our view, the MRO is a key participant in the process, whose role is to be the most important protector of the accuracy and integrity of the process. A potential conflict of interest between an MRO and a laboratory, whose results the MRO must review, oversee, and, if necessary, question, is a particularly sensitive matter for the integrity of the program. We urge appropriate caution, use of firewalls, etc. to avoid potential conflicts of interest among all participants, but we believe that clear regulatory guidance is important in the MRO/laboratory relationship.

While we recognize that commenters' views differ, we believe the program is best served by avoiding MRO/laboratory conflicts of interest or their appearance. We believe that a clear separation of their respective roles is necessary for this purpose. We have maintained this separation under the current rule, and we do not have evidence that this has unduly hampered the efficiency of the program.

In response to comments, we have added list of actions that we view as creating the reality or appearance of a conflict of interest. These examples are not new creations: they codify guidance that the Department has given in several specific situations over the years. They are essentially the same examples listed in the preamble to the NPRM, with the clarification that they apply to MROs who actually review test results produced by the laboratory in question. This list of examples is not exclusive or exhaustive: other situations may arise that would constitute conflicts. The list is the following:

(1) The laboratory employs an MRO who reviews test results produced by the laboratory.

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory.

(3) The laboratory designates which MRO the employer is to use, recommends certain MROs, or gives the employer a slate of MROs from which to choose. We do not interpret this provision to prohibit laboratories from referring employers to a large, global list of MROs (*e.g.*, a list of all MROs who have been certified by one of the

national MRO training organizations), so long as the laboratory does not edit the list or express a preference or recommendation among the MROs on the list.

(4) The laboratory gives the employer a discount or other incentive to use a particular MRO.

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory;

(6) The laboratory derives a financial or other benefit from having an employer use a particular MRO; or

(7) The laboratory permits an MRO, or an MRO's organization, to have a significant financial interest in the laboratory.

Validity Testing

By validity testing, we mean testing that laboratories conduct to deter and detect tampering with tests. The two most important categories of tampering are adulterating a specimen (*e.g.*, putting a substance into a specimen designed to mask or destroy the drug or drug metabolite that the specimen may contain) or substituting a specimen (*e.g.*, supplying water or some other substance in place of urine). The NPRM proposed to require laboratories to conduct validity testing on all specimens. It asked for comment on whether MRO review and split specimen testing should be applied to specimens that laboratories found to be adulterated or substituted, as they are to specimens that test positive for drugs. Validity testing is probably the most difficult and controversial issue in this rulemaking.

Comments

1. Adulteration

A significant majority of commenters on the subject supported the idea of testing for adulterants. Commenters said that the purpose of such testing was to counteract tampering, which some said appeared to be on the rise in their experience. They cited the increased availability of substances and techniques claiming to protect drug users from testing positive for drugs, which are quite commonly advertised in publications and on the internet.

Many commenters cited the volatility of the adulterant market, noting that the popularity of particular adulterants rise and fall. As countermeasures to one substance are found, other adulterants come into prominence, in a continuing ''arms race'' between those who try to facilitate and those who try to deter and detect ways of ''beating the test.'' Therefore, commenters said, there needs to be flexibility in the ''adulteration panels'' that laboratories use, to allow them to keep up with an ever-changing adulterant market. It is not helpful, in view of this need for flexibility, to mandate testing for specific substances such as nitrites, several commenters said.

Two employee groups said that there was no evidence supporting the need for adulterant testing. They also said that adulterant testing was too burdensome. One laboratory suggested that adulterant testing should remain discretionary with laboratories, rather than mandated by the rule. Another commenter said that there should be standardized DHHS testing methodologies for adulterants, just as there are for drugs. Several commenters supported extending the blind testing program to adulterated and substituted specimens as a further safeguard. A few commenters addressed the issue of cost, but they did not agree with one another about whether adulterant testing would add significant costs to the program. Supporters of alternative testing methods (*e.g.*, saliva, hair, on-site testing) argued that their methods would be quicker and more effective at detecting adulterants than the present laboratory-based urine testing system.

2. Substitution

Generally, commenters who supported testing for adulteration also supported testing for substitution. However, a number of commenters had greater concerns about substitution testing. Some comments, including one extensive comment submitted by a union, contended that the criteria for substitution developed by HHS, and incorporated in the NPRM, were faulty and based on inadequate studies. In particular, this comment criticized the HHS criteria because the literature on which the specific gravity and creatinine levels had been based included very few ''paired studies'' looking at both criteria at once. Other comments criticized the studies because they had not specifically covered certain employee subgroups. A few comments suggested changing the name of this sort of specimen from ''substituted,'' which they found too conclusory, to ''hyper-dilute'' or something similar, which they believed to be more neutral and descriptive.

During the listening sessions and in written comments, a number of individuals said they, or people they know, had been unfairly terminated on the basis of substitution. These individuals were not drug users, they said, but had consumed large quantities of water over a long work period. In addition, they were often small-framed minority women, vegetarians in some cases. They suggested that a combination of these circumstances could have resulted in the natural, innocent production of urine meeting the substitution criteria. They sought additional procedural protections and revision of the substitution criteria to prevent people from being unfairly found to have substituted a specimen.

3. Split Specimen Testing

The Department presented three basic options for comment concerning the application of split specimen testing to findings of adulteration and substitution. The first option would have continued the Department's current policy of prohibiting split specimen testing in these cases. The second option would require split specimen testing in adulteration and substitution cases, on the same model as the current requirement for drug positives. The third option would add to the present system a requirement for the laboratory to test an additional aliquot of the specimen to ensure that the result could be replicated.

All unions who commented favored the second option. They believed this was necessary if the system was to be fair and provide due process to employees whose specimens were found to be adulterated or substituted. They asserted that the scientific basis and technical standards for adulteration and substitution findings were weaker than in the case of drug positives, but pointed out that the consequences were equivalent (or more severe, in some cases). Employees should have the same chance to double-check the former as the latter. Some employers and service agents also supported this approach, principally on fairness grounds.

Supporters of the first and third options, including a number of employers and service agents, opposed split specimen testing in adulteration and substitution as providing a second opportunity for an employee to beat the test. In addition, they said that the properties of many adulterants were unknown, and an adulterant might degrade in so short a time so that it would fail to reconfirm on a split specimen test. Variations in the findings about the urine could result from something as simple as the freezing and thawing of the split specimen, one commenter said. Among commenters in this group, a number supported Option 3 in preference to Option 1 because it would provide some additional protection for employees without having the disadvantages of opening the split specimen.

4. MRO Review

Generally speaking, commenters lined up in the same way concerning whether MROs should review and verify adulterated and substituted test results as they did concerning split specimen testing for these results. Unions and other supporters said that MRO review, parallel to that for drug positives, should be made available as a matter of fairness. For example, if a small female flight attendant who has consumed a lot of water on a long flight gets a substituted test result, she should have the opportunity to offer an explanation to the MRO. If she made her case, the MRO should verify the result negative, just as in the case of a drug positive with a legitimate medical explanation.

Opponents of MRO review for adulteration and substitution cases said that it would be cumbersome. Also, there are not established standards for a ''legitimate medical explanation'' in the adulteration and substitution area as there are with respect to drugs, meaning that MROs would be acting in a less well informed way. Some commenters said that there were no legitimate medical explanations for the presence of adulterants, so the medical review process would be an empty exercise.

DOT Response

We begin with the premise that tampering with drug tests is a bad thing and a serious safety concern. When people do so, it is probably because they want to continue using drugs while also continuing to perform safety-sensitive duties. Continuing to do both these things is precisely what the DOT drug testing program, in the interest of safety, is designed to prevent. To the extent that people believe that they can successfully beat a test, the deterrent effect of the program is diminished. One can oppose the concept of testing to catch tampering only if one believes that it is acceptable for people both to continue using drugs and to continue performing safety-sensitive duties.

There were no commenters who said that they opposed the concept of testing to catch tampering with drug tests. Some commenters, however, said that it was not proven that tampering was so serious a problem as to warrant validity testing. The majority of commenters disagreed, and many were parties (laboratories, MROs, C/TPAs) who have significant experience in reviewing specimens and test results. Our own experience in working with participants in the program is consistent with that of commenters who believe that adulteration and substitution are relatively prevalent, serious issues requiring a regulatory response. The wide public advertising of substances and techniques to protect drug users from tests is further suggestive of a thriving cottage industry designed to help people beat drug tests.

The Department consequently will make validity testing mandatory. Laboratories will test all incoming primary specimens for dilution, substitution, and adulteration. We believe that mandating that all laboratories test all primary specimens will result in greater uniformity of testing methods. Testing methods must be consistent with HHS requirements and guidance (HHS Program Documents 35 and 37 at the present time), upon which DOT will rely for purposes of this rule. As noted above, we will coordinate the effective date for mandatory validity testing with the issuance of HHS mandatory requirements on validity testing. The Department is convinced that testing in accordance with HHS requirements and guidance results in scientifically valid tests for pH, creatinine, specific gravity, and various adulterants.

Consistent with comments that it was not advisable to list specific adulterants in the rule, since they change rapidly, the Department will simply rely on HHS rules and guidance, which can change to reflect new adulterants for laboratories to test. The Department's final rule also minimizes statements of requirements for laboratory testing methodology, since that is also an area in which we rely on HHS requirements and guidance. We do not believe that extensive duplication is necessary.

The Department has thought a great deal about the HHS substitution criteria, which were the subject of extensive comment. HHS developed these criteria based on an extensive review of the literature (''NLCP: STATE OF THE SCIENCE—UPDATE # 1—Urine Specimen Validity Testing: Evaluation of the Scientific Data Used to Define a Urine Specimen as Substituted (February 14, 2000)''). We are aware that this literature review included only a few ''paired studies'' that simultaneously looked at both the specific gravity and creatinine criteria. Nevertheless, there is nothing in the HHS literature review that suggests any other criteria that would be more appropriate for determining substitution or that the existing criteria are erroneous. Notwithstanding the critique in the comment we received, no scientific paper of which we are aware has suggested criteria that it claimed was more appropriate. It is very significant that even the most vocal opponents of the substitution criteria were unable to provide a single documented instance of an individual meeting both substitution criteria through natural means in a controlled setting.

We are also aware that most of the studies in the HHS literature review were studies of the general population that did not focus on specific subgroups. This is an acceptable practice in medical and scientific studies. Moreover, the Department does not believe that, to adopt generally applicable substitution criteria, it must demonstrate the suitability of the criteria over and over again for every conceivable subset of the population.

To provide further information about these issues, the Department conducted its own study. The text of this study is available on the ODAPC web site (www.dot.gov/ost/dapc). The study was designed specifically to focus on two issues on which commenters criticized the HHS literature review, the absence of paired studies and insufficient study of female subjects. The DOT study made paired measurements of urine creatinine and specific gravity in a predominately female (40 of 56) group of subjects.

All participants in the study were of reasonable working age (19–56). All participants volunteered to consume at least 80 ounces of fluid spread evenly over six consecutive hours. The protocol asked for 40 ounces to be consumed within the first three hours of this six-hour test period. This would be immediately followed by the consumption of at least another 40 ounces in the last three hours of the six-hour test period. Urine specimens were collected prior to the start of the six-hour period and at the end of each subsequent hour in the test period. Urine specimens were also collected on awakening the morning of the test day and on awakening the morning following the test day (this amounted to a total of nine urine specimens being requested from each participant).

Each participant was asked to document the amount and type (water, coffee) of fluid consumed from awakening through completion of the six-hour period, along with the total amount of urine produced from awakening through the six-hour period. Height, weight, age, gender, ethnicity, eating habits, and medications taken regularly and on the day of the collections were also documented. All urine specimens were sent to an HHS-certified laboratory where creatinine and specific gravity were measured using well-established laboratory techniques.

The 56 subjects provided a total of 500 urine specimens. 504 specimens

were expected; however, three individuals did not collect one of the specimens on awakening, and one person was unable to complete the second three hours of drinking per the test protocol. Two participants were unable to consume the minimum amount of fluid originally intended (total of 80 ounces, or approximately 2370 mL, spread evenly over the six hours). The remainder consumed at least the minimum requested. Twelve participants (five men and seven women) consumed over one gallon of fluid by the end of their test periods.

Not one of the 500 specimens was identified as ''substituted'' based on the HHS criteria. This point deserves emphasis. The DOT research involved paired studies of predominately female subjects who drank copious quantities of water under controlled conditions. This examination of paired values of creatinine and specific gravity from 500 specimens collected under water loading conditions strongly supports the criteria developed by HHS. There was no evidence that individuals, regardless of gender or other factors and despite consuming unusually large amounts of fluids, are capable of physiologically producing urine meeting the HHS substitution criteria. We do note that 113 of the specimens did meet the criteria for ''dilute'' specimens, as defined by HHS. Under Part 40, a dilute specimen does not constitute a refusal to test.

The propriety of the HHS substitution criteria was not the only area on which comments were received on validity testing. Several commenters questioned the tests used to determine validity as not being equivalent to the tests used in drug testing. Specifically at issue was whether or not the use of two different technologies is required for the initial and confirmatory tests.

These comments, and their references to statements by two professional toxicology organizations—the American Academy of Forensic Sciences (AAFS) and the Society of Forensic Toxicologists (SOFT)—do not successfully make a case that the HHS-approved testing methods for adulteration and substitution are faulty.

Not all types of tests are the same. In testing for the ''HHS five'' drugs, we are looking for chemically complex substances that we do not expect to find in most specimens. We use an immunoassay followed by gas chromatography/mass spectrometry (GC/MS). As applied, for example, to amphetamines, the immunossay test identifies a broader category of substances including, but not limited to, amphetamine and methamphetamine. The GC/MS test is used to increase the specificity of the testing process and accurately prove the presence of amphetamine or methamphetamine.

By contrast, creatinine is a very simple substance that we always expect to find in urine. It is readily identified by colorimetric techniques, in which a chemical is added to urine to cause a color change and a special instrument measures light absorbed by the solution. It is not necessary with creatinine to differentiate specific complex substances from other substances that may be present in the specimen. Therefore, a second analytical technique to provide greater specificity is not needed. A single analytic technique repeated on a second specimen to ensure that we have a reproducible result is much more to the point.

In the case of creatinine, the initial validity test result is analogous to that of a confirmation drug test result. It produces a quantified result suitable for use in determining whether the specimen is substituted or diluted. The second validity test performed on the specimen is sufficient to support fully the first validity test result. Because of the nature of the creatinine, it is not necessary to use two different testing technologies to establish a test result with certainty. (A similar point can be made about alcohol.) The quoted AAFS and SOFT statements, which apply principally to tests for drugs and drug metabolites, do not conflict with this analysis.

We also point out that one important purpose of the initial immunoassay test for drugs is to eliminate negatives in a cost-effective manner. It would be possible to run two consecutive GC/MS tests on a specimen and never use the separate immunoassay technique. Such an approach would lead to results that are completely accurate and reliable, but the reason we do not require this approach is that it would be much more expensive.

In the case of substitution, the specific gravity test corroborates the creatinine result. This provides a level of forensic certainty equivalent to immunoassay followed by GC/MS in the drug testing case. Although the specific gravity tests appear to be based on simple technology, they have been established as reliable through extensive use over the many years in many clinical settings.

One commenter suggested replacing specific gravity with osmolality, asserting that measurements of osmotic concentration of urine are considered more valid than specific gravity measurements. HHS and DOT believe that there is not a significant difference between osmolality and specific gravity for validity testing purposes. In fact, specific gravity is used clinically much more than osmometry. HHS-certified drug testing laboratories have 12 years of successful experience in testing for creatinine and specific gravity testing under the HHS guidelines, and we do not believe that commenters have made a compelling case for change.

We also note that there are additional testing methods available for such substances as creatinine, nitrites, glutaraldehyde, chromium, and various possible adulterants. The fact that other tests exist does not mean that they must be used to produce an accurate result. The key point is that the methods we do use must be accurate and above reproach. DOT and HHS are convinced that the methods we use do produce the required accuracy for correct results.

Contrary to one commenter's assertion, the Department's approach to validity testing does not create a ''presumption of guilt.'' A confirmed laboratory finding, whether for drugs, adulterants, or substitution, is a matter that calls for explanation. In the absence of a satisfactory explanation, we are justified in basing regulatory consequences on the finding.

The Department, in short, has a rational and sound scientific basis for using the adulteration and substitution criteria we have chosen. Nonetheless, to ensure fairness and to provide safeguards parallel to those available in cases of positive drug tests, the Department will add split specimen testing and MRO review to its procedures in these cases.

The Department is not legally compelled to include split specimen testing and MRO review in validity cases. As explained in the preamble to the NPRM (see 64 FR at 69081–82; December 9, 1999), these additional safeguards are required neither by the Constitution nor by statute. The Department's decision is a matter of policy, in the interest of providing greater fairness to employees in the drug testing program. The Department notes that situations in which an adulterant is naturally found or a substitution naturally occurs are likely to be extremely rare. At the present time, we do not know of any such situations. However, our policy to allow medical review and use of the split specimen will provide employees with an additional level of protection and an added degree of fairness.

With respect to the use of split specimens in validity testing, the Department's process will parallel the existing split specimen procedure in the case of drug positives. Within 72 hours

of being notified by the MRO that his or her test has been verified adulterated or substituted, the employee may request a test of the split specimen. A second laboratory will test the split specimen.

Laboratories will use the testing criteria set forth in HHS rules or guidance. Under current HHS criteria for adulterants, the test of the split specimen is for the presence of an adulterant, or, in the case of an adulteration finding based on pH, to ensure that the pH of the specimen meets the same regulatory criteria as for the primary specimen. In the case of substitution, the split specimen must meet the same regulatory criteria as for the primary specimen in order to be reconfirmed. As with drug positives, the consequence of a failure to reconfirm is a cancelled test.

With respect to MRO review, the Department's process will also parallel the existing procedure for drug positives. The employee will have the opportunity to present a legitimate medical explanation. The employee, as is the case for all drugs except opiates, has the burden of proof to demonstrate to the MRO that a legitimate medical explanation exists. To meet this burden in the case of an adulterated specimen, the employee will have to demonstrate that the adulterant entered his or her specimen through physiological means. This will not be easy to do. Most adulterants are substances that do not naturally occur in urine. There is no way one can physiologically produce urine that includes such substances as bleach, glutaraldehyde, or soap, for example. There cannot be a legitimate medical explanation for the presence of these substances in urine, any more than there can be a legitimate medical explanation for the presence of PCP in a specimen.

In cases where there is no reasonable apparent legitimate medical explanation, the MRO would verify the adulterated result. However, if an employee presents what the MRO believes could be a legitimate medical explanation, the MRO will tell the employee he or she may obtain additional evaluation from another physician, acceptable to the MRO, who has expertise relevant to the explanation. This would ensure that the MRO, standing alone, would not be called on to make a decision for which he or she lacked the needed expertise. The referral physician would make a recommendation about whether there was a legitimate medical explanation. The referral physician would evaluate any information presented by the employee in making his or her determination. If the referral physician found that there was a legitimate medical explanation, the MRO would review the referral physician's recommendation and, if appropriate in the MRO's judgment, cancel the test.

MROs would follow the same process in the case of a substitution result. The MRO review provision for substitution emphasizes that it is not enough for the employee to show that he or she has a medical condition or has certain personal characteristics. The employee must establish the link between these facts and the ability to physiologically produce urine meeting the substitution criteria. For example, a replication of the employee's original test result, under carefully controlled conditions (including direct observation) could establish such a link.

To meet our fairness objectives, we believe it is necessary to provide MRO review that can result in the cancellation of a test if the employee provides a legitimate medical explanation. Nevertheless, the Department emphasizes that it is the employee's burden to prove that such an explanation exists. The MRO is not responsible for disproving an employee's assertions.

The Department will retain the word ''substitution,'' rather than changing to a term like ''hyper-dilute.'' Given the structure of the final rule, it seems clear that a laboratory ''substituted'' result is simply a confirmed result that must be verified by an MRO before becoming final, just like a confirmed drug positive. HHS uses this term in the Federal employee program, and it is useful to keep terms as consistent as possible between the two related programs.

The Department works closely with HHS on validity testing issues, and the Department will use validity testing criteria set forth in HHS requirements and guidance. Validity testing is a subject that HHS, like DOT, takes very seriously, and HHS will issue additional guidance, as needed, to support the DOT validity testing program. We will work with HHS to ensure that validity testing remains as technically sound as the rest of the DOT program. The updated and clarified collection procedures in this final rule will help insure the integrity of the urine specimen. In addition, each laboratory will conduct validity testing under specific HHS guidance and quality control review, and the blind specimen quality control program will include adulterated and substituted specimens. Validity testing has now become a factor in the HHS evaluation of laboratories for certification and recertification. In addition, the application of split specimen testing and MRO review to validity tests will provide further safeguards for employees, parallel to the existing drug testing program.

Laboratory Problems

In September 2000, the Department learned of a significant series of errors by one laboratory involved in validity testing. The first error that came to our attention involved apparent misconduct by laboratory personnel. Following a test result that met HHS substitution criteria, laboratory personnel apparently backdated documents explaining a minor irregularity in laboratory controls used to check the accuracy of testing machinery. These documents were then placed in the ''litigation package'' intended for use in an FAA certification proceeding involving the employee. To make matters worse, someone allegedly tore up a purported photocopy of the original of the backdated documents, and the laboratory official who signed the litigation package (no longer employed by the laboratory) allegedly had claimed credentials he did not have. These events undermined the credibility of the laboratory in this case so much that FAA enforcement attorneys felt compelled to settle the certification action.

Second, the laboratory made significant errors in reading test results. One error was the practice of ''truncating'' creatinine measurements (*i.e.,* expressing results only in whole numbers). This practice, which was not specifically mentioned in HHS Program Document 35 but was specifically contrary to Program Document 37, causes any result in the 5 to 5.9 range to be reported as a 5. Since a result of 5 or less is one of the criteria for substitution, this practice could have the effect of causing a specimen that was outside the creatinine criterion for substitution to be interpreted as meeting this criterion. This throws into question substitution results where the creatinine measurement was a 5. (It does not affect results where the creatinine result was below 5.) In addition, laboratory personnel apparently interpreted an error message (''LLL'') from a machine used to measure specific gravity as a measurement of 1.000. There is not a sound basis for making this interpretation.

When we learned of these problems, we immediately involved HHS. The DOT and HHS Inspector Generals reviewed the apparent evidence-tampering. In addition, this situation led us to add tampering with documentation by a laboratory as a type of noncompliance that can be subject to a PIE proceeding (see § 40.365). The

employer who had used the laboratory in question terminated its contract with the laboratory and offered to rehire five employees whose test results had been thrown into question by the laboratory's errors. The laboratory director subsequently resigned.

HHS promptly conducted a special inspection of the laboratory. Following the inspection, HHS determined that the laboratory had corrected the result-reading problems with substitution and had been, since January 2000, in full compliance with DOT and HHS requirements. HHS also surveyed all other laboratories to determine if any had made similar errors in reading results and to determine whether they were in compliance. No one else had made the error message interpretation mistake concerning specific gravity. However, HHS determined that, for varying periods of time (in many cases before the specific guidance on this point was issued in Program Document 37, but in some cases after), 40 or more laboratories had engaged in ''truncating'' creatinine results. All the laboratories involved subsequently stopped this practice, and all are now reading these results properly.

In addition to these problems, HHS also discovered that in some cases, laboratories had reported tests as substituted that did not meet both HHS substitution criteria. That is, the laboratories reported tests as substituted that met the creatinine criterion, even though they did not also meet the specific gravity criterion.

HHS has examined each individual substitution and adulteration test result that a laboratory has reported since September 1998, when Program Document 35 took effect. In any case in which a substitution result was based on a creatinine reading of 5 at a laboratory that was truncating results at the time, or in which a substitution result was reported that did not meet all HHS criteria, HHS and DOT are working to remedy the problem as it may have affected individual employees. HHS is in the process of sending a letter to each MRO involved with one of the approximately 300 specimens involved informing the MRO that the test must be cancelled. The letter directs the MRO to inform the employer of the cancellation and to tell the employer to attempt to contact the employee with this information. The employer is also told to take any appropriate personnel action in light of the cancellation.

HHS is also conducting special certification inspections of each laboratory that is performing validity testing to ensure that all its validity testing procedures are fully consistent with HHS guidance. These inspections will be completed this month. The laboratories involved full compliance with HHS validity testing requirements will now be a condition of maintaining their certification to participate in the Federal and DOT drug testing programs.

We are deeply concerned about this situation, because laboratory problems of this kind can result in unfair treatment of employees and adversely affect the credibility and integrity of our program. We point out, however, that nothing in this situation suggests that there is anything wrong with the criteria and methods for validity testing. The problems in this case were human implementation errors, now corrected, involving the reading of results and the documentation and reporting of tests, not in the testing process itself or the scientific basis for it. The Department believes that it is appropriate to continue to implement validity testing as called for in this rule.

Section-by-Section Discussion

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

Subpart A—Administrative Provisions

Section 40.1 Who Does This Regulation Cover?

This section attracted little comment. One commenter expressed concern about potential coverage of volunteers in one FTA program, while another wanted to specify that contractors could also be covered. The final rule specifies that contractors, volunteers, and others would be covered by Part 40 to the extent that they are subject to other DOT agency drug and alcohol rules.

The Federal Railroad Administration (FRA) operates a post-accident drug and alcohol testing program that antedates Part 40 and differs in a number of ways from the rest of the Department's programs (*e.g.,* with respect to fluids tested, drugs that are tested for). We do not intend to interfere with the implementation of this long-standing program, and we have added a paragraph making this clear.

Section 40.3 What Do the Terms Used in This Regulation Mean?

Commenters expressed interest in several of the definitions of terms in the NPRM. A commenter made a technical point that some kinds of evidential breath testing devices (EBTs) do not literally sample the ambient air, as the definition of ''air blank'' provides. We added a sentence to the definition noting that for some devices, the ''air blank'' is a reading of the device's internal standard.

A commenter noted that the definition of ''alcohol use'' talks of ''drinking or swallowing'' rather than ''consumption,'' as in the past. The reason for this change is to avoid interpretations by enforcement personnel that such actions as using an inhaler that contain alcohol are ''alcohol use'' for purposes of this part. For example, the use of rubbing alcohol, applied topically rather than imbibed, is not intended to be a violation of this part.

Commenters interested in the role of service agents in the program asked for definitions of ''consortium'' and ''third party administrator.'' One commenter provided proposed definitions, which included a requirement for individuals with certain certifications to play key roles in the organization. We considered the possibility of separate definitions for ''consortium'' and ''third-party administrator,'' but we did not find any basis for defining the terms separately. There are no meaningful conceptual or operational distinctions between organizations that call themselves one thing or the other of which we are aware or which commenters explained. In the way the terms are used in the regulation, they are for all practical purposes interchangeable. Consequently, the final rule uses the term consortium/third party administrator (C/TPA) to refer to any organization, however structured, that provides or coordinates a variety of drug and alcohol testing services to employers. Organizations would not have to change their names to conform to this definition (*i.e.,* a C/TPA that currently calls itself a ''consortium'' would not have to call itself something else).

Some commenters asked that C/TPAs be regarded as ''employers'' (especially consortia that serve small transportation companies). (This comment is related to the issue of C/TPAs serving as DERs, discussed above in the ''Principal Policy Issues'' portion of the preamble.) While this rule broadens the authorized role of C/TPAs in a number of respects, we believe that the program works best when C/TPAs and employers stay within their respective roles. An employer is an organization like an airline, trucking company, transit authority, etc. that provides transportation services and employs safety-sensitive workers. C/TPAs do none of these things. They contract with employers to provide drug and alcohol testing services. We believe the distinction between ''employers'' and C/TPAs helps to avoid confusion and

counterproductive overlap in roles between the two types of organizations, and we are retaining the NPRM's statement that C/TPAs are not employers. Any statements to the contrary in DOT agency rules would be changed in the agencies' proposed conforming amendments to this rule.

One commenter expressed concern that it was troublesome to have service agents contact a DER when there was another company representative on the scene of a testing event. This comment appeared to assume that an employer can have only one DER. This is not the case. An employer can designate as many DERs as it needs to carry out its program effectively.

Several comments on the definitions of ''medical review officer'' (MRO) and ''substance abuse professional'' (SAP) asked that other professions or members of professional groups be included within the definitions. We will discuss these issues in connection with the MRO and SAP provisions of the rule. Training and qualification matters are found in substantive sections of the rule (*e.g.,* § 40.121 for MROs), and it is not necessary to duplicate them here. However, we have added to this section definitions of terms that are used to label different types of training for MROs, SAPs, collectors, and BATs/STTs (*e.g.,* qualification training, refresher training).

With respect to the term ''chain of custody,'' we note that the definition of this term is not intended to suggest that the MRO is responsible, as part of his or her chain of custody review, to examine the internal laboratory chain of custody. The MRO need only review the CCF itself.

Commenters questioned the definitions of ''dilute'' and ''substituted'' specimens. One commenter noted that it was unnecessary to suggest that a ''dilute'' specimen had been watered down by the improper action of an employee. We agree, and have expressed the definition, like that of ''substitution,'' in neutral, descriptive terms. These definitions are augmented later in the rule by quantitative criteria for dilute and substituted specimens.

One commenter suggested slightly rewording several definitions of terms for the alcohol testing part of the program. These suggestions generally did not result in any significant substantive changes in these definitions, and we have left the definitions as they were in the NPRM. A few commenters asked for a different term in place of ''service agent,'' one suggesting ''substance abuse service professional (SASP).'' The Department believes the ''service agent'' term is short, easily understood, and inclusive, so we are retaining it. Finally, for greater clarity, we have added definitions of the ''Office of Drug and Alcohol Policy and Compliance (ODAPC)'' and ''validity testing'' to this section.

Section 40.5 Who Issues Authoritative Interpretations of This Regulation?

Section 40.7 How Can You Get an Exemption From a Requirement in This Regulation?

There were few comments about these administrative provisions. One commenter asked how to obtain answers to interpretation questions, and another asked how one might object to interpretations of Part 40. We recommend calling or writing ODAPC. A commenter suggested publishing all interpretations in the **Federal Register** periodically. We believe that it is useful to make all interpretations widely available, and we will post them on the ODAPC web site (www.dot.gov/ost/dapc). We will also consider whether publication in the **Federal Register** would be a useful additional step.

This interpretation authority applies to the application factual situations of the provisions of this rule. The Department is often asked whether, for example, the rule requires the cancellation of a test in a particular circumstance. The answer to this question is, in effect, an interpretation of the text of the rule as applied to the facts of the situation. ODAPC and the General Counsel's office work closely with the operating administrations to ensure consistency of all such interpretations with both Part 40 and the other DOT agency rules.

We will retain the provision that makes only new guidance, issued after publication of this rule, valid. We have substantially rewritten Part 40. Much of the substance of interpretations of the former version of the rule is found in the text of the new rule. Other guidance pertains to a version of the rule that will no longer exist. We anticipate publishing additional guidance pertaining to the new Part 40 (*e.g.,* an MRO manual) before the effective date of the new rule.

We want to emphasize that an exemption is not the same thing as a waiver. An exemption is, in effect, a rulemaking of particular applicability that responds to an unusual situation, not contemplated in the rulemaking and not having general application to a wide variety of situations. An agency cannot properly make *de facto* generally applicable amendments to a rule through exemptions, because this would circumvent the rulemaking process requirements of the Administrative Procedure Act. A waiver, on the other hand, is a generally applicable provision in a rule that permits regulated parties to comply through an alternative means, if certain conditions are met (*e.g.,* § 40.21).

Part 40 is an Office of the Secretary (OST) rule. Consequently it is OST, and only OST, that has the authority to grant exemptions from it. Since Part 40 is applied to regulated employers through the other DOT agency drug and alcohol testing regulations, exemptions to Part 40 are implemented via the other DOT agency regulations. There may be situations in which DOT agency regulations impose requirements that go beyond those of Part 40. In such a case, a regulated party might need to obtain an exemption from the additional DOT agency provision as well as from a Part 40 provision.

Subpart B—Employer Responsibilities

Section 40.11 What Are the General Responsibilities of Employers Under This Regulation?

Most of the comments about this section concerned proposed paragraphs (d)–(f), which would have required contracts or written agreements between service agents and employers to include a clause making compliance with Part 40 a material term of the contract. These comments and the Department's response are discussed in the ''Principal Policy Issues'' portion of the preamble.

A few commenters also objected to language in the proposed paragraph (b) saying that employers must ensure that service agents comply with their regulatory responsibilities. The thrust of these comments was that employers do not have the resources or expertise to monitor the compliance of their sometimes far-flung service agents. In response, we have merged language of paragraph (b) with § 40.15(c). It no longer places an active compliance monitoring responsibility on employers, but simply says that the employer's good faith use of a service agent is not a defense to a DOT enforcement action. For example, if an employer's MRO fails to conduct verification interviews, the employer could be subject to civil penalties from a DOT agency (the MRO could independently be subject to a PIE proceeding). As an employer, you can contract out your drug and alcohol testing program functions, but you cannot contract away your compliance responsibilities.

Proposed § 40.13 Nuclear Regulatory Commission (NRC) Program

The NPRM proposed that there be reciprocity between the DOT and NRC drug and alcohol testing programs. A number of commenters favored this approach in principle, some asking that the notion of reciprocity be extended to other Federal testing programs. A few commenters opposed the proposal, saying that NRC rules did not measure up to DOT rules. Other commenters pointed to numerous differences between the two regulatory programs, with respect to program concepts, specific requirements, forms, and administration. Some suggested that a reciprocity agreement be created between the two agencies detailing how these differences would be handled. Others said that the more stringent of the two rules on each particular point should govern.

The Department has concluded that the wide variety of program differences between the DOT and NRC regulations make it impractical to establish reciprocity between the two systems. These differences involve such matters as testing methods, consequences of some alcohol test results, alcohol testing forms, reporting and recordkeeping, inspection and enforcement procedures and responsibilities, and return-to-duty procedures. We believe it would be very difficult to craft a provision that did justice to both programs and decreased, rather than increased, confusion among employers and employees. While we believe reciprocity and ''one-stop shopping'' are worthwhile objectives, we do not believe they are practically achievable in this case. In addition, the numbers of double-covered employees and employers (either with NRC or other Federal agencies) are quite small in comparison to the total number of parties covered by the DOT program. For these reasons, we are not making this proposed section part of the final rule.

Section 40.13 How Do DOT Drug and Alcohol Tests Relate to Non-DOT Tests?

This section is based on proposed § 40.15 of the NPRM. It continues to require that DOT and non-DOT tests be kept strictly separate. Comments were generally supportive of this concept, but some asked for clarification. Paragraph (b), for example, clearly concerns collections rather than other parts of the testing process, and the text has been changed to make this explicit. This provision does not, as one commenter wondered, mean that laboratories must process DOT and non-DOT specimens in separate batches. Another commenter suggested that the ''firewall'' between DOT and non-DOT tests would be stronger if we required that an employer use separate laboratories for the two types of tests. We have not become aware of any problems that use of the same laboratory has created, and we think that this idea would increase costs and administrative complexity for employers.

A few commenters mentioned a desire to permit tests for other drugs, beyond the ''HHS five.'' This is a long-standing issue in the program, and DOT continues to take the position that we ought not go beyond the testing that HHS has authorized and for which HHS has certified laboratories. We agree with comments that inadvertent use of non-Federal forms should be a correctable flaw and that employers may appropriately use the CCF for Federally-regulated tests (*i.e.,* under the HHS program for Federal agencies). The final text makes changes to these effects. The Department does not object to laboratories creating a standard form for non-DOT tests.

One of the most important provisions of this section prohibits the use of DOT specimens for tests other than the ones explicitly authorized by this part. For example, the rule forbids laboratories and other parties from making a DOT specimen available for DNA testing. This incorporates in the rule text a long-standing DOT interpretation of Part 40. We say this for two main reasons. First, under these regulations, a properly completed chain of custody conclusively establishes the identity of a specimen. No additional tests are required for this purpose.

Second, the only thing a DNA test can do is to determine, to a high level of probability, whether a specimen and a reference specimen were produced by the same individual. If the DNA test establishes a high probability that the original specimen tested for drugs and a reference specimen came from different individuals, this may mean one of four things. It could mean that there was an error in the collection, transmission, or handling of the specimen. It could mean that the employee provided a substituted specimen (*e.g.,* someone else's urine) at the original collection and provided his or her own urine for the reference specimen. It could mean that the employee provided his or her own urine at the original collection and substituted someone else's urine for the reference specimen. It could mean that the individual provided substituted specimens from two different sources at the original collection and for the reference specimen. A DNA test cannot distinguish among these possibilities. Given a proper chain of custody, the last three possibilities are significantly more probable in practice than the first. A DNA finding of difference between the two specimens is not, then, a valid basis for canceling a test.

Even if a DNA test is performed, contrary to these rules, this section prohibits employers from changing or disregarding a verified positive test. In such a case, regardless of the result of the unauthorized test, the employer cannot return the employee to the performance of safety-sensitive functions until and unless the employee successfully completes the return-to-duty process. The same point applies to other unauthorized tests (*e.g.,* if the employee goes to his or her own doctor and gets a second urine test or a blood test).

Section 40.15 May an Employer Use a Service Agent to Meet DOT Drug and Alcohol Testing Requirements?

This provision is based on § 40.17 of the NPRM. It provides that an employer may use a service agent to carry out drug and alcohol testing program tasks. There were not many comments on this section, and they generally supported the provision. Some commenters sought to limit the responsibility of employers, saying they should not be accountable if they failed to comply with the rules because a service agent erred. As noted above, we disagree: employers always remain accountable for noncompliance, whether they run their own programs or outsource them. Another comment suggested laboratories should not be subject to DOT regulations, since they are regulated by HHS. It is certainly true that DOT relies on HHS for laboratory certification matters. However, laboratories have responsibilities under Part 40 independent of their HHS responsibilities (*e.g.,* with respect to relationships with MROs, release of information, and validity testing), and laboratories must be accountable to DOT in those matters.

We agree, however, that we should not require employers to have active monitoring responsibilities with respect to service agents, though employers may choose to monitor their service agents' performance. Therefore, we have altered paragraph (b) to require employers simply to make sure that service agents meet regulatory qualifications. To this end, employers may ask to see documentation from service agents, who are obligated to provide it.

Section 40.17 Is an Employer Responsible for Obtaining Information From its Service Agents?

This is a new section, responding to problems that the Department has encountered in the enforcement process. It is closely related to the point, made in previous sections, that an employer is responsible for its own compliance with DOT rules even in the face of mistakes by service agents. The section says that an employer has an affirmative responsibility to get information from service agents that is needed for compliance purposes. For example, suppose an applicant for a safety-sensitive job takes a pre-employment drug test, but there is a significant delay in the receipt of the test result from an MRO or C/TPA. The employer must not assume that ''no news is good news'' and permit the applicant to perform safety-sensitive duties before receiving the result. Rather, the employer would have to seek out the information about the test result from the service agent before putting the employee to work.

Section 40.21 May an Employer Stand Down an Employee Before the MRO Has Completed the Verification Process?

Proposed §§ 40.19–40.21 have been relocated to Subpart Q, and we will respond to comments on them in the corresponding part of the preamble. There is no § 40.19 in the final rule. Section 40.21 concerns the issue of stand-down. This issue was raised by proposed § 40.159(a) of the NPRM. We have relocated the section here since it pertains primarily to the responsibilities of the employer. We discussed the general policy issues surrounding stand-down in the ''Principal Policy Issues'' portion of the preamble.

The comments responding to proposed § 40.159(a) focused almost exclusively on the pros and cons of stand-down as a policy. They did not address the details of how a stand-down policy would be implemented. In formulating § 40. 21 of the final rule, we have crafted provisions specifically responsive both to the safely and privacy/employee protections sides of the issue that commenters raised.

Paragraph (a) states the general policy prohibiting stand-down, except where a DOT agency grants a waiver. We note that this prohibition, and waivers of it, apply in adulteration and substitution cases as well as cases in which there is a confirmed test result for drugs or drug metabolites. Paragraph (b) tells employers to send their waiver requests to the DOT agency whose rules apply to the majority of the employer's covered employees. For many employers, whose employees are covered by only one DOT rule, the decision is obvious. An employer with covered employees in more than one DOT agency category would count the employees in each category. For example, an employer with 500 aviation personnel and 1000 truck drivers would send its request to FMCSA. In such a case, FMCSA would coordinate with FAA before making a decision on the waiver request.

Paragraph (c) lists the items that an employer must include in a waiver request. The first set of items are information that DOT agencies will use in determining whether to grant a waiver. It should be emphasized that none of the items in paragraphs (d)(1) are intended to create mandatory prerequisites to receiving a waiver. That is, we do not require that an organization be a particular size, or have an in-house MRO, or have had an accident during the period before verification was completed, in order for its waiver request to be granted.

Any organization that wants a waiver to do stand-down must have a written company policy on the subject. An employer must include its proposed policy with its waiver request, making sure that it covers seven mandatory elements. The first is distribution of the written policy to all covered employees. Each employee subject to stand-down must receive an individual copy of the policy: posting on bulletin boards or web sites is not sufficient. The second pertains to confidentiality. There must be an effective means of ensuring that only those persons with a need to know—the employee, the DER, and the MRO—are told that the employee is being stood down because of a confirmed laboratory positive, adulterated, or substituted test result. We understand, of course, that the employee's supervisor will need to know that the employee is being removed from performance of safety-sensitive functions, but the supervisor must not be told the reason for the action. It is sufficient that the supervisor be given a general explanation (*e.g.,* medical qualification reasons, personnel evaluation reasons).

The third item is equality of treatment within a given job category. An employer cannot pick and choose the employees to whom it will apply a stand-down policy. That would be unfair. The employer must choose to stand-down all DOT-regulated employees in each job category or none. For example, an airline's policy could provide that all pilots would be subject to stand-down, but mechanics would not. However, the airline could not choose to stand down some pilots, but not others. When we use the term ''job categories'' in this paragraph, we mean broad, inclusive categories of employees, rather than narrower subsets of employee categories that might be used for pay or personnel purposes.

The fourth item is a means of ensuring that stand-down is applied only with respect to the performance of safety-sensitive duties. For example, suppose a motor carrier's policy calls for stand-down with respect to drivers. The laboratory reports a confirmed positive drug test for Driver X. Driver X is scheduled to drive a commercial motor vehicle over the next few days. The company would stand Driver X down, so the driver would not be performing a safety-sensitive function during the verification period. The laboratory also reports a confirmed positive drug test for Driver Y. However, during the next few days, Driver Y is scheduled to be in training or to be on personal leave. The motor carrier would take no action with respect to Driver Y (including notification of a supervisor), because he or she would not be performing safety-sensitive duties during the verification period.

The fifth item, concerning pay status of employees, is a very important matter of policy. As discussed above, employers who stand employees down must continue to pay them until and unless there is a verified adulterated, substituted, or positive test result. This obligation is to pay the employee in exactly the same way he or she would have been paid but for the stand-down. For example, suppose an employer stands down an employee from Monday through Thursday. If the employee would have been paid for 8 hours of work on each of the four days in the absence of the stand-down, then the employee would be paid for this amount of work. If the employee would only have worked on, and been paid for, only Tuesday and Wednesday, then the employer would pay the employee for these two days' work. We note that this obligation to pay the employee ends with a verification of a positive, adulterated, or substituted test, even if the employee subsequently asks for a test of the split specimen.

For the sake of both employers and employees, it is very important that verifications proceed quickly when an employee is in a stand-down status. Therefore, the sixth condition is that the verification process must start at once and take no more than five days (a time period consistent with requirements for the verification process elsewhere in the rule). The process could exceed this five-day limit only for extenuating circumstances (*i.e.,* the MRO provides a

written statement to the employer that a longer time is needed to complete verification).

The seventh mandatory part of the employer policy is that, if an employee is stood down and the MRO verifies the test negative or cancels it, the employer must immediately return the employee to safety-sensitive duties. The employee must not suffer any adverse personnel or financial consequences. The employer must not maintain any individually identifiable records of the confirmed positive laboratory test. That is, the employer would have to expunge any individually identifiable record of the confirmed positive laboratory test and maintain only the record of the individual's verified negative or canceled test. This places both the employer and employee in the same position they would be in if the employer did not have a stand-down policy. The MRO will have a record of the laboratory test result that inspectors can access if necessary.

This provision goes into effect on August 1, 2001. DOT agencies will not consider petitions for waivers before this effective date. In considering waivers, each DOT agency will use its own procedures applicable to waivers from its regulatory requirements. The concerned DOT agency Administrator, or his or her designee, will make each decision about whether to grant a waiver considering both the safety and the employee protection aspects of the matter. Administrators will informally coordinate proposed responses to waiver requests with ODAPC and other affected DOT agencies, in order to ensure intermodal consistency in the Department's responses. DOT agencies will respond to all waiver requests in writing, stating the reasons for their decisions.

An Administrator can impose additional conditions on the grant of a waiver. The Administrator can also revoke a waiver if the employer fails to implement mandatory provisions of its stand-down policy or conditions the Administrator has placed on it. Finally, if an employer implements a stand-down policy without having a waiver, or violates the terms of the waiver (*e.g.,* tests some employees but not others in a job category, fails to implement confidentiality safeguards, fails to pay employees during stand-down periods), the employer will be subject to DOT agency enforcement action (*e.g.,* civil penalties), just as in any other case in which an employer violates DOT agency drug and alcohol regulations.

Section 40.23 What Actions Do Employers Take After Receiving Test Results?

This section is based, in part, on § 40.159(b)–(g) of the NPRM. We have added some material to it and placed it in Subpart B in order to provide employers with a convenient summary of their obligations when they receive various kinds of drug and alcohol test results. We believe that the regulatory text is self-explanatory, so we need not comment on it further here.

There were very few comments on § 40.159(b)–(g). One commenter said that the company should wait for the signed report from the MRO before taking action to remove an employee from safety-sensitive functions after a violation. We understand the usefulness of having paper in hand, but we believe that speed is more essential for safety reasons once the MRO or BAT informs the employer of a violation. Of course, the requirement to immediately remove an employee from the performance of safety-sensitive duties necessarily implies that employers may not ''stay'' this action pending any administrative or legal proceeding (*e.g.,* grievance, arbitration, lawsuit) resulting from the outcome of the testing process.

Paragraph (i) prohibits employers from changing test results (*e.g.,* determining that the laboratory result was incorrect or that the MRO's judgment on a verification issue should be overturned). Obviously, there may be some cases in which a court or administrative hearing officer will require a test result to be expunged from the record, or a test cancelled, because of a problem in the testing process (*e.g.,* a previously undiscovered fatal flaw). However, this action does not involve altering the laboratory finding or MRO determination, as such.

Section 40.25 Must an Employer Check on the Drug and Alcohol Testing Record of Employees It Is Intending To Use To Perform Safety-Sensitive Duties?

The NPRM (proposed § 40.329) would have required MROs to transmit drug test result information to additional employers in certain circumstances. If an MRO had personal knowledge that an employee whose test the MRO had verified positive worked in a safety-sensitive position for another DOT-regulated employer, the MRO would, under certain conditions, tell the second employer about the positive test, without the employee's consent. As described in the ''Principal Policy Issues'' section of the preamble, we are not adopting this proposal as part of the final rule.

In place of the proposed § 40.329, and in the absence of a Federal data base, the Department is incorporating in the final rule a provision based on an existing FMCSA provision. This provision requires employers to check on the drug and alcohol testing background of new hires and other employees beginning safety-sensitive work. Employers would have to get written consent from the applicant (in the absence of which the employer would not hire the person). The employer sends the request for information and the employee's consent to all other DOT-regulated employers for whom the employee had worked within the previous two years.

The employer cannot let the employee perform safety-sensitive duties for more than 30 days unless the employer has obtained, or made and documented a good faith effort to obtain, the required information from previous employers (as well as from firms to whom the employee applied for safety-sensitive work, where there was a positive test result or a refusal). Of course, if the employer finds that the employee has a violation on his record, and the employee has not successfully completed the return-to-duty process, the employer must immediately stop using the employee to perform safety-sensitive functions.

The Department believes that this section will help to achieve some of the purposes of the proposal to allow MROs to share test results, with fewer drawbacks. Admittedly, it affects only new employees rather than current safety-sensitive employees. However, FMCSA has had success implementing this provision, and it will help to screen out employees who are not eligible to perform safety-sensitive functions. It will also ensure that employees who violate the rules will have to go through the SAP/return-to-duty process before performing safety-sensitive duties. It will therefore have safety benefits. Because a substantial majority of all DOT-regulated employees and employers are in the motor carrier industry, this provision will result in only a modest increase in the information collection burden of the DOT program. The written consent provision of the section avoids some of the privacy concerns of the MRO information sharing proposal.

In addition to seeking information from previous employers, this section also requires employers to ask prospective employees if they have failed or refused a DOT drug or alcohol pre-employment test within the past two years from an employer who did not hire them. While we recognize that

applicants may not always tell the truth about such events, we believe that it is important to make this inquiry to help ensure that employees are not put to work in safety-sensitive positions following a pre-employment test violation without having completed return-to-duty process requirements.

Section 40.27 Where Is Other Information on Employer Responsibilities Found in This Regulation?

This is a new section, parallel to several sections (*e.g.*, concerning MROs) in the NPRM. It is a list of other sections of the rule that touch on matters of particular interest to employers. We believe it will make the rule easier for employers to use if they have a quick guide to other references in the rule to employer responsibilities.

Subpart C—Urine Collection Personnel

Section 40.31 Who May Collect Urine Specimens for DOT Drug Testing?

This introductory section to the urine collection personnel subpart states that only collectors meeting Subpart C requirements can collect specimens in DOT-regulated tests. They must meet § 40.33 training requirements. The only subject of significant comment on this section had to do with the requirement that supervisors could not collect urine specimens from employees they supervise, unless no other qualified collector was available and DOT agency drug and alcohol regulations permitted the supervisor to act in this capacity.

The intent of this provision is to prevent potential conflicts between supervisors and subordinates, as well as to avoid any claims that a supervisor was out to get an employee through manipulation of the testing process. However, commenters asked for clarification of who we meant to cover when we applied this prohibition to supervisors. Several suggested we should limit the prohibition to ''immediate supervisors,'' so that individuals higher in the organizational chain of command, who did not supervise the employee day-to-day, could act as collectors. The Department agrees, and we have added this language to the section.

Section 40.33 What Training Requirements Must a Collector Meet?

There is a strong, though not unanimous, consensus among people familiar with the DOT drug testing program that collections is the area of the program where the most errors occur that cause tests to be cancelled. For this reason, the NPRM proposed several requirements to strengthen training for collectors, though it did not go so far as to propose an equivalent of the BAT course used for alcohol testing personnel. We discussed the key points of this issue in the ''Principal Policy Issues'' section of the preamble.

We note here two additional changes we made to reduce paperwork burdens. In response to comments, we dropped the proposed requirement that called on collectors to ''attest in writing'' that they have read and understood the rules and DOT guidance. We also eliminated requirements (from proposed § 40.35) requiring organizations employing collectors to maintain records of their training. Collectors will maintain their own training documentation, which they must show on request to DOT agency representatives as well as employers or C/TPAs who use their services.

In this section and a number of others, the final rule makes reference to guidance documents being available on the ODAPC web site. These will be true statements by the time the rule becomes effective in August 2001. At the present time, however, these documents are ''under construction,'' and they have not yet made their debut in cyberspace.

Section 40.35 What Information About the DER Must Employers Provide to Collectors?

This section is not based on proposed § 40.35 of the NPRM which, as mentioned above, is not included in the final rule. It is a new section incorporating a brief statement that employers must make sure that collectors have the name of and contact information for the employer's DER, so that the collector can contact the employer concerning any problems that come up in the collection process (*e.g.,* no shows, refusals). We recognize that there may be some situations (*e.g.,* post-accident tests at locations remote from the employer's place of business) where this may not be feasible.

Section 40.37 Where Is Other Information on the Role of Collectors Found in This Regulation?

This is a section listing other sections in the rule that collectors will find useful in understanding their functions in the drug testing program.

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

Section 40.41 Where Does a Urine Collection for a DOT Drug Test Take Place?

Most comments on this section focused on two issues. The first was the conditions on use of a multistall restroom. The NPRM proposed that a multistall restroom could be used only if a closed room for urination was not available, and could be used only for monitored collections. The proposed rule text also said that a multistall restroom must provide aural privacy to the extent practicable. Several commenters said these conditions were too restrictive and would effectively preclude employers from using multistall restrooms for collections. This was a problem, they said, because in some industries, this was the most readily available type of urination facility. Some commenters also noted what they viewed as an inconsistency between the aural privacy provision of this section and the provision in § 40.69 that called on monitors to listen for sounds that might indicate tampering.

Some commenters also thought that provisions of the proposal concerning closed room urination facilities were too restrictive, particularly the statement that the room should have an external water source, if practicable. They said that many such facilities (*e.g.*, patient rest rooms in doctors' offices) had internal water sources, and the ''if practicable'' language could lead to legal challenges. They said it would be better simply to require collection sites to secure all water sources.

The Department has modified this section in response to these comments. The final rule provides that either a closed room or multistall urination facility is acceptable. In the former, while it is preferable to have an external water source, the rule makes clear that a facility that has an internal water source is also acceptable, if all sources of water and potential adulterants are secured and moist towelettes are provided. This kind of urination facility must have a full-length privacy door. This means a door that is both opaque and solid. For example, a glass door, a door with a window or other means of viewing the interior of the room from outside, or a curtain is not adequate for this purpose. Nor would it be appropriate to have a video camera or microphone monitoring the room.

If a multistall restroom is used as the urination facility, the facility must meet either of two requirements. First, a multistall restroom may be used without a monitor if all sources of water and potential adulterants are secured. Second, if these sources are not secured, the collection must be a monitored collection, meeting the requirements of § 40.69. The facility must have a partial-length privacy door (*i.e.*, for the stall in which urination takes place) to provide as much visual privacy as possible. We

have deleted the references in this section to aural privacy and in § 40.69 to ''active listening'' by the monitor.

Regardless of which type of urination facility a collection site uses, the employee is the only person permitted in the urination facility during the collection of a specimen. This requirement is intended to safeguard both the employee's privacy and the integrity of the process. The only exceptions to this rule are the observer in a directly observed collection or the monitor in a monitored collection.

Section 40.43 What Steps Must Operators of Collection Sites Take To Protect the Security and Integrity of Urine Collections?

Commenters made a number of suggestions about this section. One commenter said that the requirement to ensure that the collection site is secure before each collection was too much work. We disagree. Making this check is vital to the integrity of the program. Several commenters suggested that we clarify the requirement that a collector can have only one collection going on at a time to allow a collector to continue other collections while another employee was drinking fluids in a ''shy bladder'' situation. We think this is a good idea that would avoid potential delays at collection sites, and we have added language to this effect.

The NPRM proposed that the collector should keep the collection container within view ''to the greatest extent [he or she] can.'' A few commenters thought this requirement should be absolute, with the consequence being a fatal flaw if the collector let the container out of his or her sight. We do not believe that the requirement should be absolute. While it is important for the collector and the employee to keep the specimen in sight, a brief absence by the collector ought not be a reason for cancelling a test that otherwise meets Part 40 requirements.

As commenters suggested, we clarified that authorized personnel who may be present at the collection site may include employer representatives, that no one but direct observers and monitors could be in the urination facility with an employee, and that collectors can remove a disruptive person from the collection site.

Section 40.45 What Form Is Used To Document a DOT Urine Collection?

Earlier this year (June 23, 2000), HHS issued a new CCF for use in both the Federal employee and DOT drug testing programs. The references to the CCF in this rule are to the new form. Most provisions of this rule become effective on August 1, 2001, the same date use of the HHS form becomes mandatory for use in the Federal employee program. (Before August 1, 2001, participants in both programs have the option of using either the old or the new form.) Consequently, there will be no disconnect between the HHS form requirements and the requirements of this rule.

A few comments suggested allowing the collector to sign CCFs in advance, presumably to save time during collections. We think this idea is fraught with potential for misuse or theft of signed forms, and we will maintain the prohibition on this short cut. We have added a specific requirement for the MRO's phone and fax numbers, as a commenter suggested. A few commenters also suggested allowing the use of foreign-language versions of the form in the U.S., as well as in other countries. We have incorporated this suggestion, with the stipulation that use of a non-English version of the form that ODAPC has reviewed is allowable in any situation (here or in another country) only if both the employee and collector understand and can use the form in that language. For example, a collector who does not read French could not use a French language form, even for a French-speaking employee.

Section 40.47 May Employers Use the CCF for Non-DOT Collections or Non-Federal Forms for DOT Collections?

Some commenters supported permitting the use of the Federal CCF for non-DOT collections. Some of these comments favored adding boxes to the form that collectors could check for ''DOT'' or ''non-DOT'' collections. We have believed since the beginnings of the DOT program that it is very important to maintain ''truth in testing.'' If a form says ''DOT'' or ''Federal'' on it, despite whatever fine print qualifications or check boxes might be included, the form may easily imply to the employee that he or she is being tested under Federal law. If this is not true, as in the case of a ''company policy'' test, then we are knowingly misinforming the employee. That is unfair. Moreover, ''company policy'' tests that do not meet DOT requirements, but are conducted using the CCF, could implicate the DOT program in legal challenges to the non-DOT tests. We will maintain the existing prohibition.

Generally, most commenters on the subject agreed with the NPRM's proposal to make use of a non-Federal form in a DOT test a ''correctable flaw.'' A few comments questioned the need for the written correction. Correcting the flaw will ensure that there was an appropriate explanation for use of the non-DOT form (*e.g.,* a post-accident test where nothing else was available, a simple mistake) and will help to educate the collector involved about the need to use the correct form. We will also keep this provision in the final rule.

Section 40.49 What Materials Are Used To Collect Urine Specimens?

There were few comments on this section, which requires the use of a ''DOT Kit'' (see Appendix A for details). Laboratories and MROs should treat as a ''red flag'' any situation in which a non-conforming kit is used. While use of a non-conforming kit is not a fatal or correctable flaw in the testing process, laboratories and MROs should, if they discover that a non-conforming kit was used for a collection, check to make sure that correct collection procedures were used and that no fatal flaws occurred. Use of a nonconforming kit is a rule violation that can subject the user to consequences under DOT agency rules.

Section 40.51 What Materials Are Used To Send Urine Specimens to the Laboratory?

This provision concerns shipping containers. In response to a comment, we have omitted a reference to a standard ''box,'' leaving the provision as a performance standard requiring a container that adequately protects the specimen from damage during shipping.

Subpart E—Drug Test Collections

Section 40.61 What Are the Preliminary Steps in the Collection Process?

Commenters responded to a variety of detailed issues in this section. With respect to employees who showed up late for a test or not at all, several commenters said it was common for employees not to have appointments. As a result, employees simply appeared at the collection site, and collection site people had no notion whether they were on time or not. Commenters suggested that the proposed ''no show'' provision be limited to situations in which the collection site was at the employee's worksite or an appointment had been scheduled. We agree, and have added language to this effect.

Some commenters thought it was unreasonable to ask collection sites to do their work on a timely basis, and they therefore objected to the proposed requirement that the collection process begin without delay. We believe that, for the sake of both employers and employees, timeliness is essential for decent customer service. However, we

will respond to concerns about the flexibility of this provision by adding the modifier ''undue.'' We will also note in § 40.209 that a collector delay is not a ''fatal flaw.''

The NPRM stated that when alcohol and drug tests were being given to the same employee at the same site, the alcohol test should be given first. In response to comments concerned about backups in the testing process, we have provided additional flexibility and added an example of a situation in which an employee's urine collection might be conducted first.

The NPRM would have prohibited the collection of urine from an unconscious employee by means of catheterization. A few comments asked for clarification in other situations involving catheters. Some also suggested testing by alternative means in these cases (*e.g.,* hair, saliva). The Department is clarifying this section to prohibit collecting urine by catheterization not only from an unconscious employee, but also from a conscious employee. The former raises consent issues, and the latter, even given consent, raises safety issues. However, in the case of an employee who normally voids through self-catheterization (*e.g.,* for medical purposes), the collector must require the employee to provide a specimen in that manner.

With respect to alternative testing technologies such as hair testing, saliva testing, and on-site testing, which commenters recommended in context of several sections of the NPRM, the Department will wait upon the action of HHS before proposing to incorporate additional methods. Approval of these or other methods, and establishment of requirements and procedures for them, are matters primarily within the expertise of HHS, which is currently considering them with the assistance of the Drug Testing Advisory Board (DTAB).

Concerning identification of employees, commenters suggested that a driver's license or similar government-issued ID would be acceptable in lieu of an employer-issued credential. On the other hand, some comments pointed out that the credibility of employer-issued ID might be doubtful in the case of a self-employed individual. We have modified the section on both points. A driver's license or other government-issued photo ID will be acceptable, and an employer-issued ID from an owner-operator or other self-employed person will not.

Many of the same commenters who objected to the proposed requirement to have collectors search boots also objected, for similar reasons, to the proposed requirement (similar to that of the existing rule) to have employees empty their pockets. We believe that taking objects out of one's pockets is a minimal intrusion into the employee's privacy, which can help deter and detect some attempts to cheat on tests. In addition, this is a provision that is paralleled in HHS guidelines. The final rule retains the proposed requirement.

A few commenters objected to the provision that would bar requiring employees to sign consent forms, waivers, releases, etc. concerning the collection and testing process. These comments did not explain the reason why exacting signatures on such documents was necessary for the DOT testing process, and we do not believe that it is. We have retained it, but moved it to Subpart Q and made it applicable to all service agents, not just collection sites. One comment suggested that collection sites be able to have employees sign consent forms with respect to non-DOT tests. This rule does not limit employers' or collection sites' actions concerning non-DOT tests, but the rule does require strict separation between DOT and non-DOT testing procedures. This includes separate paperwork for a DOT and non-DOT test conducted with respect to the same employee during his or her visit to a collection site. Such a consent form must not be part of the paperwork for a DOT test, and it could not apply to the DOT test or be filled out at the same time the employee was filling out the paperwork for the DOT test.

Section 40.63 What Steps Does the Collector Take in the Collection Process Before the Employee Provides a Urine Specimen?

Commenters raised few issues concerning this section. A commenter wanted to eliminate the prohibition on the employee flushing the toilet after providing the sample, but we will retain this provision because it limits opportunities to flush away evidence of adulteration. (However, inadvertantly flushing the toilet does not create a ''fatal flaw.'') Another commenter suggested training collectors in how to detect attempts to tamper with specimens. We think this is a good idea, and our guidance will suggest it. However, we do not think it is necessary to incorporate it in rule text.

Section 40.65 What Does the Collector Check for When the Employee Presents a Specimen?

Some commenters noted that the NPRM omitted the existing provision concerning taking an employee's body temperature when the specimen temperature was out of range. This was intended. Many collectors are not medically trained, and the accuracy of some thermometers is not certain. The provision has not been too useful under the existing rule, and we will not include it in the final rule. Other comments requested revision of the temperature range (*e.g.,* to be between 94 and 100 degrees). While this idea has some appeal, we believe we need to keep Part 40 consistent with HHS provisions on this matter.

Other commenters asked for clarification whether, when one specimen has not met regulatory requirements (*e.g.,* out of temperature range, insufficient volume), the specimen should be sent to the laboratory for testing, as well as any subsequent specimen that is collected. We agree, and have included specific directions on this point. For example, when the first specimen is out of temperature range, and a second specimen is collected under direct observation, both specimens would be sent to the laboratory and tested. On the other hand, if the first specimen were out of temperature range, and the employee refused to provide a second specimen under direct observation, the first specimen would be discarded and the event simply treated as a refusal.

Section 40.67 When and How Is a Directly Observed Collection Conducted?

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. In any case, these commenters opposed adding any situations in which direct observation was required or authorized. Other commenters said that the benefit of greater protection against specimen tampering warranted direct observation in situations that suggested a heightened risk of tampering.

The Department agrees with the latter comments. In situations that may create a higher risk or greater incentive for tampering (*e.g.,* the previous collection was verified positive, adulterated, or substituted, but the test had to be cancelled because the split specimen was unavailable for testing; the previous specimen was invalid and there was no adequate medical explanation; temperature out of range; apparent tampering with the specimen at the collection site), the interests of the integrity of the testing process, with its

safety implications, outweigh the additional privacy impact of the direct observation process. On the other hand, dilute specimens may have a number of innocent causes (*e.g.,* someone likes to drink a lot of water). A dilute specimen does not necessarily imply the same higher risk of tampering upon recollection, so the final rule does not authorize direct observation in this case.

The existing rule and the NPRM both called for use of a same-gender direct observer. Some comments objected to this requirement, saying it created practical problems in collection sites that were staffed by only one collector. Other commenters insisted on retaining this requirement as a matter of privacy. We believe there is no alternative to retaining the same-gender observer requirement. Use of opposite gender observers would not only go counter to deeply held societal norms of privacy (*i.e.,* the basic reason for separate men's and women's rest rooms in public places), but might raise genuine safety concerns, particularly on the part of female participants. We would point out that the observer need not be a trained collector, so that another same-gender person could be enlisted for the task.

One commenter recommended we add a provision telling the collector or employer, as appropriate, to explain to the employee why a directly observed collection needs to be conducted. We believe that this is a good idea, and we have included a requirement in the rule to this effect.

Section 40.69 How Is a Monitored Collection Conducted?

Much of the comment on this section echoed the comments on § 40.41, supporting the use of multistall restrooms as urination facilities and urging the Department to permit the use of monitored collections at the collection sites at the employer's discretion. The discussion of multistall restrooms and monitored collections in § 40.41 is the Department's resolution of these issues. This section sets forth the procedures to be used for monitored collections.

A few commenters focused on the use of toilet bluing agents in monitored collections. They suggested that bluing not be required except in the toilet the employee is using while providing the specimen. We agree with this point with respect to a monitored collection. In a case in which a collection uses a multistall restroom as a urination facility but does not conduct monitored collections, however, all toilets must be secured, including the use of bluing.

A number of commenters again objected to the requirement that the monitor be of the same gender as the employee, essentially for the same reasons that commenters objected to the same gender requirement for direct observers. They added that, in the case of monitors, there is a less intense privacy concern because the monitors do not actually watch the employee urinate. We agree that the privacy concern is less intense in this case, and for that reason we permit the use of opposite-gender monitors who are medical professionals. Medical professionals are trained to conduct themselves properly and are less likely than other persons to raise privacy and safety concerns among employees. But legitimate privacy and safety concerns still exist to a degree in the monitored collection situation, and we believe that monitors who are not medical professionals should continue to be the same gender as the employee, as under the current rule.

Section 40.71 How Does the Collector Prepare the Specimens?

Proposed § 40.71, concerning single specimen collection procedures, has been deleted, as all collections will now be split specimen collections. This section is based on proposed § 40.73. There were few comments on this section. One suggested that the failure of the employee to initial the tamper-evident seals be regarded as a refusal to test. We do not think that that is the best solution to this problem. The individual has, after all, provided a specimen. By having the collector note the problem in the remarks line of the form, we preserve a record that the collection proceeded properly. In this section, we also clarify at several points that the collector, not the employee, performs several tasks.

Section 40.73 How Is the Collection Process Completed?

This section is based on § 40.75 of the NPRM. Commenters addressed a number of technical points. Some commenters wanted to put a time line in the section to expedite proceedings. We agree, and we have added a 24-hour/next business day requirement for transmittal of relevant copies of the CCF and the specimen itself. As another commenter suggested, we do encourage the immediate faxing of CCF copies to the MRO and DER.

A commenter asked that we specifically prohibit employees from providing medical information on the CCF. We agree, and we have spelled out this point in § 40.61(g). Another commenter suggested deleting the requirement for a ''box'' as the shipping container. We have deleted this requirement as a matter of flexibility, both here and in Appendix A, though we retain mention of a box as an example of something that can be a shipping container.

A commenter suggested that we eliminate the proposed requirement to note the entry for a specific courier or shipping service on the CCF. This requirement is part of the HHS CCF and instructions, so for consistency's sake we will retain it. However, we also specify in § 40.209 that omitting this information is not a fatal flaw.

As indicated previously, the shipping container seal was used primarily to seal the shipping container (box). Laboratories still tested the specimens when the shipping container seal was broken, provided the seals on the bottles remained intact. Based on this fact, we have removed the requirement for a shipping container seal to be placed on a shipping container. The same rationale applies to placing a shipping container seal on the plastic bag. The construction of the plastic bag is such that any tampering will be evident, even without the seal. Consequently, the final rule does not include any requirement for placing a shipping container seal across the opening of the plastic bag or for the collector to sign or initial and date such a seal.

Subpart F—Drug Testing Laboratories

Section 40.81 What Laboratories May Be Used for DOT Drug Testing?

The only comments on this section concerned the application of the PIE process to laboratories. Some laboratories and other commenters believed laboratories should not be subject to PIEs, since they are subject to HHS certification requirements. We believe that laboratories are service agents providing services to DOT-regulated employers no less than other parties subject to the PIE provision. Moreover, some Part 40 requirements affecting laboratories (*e.g.,* information release, conflicts of interest, validity testing requirement) are not enforced by HHS through its certification procedures. For these reasons, we believe laboratories should remain subject to the PIE process. However, we specify in § 40.365 that the Department does not intend, as a matter of policy, to initiate a PIE proceeding concerning a laboratory with respect to matters on which HHS has taken action under its certification process.

Section 40.83 How Do Laboratories Process Incoming Specimens?

We have added a provision to this section specifically requiring

laboratories to comply with HHS guidelines concerning accessioning and processing specimens. We do not believe it is necessary to duplicate significant portions of the HHS guideline provisions concerning laboratory processing of specimens, and we have therefore eliminated some provisions of the proposed Subpart F, such as § 40.87 and portions of this section and § 40.95.

Some commenters addressed the portion of the NPRM that discussed situations in which the color of the primary and split specimen differ. Because we will require a standardized collection kit using a single collection container, we believe that specimens failing to be color-coordinated should no longer be a problem, so we have deleted this provision. This material is covered in the HHS guidelines, so we do not need to repeat it here. We did incorporate a commenter's suggestion to direct the laboratory to retain a specimen for five working days while waiting for the correction of a correctable flaw.

A few commenters recommended that, when a laboratory notes that a split specimen is unavailable for testing, the laboratory should cancel the test then and there. We disagree. Most tests turn out to be negative, and employees do not request a test of the split specimen in all other cases. Therefore, there is a good probability that the test of the primary specimen will not turn out to be futile.

Section 40.85 What Drugs Do Laboratories Test for?

Section 40.87 What Are the Cutoff Concentrations for Initial and Confirmation Tests?

These technical sections have changed very little from the existing rule. A few commenters supported, and a few others opposed, allowing to test for other drugs (*e.g.*, barbiturates, benzodiazopenes, ''designer drugs'') in addition to the ''HHS five.'' This issue has been debated from the inception of the program. As the Department has said in the past, we believe the stability and reliability of the program are well served by limiting testing to the ''HHS five.'' HHS has established testing protocols and cutoffs for these drugs, and laboratories are subject to HHS certification for testing of these five drugs. This is not true for other drugs.

Section 40.89 Are Laboratories Required To Conduct Validity Testing?

Section 40.91 What Validity Tests Must Laboratories Conduct on Primary Specimens?

Section 40.93 What Criteria Do Laboratories Use To Establish That a Specimen Is Dilute or Substituted?

Section 40.95 What Criteria Do Laboratories Use To Establish That a Specimen Is Adulterated?

These sections are the laboratory-related provisions concerning validity testing. We discussed validity testing extensively in the ''Principal Policy Issues'' portion of the preamble, including issues pertaining to the scientific validity of adulteration and substitution criteria.

Section 40.89(b) states that laboratories continue to be authorized to conduct validity testing. This sentence is included to avoid anyone mistakenly concluding that, until validity testing becomes mandatory, there is a question about whether it can remain a voluntary part of the DOT drug testing program, as it is today. (The parallel section of the amendments to current Part 40, § 40.205(b), is for the same purpose.) When HHS issues its mandatory requirements on validity testing, DOT will amend § 40.89(c) to insert a date on which DOT will require all DOT specimens to be subject to validity testing. We would not make this date earlier than August 1, 2001, even if HHS issues its requirements before that date.

As noted in that discussion, this rule will not specify adulterants that must be tested, given the changes that can be expected in the popularity of various substances. However, we expect laboratories to be able to identify all those listed in up-to-date HHS guidance or rules. For example, we have not listed nitrites in this rule, but current HHS guidance calls on laboratories to test for nitrites. If nitrites cease to be a significant adulterant, and other substances arise to take its place, HHS guidance or rules will change as well.

One point we believe to be quite important is that laboratories should remain vigilant for new adulterants. If a laboratory finds a substance it cannot identify that appears to act as an adulterant or interfering substance, the rule directs the laboratory, after checking with another laboratory, to inform ODAPC and HHS about it. Doing so will enable us to react as quickly as possible to new adulterants being marketed.

We also note that, while the requirements for split specimen testing for adulterated and substituted specimens and MRO review will take effect within 30 days of the publication of this rule, mandatory validity testing is not required to begin until further notice from DOT. We will issue this notice in conjunction with the issuance by HHS of its mandatory requirements for validity testing. We hope that this will be on or before August 1, 2001. This should give those laboratories who currently are not conducting validity testing sufficient time to prepare to implement these requirements fully.

Section 40.97 What Do Laboratories Report and How Do They Report It?

This section is based on parts of proposed §§ 40.95 and 40.97. Some portions have been deleted as duplicative of HHS materials. The topic of greatest interest to commenters was the proposal to continue the current requirement that laboratories transmit test results directly to MROs, without using a C/TPA or some other party as an intermediary. C/TPAs made many of the same arguments on this point as they did with respect to the transmission of results from the MRO to the employer.

There is only one party in the DOT drug testing system who is entitled to see a confirmed laboratory result. That is the MRO. Other parties, including collectors, employers (except in a limited way if a stand-down waiver is granted), SAPs, and C/TPAs are not. These other parties are entitled to learn of a result *only* after the MRO has verified it. To permit a C/TPA to receive a confirmed laboratory result and then transmit it to the MRO would directly violate this key principle. We do not think that, in the present state of the health care industry, there should be serious problems with MROs having appropriate technology to receive results.

As discussed in the ''Primary Policy Issues'' part of the preamble, the Department has agreed to permit C/TPAs to act as intermediaries in transmitting results from MROs to employers. However, we believe that this situation is quite different from allowing C/TPAs to act as an intermediary in transmitting laboratory results to the MRO.

A number of commenters supported allowing the electronic transmission of result reports, especially negatives. Paragraph (b) of this section does permit considerable use of electronic methods. Beyond that, the Department will consider additional use of electronic methods through the advisory committee process discussed in the ''Primary Policy Issues'' portion of the preamble.

The NPRM mentioned transmitting negative results within 72 hours. Some commenters thought this period should be shortened to 24 or 48 hours, while one laboratory thought it would be too burdensome to use couriers on weekends to meet this goal. The final rule says that results should be transmitted to the MRO on the same day or business day after review by the certifying scientist is complete. Besides taking care of any weekend worries, this provision, in tandem with the use of electronic methods permitted under the rule, should result in expeditious transmission of results.

Section 40.99 How Long Does the Laboratory Retain Specimens After Testing?

We have simplified this section. Specimens which were positive, adulterated, substituted, or invalid must be kept for one year. In response to requests from commenters, we have provided that the laboratory must keep the specimens longer only if they receive a request from an employer, employee, MRO, C/TPA, or DOT agency representative. Absent such a request, the laboratory may discard the specimen. This rule applies to primary and split specimens alike. With respect to negative tests and specimens rejected for testing (*e.g.,* because of a fatal or uncorrected flaw), the laboratory should follow HHS guidance. We do not believe it is necessary to restate the guidance here.

Section 40.101 What Relationship May a Laboratory Have With an MRO?

This section focuses on potential conflicts of interest between MROs and laboratories. We discussed comments on this issue and the Department's responses in the ''Principal Policy Issues'' portion of the preamble.

Section 40.103 What Are the Requirements for Submitting Blind Specimens to a Laboratory?

The NPRM proposed to reduce the number of blind specimens employers and other program participants were required to send to laboratories. We made this proposal because it would reduce costs and burdens and because the laboratory testing program appears to be running very smoothly. Comments were divided on this issue. A majority of commenters, especially from employers and their groups, supported the proposal. Some said they had never heard of a laboratory error. Others said that blind specimen testing had outlived its usefulness and should be eliminated. On the other hand, a number of commenters said that to reduce the number of blind specimens would endanger the accuracy and integrity of the laboratory testing program.

We also received a number of comments saying that if we make validity testing mandatory, adulterated and substituted samples should also be included in the blind testing program. Some commenters expressed concern about being able to find adulterated blind specimens. A few comments from TPAs suggested that they should not have to send in blind specimens, even when they submitted more than 2000 specimens in the aggregate, because doing so should remain the individual employer's responsibility.

The Department believes the NPRM proposed a good balance between considerations of reducing burdens and maintaining an effective check on laboratory performance. We have had few if any laboratory accuracy problems over the history of the program, and we believe that we can continue to ensure that this pattern continues while reducing burdens and costs on participants. We agree that adulterated and substituted specimens should be made part of the blind specimen testing program, and we have consequently changed the proportions of specimens in the program to be 75 percent negative, 15 percent positive, and 10 percent adulterated or substituted. This is particularly important given the recent problems at some laboratories concerning validity testing. Given that this provision will not take effect until next August, we think that producers will have time to market adulterated and substituted blind specimens.

We believe that any organization that transmits to laboratories the requisite number of specimens in the aggregate should be responsible for participating in the blind testing program. This is true no matter whether the organization is an employer, a C/TPA, or some other service agent. The structure of the organization is irrelevant for this purpose. To decide otherwise would permit large gaps in the blind testing program. If 100 employers with 20 employees each are served by a C/TPA, and the C/TPA does not submit blind specimens, then no one will submit such specimens with respect to these employees, since each of the employers is too small on its own to be required to participate. Permitting this gap to exist would be disadvantageous from the program integrity standpoint.

We would also point out that C/TPAs, in virtually every other area of program administration, assert that they can perform a multitude of functions for everyone involved in the program. We do not see any compelling reason for looking differently at their involvement in blind specimen testing.

Section 40.105 What Happens if the Laboratory Reports a Result Different From That Expected for a Blind Specimen?

Some commenters objected to the proposed requirement for notification of DOT in the event of a laboratory error, or to the idea that ODAPC could direct laboratories to take corrective action. The main argument of these comments was that HHS had what they viewed as exclusive jurisdiction over testing matters, on which DOT should not infringe. We have refocused the section on unexpected blind specimen results.

The Department would always coordinate closely with HHS on matters affecting laboratories, as indeed we have done in drafting this provision. The fact remains that many MROs and other participants in the DOT program have their primary Federal agency relationship with DOT agencies, and it makes sense to have them report problems to DOT. It is also important to realize that testing laboratories, while certified by HHS, receive significantly more specimens as a result of the DOT program than as a result of the Federal employee testing program. Under these circumstances, a DOT role in noting and helping to correct any laboratory-related problems affecting the DOT program seems most appropriate.

Because we are requiring blind specimens in connection with validity testing, this section necessarily covers errors in validity testing.

Section 40.107 Who May Inspect Laboratories?

In response to comments, we are clarifying that the employers who may inspect laboratories are those who use or are negotiating to use its services for DOT-regulated testing.

Section 40.109 What Documentation Must the Laboratory Keep, and for How Long?

The Department has simplified this section and acted to reduce paperwork burdens, as a number of commenters recommended. All records supporting test results and those cited in § 40.111 must be kept for two years, unless an MRO, employer, employee, or DOT agency representatives requests an extension within the two-year period (*e.g.,* for litigation purposes). If no such request is received, the laboratory may discard the records.

Section 40.111 When and How Must a Laboratory Disclose Statistical Summaries and Other Information It Maintains?

The NPRM proposed to reduce paperwork burdens by reducing the reporting frequency for this information from quarterly to semi-annually. A number of comments supported this reduction. Other commenters favored eliminating the requirement altogether, or at least for small employers, on burden and cost reduction grounds. We believe that cutting the reporting burden in half is a sufficient burden reduction on this item and that even small employers will find summarized information on their workforce's participation useful. We underline the fact that the smallest employers, laboratories and C/TPAs will not experience the burden of sending ''non-reports,'' since there is no requirement to send a letter saying there is nothing to report unless specifically requested as part of a DOT audit. This will further reduce the paperwork burden of the rule.

Section 40.113 Where Is Other Information Concerning Laboratories Found in This Regulation?

This is a cross-reference section to inform readers where they may find other material relevant to laboratories' participation in the program.

Subpart G—Medical Review Officers and the Verification Process

Section 40.121 Who Is Qualified To Act as an MRO?

The Department believes that MROs play a key role in maintaining a fair and accurate drug testing program. Ensuring that MROs are in the best possible position to play this role requires, in our view, that they be well trained both in the substance of drug testing issues and the rules they are called on to apply. For these reasons, the NPRM proposed that MROs participate in a training course every two years or, in the alternative, self-certify that they have reviewed and understand these rules.

Commenters raised a number of issues. First, some commenters said that groups of health professionals other than physicians, like chiropractors, nurse practitioners, and physicians' assistants, should be able to be MROs. They perform other functions like physicians (*e.g.,* DOT physical examinations for commercial drivers) and are qualified to perform this one, commenters asserted. The Department does not agree with this assertion. That other health professionals have some training similar to that of physicians is undeniable, but the Department believes that the variety and depth of expertise needed to carry out MRO responsibilities effectively is unlikely to be found in other health professionals. There are clearly differences in the level of training needed to qualify for the various health professions, and we believe that only those professionals with the highest level of training should play this key role. Being qualified to perform routine physical examinations, for example, is not necessarily the same thing as being able to make capably the difficult judgment calls that MROs are called upon to make.

Second, many commenters disagreed with the proposal to allow self-certification of training. More formal training, including a certification program, was necessary, commenters said. Commenters pointed to three existing MRO training and certification programs as models for what the Department should require. These have a five-year retraining cycle, and a number of commenters thought that five years, as opposed to two, was sensible. On the other hand, a smaller number of commenters opposed additional training requirements for MROs, saying it would drive up the cost and difficulty of being an MRO, and hence reduce the supply of MROs available to employers.

The Department is modifying this section in response to these comments. We are persuaded that MROs, given their critical role, should not only have the highest professional credentials to begin with, but also receive formal training in the rules and decision process of their critical role in this program. Therefore, we are dropping the self-certification proposal of the NPRM. We will require MROs to take a formal training course, like one of the three national programs currently being offered. We will also require an examination administered by a nationally-recognized MRO professional certification board. We are not requiring ''certification'' of MROs, as such, however. While people who take the MRO courses typically get a ''certificate'' from the program, DOT is not certifying doctors in a way analogous to the way that the FAA certificates pilots. We believe that certification by professional organizations is beneficial, but we believe that there are sufficient market incentives for certification that we do not need to require it in this rule. Finally, we are adding a continuing education requirement to ensure that MROs keep up with changes and developments in the field and the DOT program.

The final rule establishes a phase-in period for this training requirement. For example, if a doctor is currently acting as an MRO, but has not yet had a formal training course, the doctor would have until January 2003 to meet the requirement. This should prevent any difficulty caused by lack of training sites or dates convenient for a particular physician.

Costs for existing MRO training courses tend to average around $750, including the examination, and the courses take a weekend. This low cost and time commitment suggest that this training requirement should not dry up the supply of MROs.

Like other participants, MROs would have to maintain their own documentation of training and qualification, which they must provide on request to representatives of the Department and employers and service agents who are using or negotiating to use their services.

One issue about which the Department inquired in the preamble to the NPRM concerned issues of MRO work that goes across state lines. Commenters expressed the concern that some state medical regulatory organizations may attempt to assert that only doctors licensed in a particular state could perform MRO services with respect to employees located in that state. The Department shares these commenters' concern. This is a national program, and MROs often perform their duties for employees located in many states. Consequently, this section specifically provides that a physician licensed to practice in any jurisdiction (*e.g.,* a state or province of the United States, Canada or Mexico, consistent with NAFTA requirements) and meeting other MRO requirements is authorized to act as an MRO with respect to employees located in any jurisdiction. We would regard any attempt by a state medical regulatory organization to limit the geographic scope of an MRO's work as pre-empted under the pre-emption provisions of DOT agency rules.

Section 40.123 What Are the MRO's Responsibilities in the DOT Drug Testing Program?

There were a few comments on this section. One commenter liked, and another disliked, referring to the MRO as a gatekeeper for the accuracy and integrity of the process. Another suggested that the MRO should be an advocate for the accuracy and integrity of the process. We have kept the gatekeeper term and added the idea of being a program advocate. As other commenters agreed, independence and

impartiality are essential to the MRO's role.

One commenter thought that the NPRM assumed, incorrectly, that MROs were solo practitioners. This commenter pointed out that there are MRO organizations with multiple MROs who perform drug testing program functions. We are very aware of this phenomenon, which is not surprising given the emphasis on group practice in today's health care industry. Nevertheless, each MRO retains individual responsibility for his or her actions. Groups don't verify test results; individual doctors do. It is the individual doctor who must make a decision and sign off on the result.

One employer organization was concerned that the NPRM placed in the hands of MROs tasks that, in its view, properly belong to the employer, like providing feedback to collection sites and laboratories on performance issues. We have added ''employers'' to the list of persons with whom it is appropriate for MROs to communicate. At the same time, however, we do not believe that it is consistent with the independence and impartiality of the MRO for employers to limit the contact of MROs with other parties.

In particular, we believe that no other party may legitimately attempt to interfere with the opportunity of an MRO to communicate with DOT agency representatives about drug testing program matters. For this reason, we have added language specifically prohibiting anyone from interfering with an MRO's access to DOT personnel or retaliating against an MRO for communicating with the Department.

We became convinced of the necessity of this provision, in part, because of an instance in which an MRO raised an issue about a decision of a major transportation employer, who had in turn been given questionable advice by a service agent. The MRO brought the matter to the Department's attention. The Department wrote a letter to the employer correcting its understanding of the issue in question. The employer responded by directing the MRO not to communicate with DOT and subsequently terminated the MRO's services. The Department wants to put all parties on notice that conduct of this kind is not permitted by the new regulation and in future will subject violators to enforcement action by DOT agencies, in the case of employers, or PIE proceedings, in the case of service agents.

As a number of commenters noted, since MROs will be involved in reviewing validity testing results, they will need to be prepared for the verification process in adulteration and substitution situations. This section now refers to this facet of the MRO's duties.

In addition, the rule does not deem MROs, in working with employees under this program, to have established a doctor-patient relationship with them. Doctors are not diagnosing or treating employees they encounter in their role as MROs; they are using their medical expertise to make decisions in the context of a forensic program. In the Department's view, drug and alcohol tests are not properly viewed as medical examinations or procedures, notwithstanding the involvement of medically-trained personnel in their administration.

Section 40.125 What Relationship May an MRO Have With a Laboratory?

This section is the reciprocal of § 40.101, prohibiting improper MRO-laboratory relationships. It refers to the same improper relationships listed in § 40.101 and directs MROs to sign a statement that they have no conflicts of interest or other improper relationships with laboratories.

Commenters generally concurred with this provision, agreeing with the need to keep MRO and laboratory functions separate. One commenter said that MROs should be able to provide a list of laboratories to customers and laboratories should be able to refer customers to MRO certifying organizations. We do not endorse this practice, though the names of HHS-certified laboratories and groups that train MROs are matters of public record that no one can be forbidden from sharing. Another commenter asked how the provisions of this section would be enforced. The answer is through the PIE process. Another commenter asked that we specifically prohibit having MROs or MRO staff within a lab facility. The list of prohibited relationships in § 40.101 includes this item.

Section 40.127 What are the MRO's Functions in Reviewing Negative Test Results?

Commenters raised two main issues concerning this section. While some commenters, mindful of the necessary role of the MRO in quality control for the testing process, supported MRO review of negative test results, most of those commenting said that the review requirements were too burdensome. It was not necessary for MROs to review 10 percent of negative results, they said, and this would raise costs that would be passed on to employers. These commenters appeared to view the processing of negative results as a simple administrative task that could safely be delegated to staff. If MROs were to review negative results at all, these commenters suggested, the amount of review should be reduced (e.g., to five percent or a numerical maximum).

Reviewing negative test result records is an administrative task, to be sure, and we anticipate that MRO staffs will do most of the work involved. But quality control is an important function for which MROs themselves must remain responsible. In response to comments, we will reduce the number of reviews by MROs to five percent of results, including all that have required some corrective action (*e.g.,* to fix a correctable flaw), to a maximum of 500 results per calendar quarter. This will reduce the potential burden on MROs, while retaining their oversight responsibility.

The second major issue was the proposed language that required review of negative results to be done by staff under the direct personal supervision of MROs. Some commenters objected to this language, believing it meant that MROs would have to be co-located with all staff and provide face-to-face supervision. This would be contrary to common working arrangements of service agents, they said.

The Department does not intend, through use of this language, to mandate that MROs must share the same physical space with all their staff members at all times. As commenters noted, direct personal supervision need not be physically face-to-face on an all-day, every day basis. Supervision can also take place through using a variety of electronic communications. However, the direct personal supervision must be meaningful. It involves personal oversight of staff members' work; personal involvement in evaluation, hiring, and firing; line authority over the staff for decisions, direction and control; and regular contact and oversight concerning drug testing program matters. It also means that the MRO's supervision and control of the staff members cannot be superseded by or delegated to anyone else with respect to test result review and other functions staff members perform for the MRO. In addition, CCFs may not contain fictitious addresses for MROs, and MROs must be personally involved with the review process when a confirmed positive, adulterated, or substituted result is received.

There were also some comments advocating the use of electronic means of transmitting negative results from MROs to employers. We agree, and provide for this in § 40.163. A number

of comments to this section also touted transmission of negative results to employers via C/TPAs, which we permit in § 40.165 and Appendix F. Some commenters also supported eliminating a requirement that the MRO have any copies of the CCF before verifying a negative result. We do not believe it is advisable to make this change, because it is important that the MRO have the MRO copy of the CCF. This allows the MRO to double-check the accuracy of a result to ensure, for example, that an employer does not allow someone to begin work in a safety-sensitive position on the basis of a mistaken or misidentified negative result on a pre-employment test. Instead, we have tightened the requirements for appropriate copies of the CCF to reach the MRO in a more timely fashion.

Section 40.129 What are the MRO's Functions in Reviewing Laboratory Confirmed Positive, Adulterated, Substituted, or Invalid Drug Test Results?

Virtually all the comment in this section concerned its references to the stand-down issue. The comments on this section were essentially the same with respect to proposed § 40.159, and we discussed this issue in the ''Principal Policy Issues'' portion of the preamble. Since we decided to allow employers to ask for a waiver to have a stand-down policy, this section now tells MROs either to inform the DER that there is a confirmed laboratory adulterated, substituted, invalid or positive test result (if the employer has a stand-down waiver in place) or to avoid telling the employer about such a result, pending verification (if there is no such waiver in place). Since MRO review will now apply to adulterated and substituted results as well as invalid and positive results, this section and all those that follow reference all four kinds of results.

Section 40.131 How Does the MRO or DER Notify an Employee of the Verification Process After a Confirmed Positive, Adulterated, Substituted, or Invalid Test Result?

Most of the discussion of this section concerned the proposed requirement, based on the Department's current rules and guidance, that MRO staff may make initial contacts with employees but not gather medical information or information pertaining to a legitimate medical explanation. A number of commenters said that staff, especially medically trained staff like physicians' assistants and nurses, should be able to perform these functions. This happens in the normal course of doctors' office and clinic work, they said, and would make the process less costly and more efficient. Other commenters thought the proposal was important for protecting employees' rights in the system.

The Department believes that this situation is distinguishable from the day-to-day operation of a doctor's office. We are talking here about a key function in protecting the constitutional rights and livelihoods of employees, a function that has no parallel in daily clinical work. Our experience is that, if employees talk to staff about substantive matters, they sometimes think they have talked to the MRO and need not have further contact with the MRO. They therefore do not take full advantage of the protections the rule makes available for them. We also are concerned that clinic staff may not have the background to talk effectively with employees about legitimate medical explanations for confirmed positive, adulterated, substituted, or invalid test results. Staff can still play a useful role by advising employees to gather all prescriptions and other information together so as to be prepared to have a productive discussion with the MRO, as well as by scheduling the discussion with the MRO.

We agree with commenters who pointed out that discussions with the MRO need not be in person. Most MRO operations use telephone contacts, and we have no objection to continuing that practice. We also agree with a commenter that, in instances where the MRO has been unable to contact the employee, MRO staff can contact the DER to take the next steps in the process.

The NPRM proposed that the MRO make at least two attempts to contact the employee over a 24-hour period. There was disagreement about this point. Some union and other commenters thought the period was too brief, while some employer and other commenters thought it was too long. We believe 24 hours is a reasonable middle ground that will provide a fair chance to contact the employee to exercise an important right while not allowing a situation to drag on interminably.

However, we have increased the minimum number of attempts to three, in order to provide a greater chance for attempts to contact the employee to be successful. These attempts need to be separated in time. It would be useless to call the employee, get no answer, and call back five minutes later to get no answer again. The attempts must be spread reasonably over the 24-hour period involved. There may also be circumstances in which the employee has provided incorrect phone numbers. If both phone numbers are ''bad numbers'' (disconnected, employee not known at that number), the MRO need not wait 24 hours to take the next actions the rules call for, since it would be futile to do so.

Section 40.133 Under What Circumstances May the MRO Verify a Test as Positive, or as a Refusal To Test Because of Adulteration or Substitution, Without Interviewing the Employee?

Commenters on this section were mainly concerned about time frames. While there was relatively little disagreement with the idea that the MRO could verify a test after 72 hours had passed from an MRO or DER contact with an employee (one commenter suggested 48), many commenters said that 14 days was too long a time for the MRO to wait before verifying a test when no one was able to contact the employee. A number of these comments suggested 5 or 7 days.

The Department will respond to these comments by shortening the time period to 10 days. We do not believe it is necessary to shorten the period further. Obviously, if the MRO or DER cannot contact the employee in that amount of time, either the employee is not performing safety-sensitive functions (*e.g.,* is away on vacation without a forwarding phone number) or is as unreachable to be pulled off safety-sensitive duties as he or she is with respect to talking to the MRO. There is no additional safety risk in either case.

Section 40.135 What Does the MRO Tell the Employee at the Beginning of the Verification Interview?

Commenters generally supported this provision, which tells MROs to inform employees about the verification process, what will be expected of the employee, and about what information can later be made available to employers and others. One commenter requested that MROs make explicit what specific medications might be reported to employers. This is potentially a very comprehensive list, and we do not believe that this suggestion is practical.

Section 40.137 On What Basis Does the MRO Verify Test Results Involving Marijuana, Cocaine, Amphetamines, and PCP?

One of the important provisions of this section, which the final rule makes explicit, is that employees bear the burden of proof that there is a legitimate medical explanation for the presence of these drugs in their specimens. One commenter asked that we not ''shift'' the burden of proof to the employee. There

is no ''shift.'' The employee has always had this responsibility.

Consistent with similar provisions in the validity testing context, we are requiring employees to present their explanation and supporting evidence at the time of the verification interview. The MRO's staff will already have told the employee to gather prescription and other relevant information for this purpose. This should help to expedite the verification process. However, if the employee persuades the MRO that there is a reasonable basis to believe that the employee can produce additional relevant evidence, the MRO can grant up to five additional days to produce the evidence. This is not mandatory: The MRO should grant more time only if it appears that there is a good reason to do so.

We agree with one comment that pointed out that there are no legitimate medical explanations for the use of PCP. This is also true of 6AM, a heroin-specific substance found in some opiate specimens. Section 40.151 now tells MROs not to accept any medical explanations for these substances.

The NPRM mentioned that an MRO could consider the employee's use of legally obtained foreign medication. One commenter objected to this provision. We believe it is appropriate to consider the fact that an employee obtained medication legally in a foreign country, when medically appropriate, even if that medication is not legally available in the U.S. To do otherwise could penalize legal, innocent conduct. We have adopted, as part of the rule text, the principles underlying the Department's existing guidance on the foreign medications issue.

We intend that, under this provision, MROs have broad discretion to determine whether the use of medications legally obtained within a foreign country should be viewed as a legitimate medical. In doing so, MROs must exercise their best professional judgment. MROs are neither required to find a legitimate medical explanation in any particular case nor prohibited from doing so (except to the extent that one of the principles set forth in this section requires the MRO to find that there was not a legitimate medical explanation). One of the reasons for the prominent position given MROs in the DOT drug testing program is precisely that we believe trained MROs are the best-equipped persons in the program to make these difficult medical judgment calls. We are confident that MROs will be thoughtful in considering the issues.

The rule articulates three principles for MROs use in exercising their discretion. First, there can be a legitimate medical explanation only with respect to a medication that is legally obtained in a foreign country. Second there can be a legitimate medical explanation only with respect to a substance that has a legitimate medical use. Even if one obtains a substance abroad legally, it cannot form the basis of a legitimate medical explanation if it does not have a legitimate medical use. For example, drugs of abuse like heroin, marijuana, and PCP have no legitimate medical uses, and they cannot form the basis of a legitimate medical explanation in any case. Likewise, use of substance which—if obtained in the United States—would not form the basis of a legitimate medical explanation (*e.g.,* hemp products, coca leaf teas) cannot form the basis of a legitimate medical explanation when obtained abroad.

Third, a foreign medication can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose. When someone uses a medication, the person has an obligation to use the substance for its appropriate purpose and in keeping with medical instructions for its use. In addressing this issue, the MRO should look at a number of factors. Did the employee have a genuine medical need for using the substance (*e.g.,* an acute condition that arose while the employee was in the foreign country)? Did the employee use the medication for an appropriate medical purpose (*e.g.,* as opposed to using a medication intended for one purpose for a different, and inappropriate, purpose)? Is the quantity of the substance in the individual's specimen consistent with its proper medical use?

In applying these principles, it is very important for the employee to provide the MRO with adequate documentation. Travel documentation (visa, passport stamps, airline tickets, etc.) can help to check an employee's assertion that he or she was in the foreign country in question at the time he or she said the medication was obtained and/or consumed. Especially where a prescription drug is involved, discussions with a foreign physician or pharmacist are relevant to confirming the prescription for the foreign medication and the reason for it. It is important to note that, in some cases, drugs may be prescribed for purposes in foreign countries different from the purposes for which the medications are prescribed in the U.S. In the case of any foreign medication, the MRO should review documentation of purchase. Ultimately, it is the employee's burden to produce this information, though the MRO may need to be involved in some aspects of the effort, such as discussing medications with a foreign doctor.

In assessing situations in which an employee obtains a medication abroad and consumes it after returning to the U.S., the MRO should take special care to ensure that the employee is using the medication for its intended, appropriate medical purpose. Import and use of some medications in the U.S. may be inconsistent with U.S. drug laws or Customs rules. This heightens the concern that an employee who is using such a medication in the U.S. may not be doing so consistent with its appropriate, intended medical purpose. In particular, routine or frequent use of such a medication in the U.S., as distinct from a one-time or infrequent, inadvertent, or emergency use of the medication, may support an inference that an individual is not using the medication for its intended, appropriate medical purpose. If an employee should have consulted with a U.S. physician before using a foreign medication in the U.S., it can be relevant for the MRO to ask whether such a consultation took place. As a general matter, we view the U.S. use of foreign medication as more problematic than the use of the medication abroad, and we advise MROs to be more conservative in their determinations where U.S. use is involved.

As in cases involving drugs obtained domestically, verification of a test as negative does not end the MRO's job. If use of a substance, even though not a violation of DOT agency drug and alcohol testing rules, creates safety or fitness-for-duty problems, MROs have a mandate to report this information to employers (see § 40.327). An employee may be medically unfit for safety-sensitive duties because of the use of a legal medication, foreign or domestic.

Section 40.139 On What Basis Does the MRO Verify Test Results Involving Opiates?

Most of the discussion on this section concerned the use of the 15,000 ng/mL level of opiates in a specimen for shifting the burden of proof from the MRO (who in most opiate cases must show clinical evidence of unauthorized use) to the employee to show a legitimate medical explanation, as is the case in § 40.137 for other drugs. As noted in the preamble to the NPRM (see 64 FR 60980; December 9, 1999), the Department has good reason to believe that this is an appropriate level (*i.e.,* one high enough to avoid imposing an unfair burden on people who eat poppy seeds or otherwise engage in legal

activities for which there are not legitimate medical explanations).

Some commenters appeared confused about the relationship of this threshold to the 2000 ng/mL cutoff for a confirmed positive test result. The two are different, and they are used for different purposes. The latter establishes a confirmed positive test; the former establishes that the employee, rather than the MRO, has the burden of proof in the verification process. In one Canadian commenter's example, codeine medications are legally available in Canada, and might produce test levels in excess of 15,000 ng/mL. In such a case, the employee would have the burden of proof with respect to a legitimate medical explanation, which the employee could meet through showing that he or she had used a legal over-the-counter medication.

When an employee cannot establish a legitimate medical explanation for opiate levels (morphine or codeine) above the 15,000 ng/mL, then the MRO would verify the test positive. There would be no need for the MRO to find clinical evidence of unauthorized use.

A commenter suggested, and we agree, that the MRO or other physician's encounter with an employee to determine if there is clinical evidence of unauthorized opiate use is better styled an ''examination'' than an ''interview,'' and we have changed the language accordingly.

The Department notes that a situation could arise in which the primary specimen is positive for opiates and 6–AM. The MRO verifies the test as positive, without determining whether there is a legitimate medical explanation or clinical signs of unauthorized use, since these steps are not necessary when a specimen is positive for 6–AM. The split specimen reconfirms the presence of opiates but not the presence of 6–AM.

In this case, the test would not be cancelled. Rather, the MRO would take additional verification steps. If the amount of morphine or codeine in the primary specimen were 15,000 ng/mL or more, the MRO would ask the employee to provide information on any legitimate medical explanation there might be for the presence of the opiates in the specimen. If the amount of morphine or coedine were less than 15,000 ng/mL, the MRO would examine the employee for clinical signs of unauthorized use or refer him or her to another physician for this purpose. The MRO would then make a decision about whether to verify the result as positive. The MRO would make this decision without reference to 6–AM, since the specimen had failed to reconfirm for 6–AM.

Section 40.141 How Does the MRO Obtain Information for the Verification Decision?

There were few comments to this section. One that we adopted suggested that in addition to reviewing evidence on its face, the MRO should take all reasonable and necessary steps to verify the authenticity of the evidence. We have deleted a provision authorizing the MRO to tell the laboratory to conduct a reanalysis of the primary specimen. Because this rule no longer provides for single specimen collections, we believe that this language is superfluous. Reanalysis of the primary specimen is no longer authorized.

Section 40.145 On What Basis Does the MRO Verify Test Results Involving Adulteration or Substitution?

This section adds MRO review provisions concerning the results of validity tests. The basic policy issue of MRO review for validity testing was discussed in the ''Principal Policy Issues'' section of the preamble, which also describes the provisions of these sections. As noted above, MRO review of validity testing results will begin 30 days after the publication of this rule.

One point we want to emphasize is that it is not enough for an employee to come up with a reason that allegedly accounts for the result (*e.g.,* a medical condition, personal characteristics, proximity to a chemical). To meet his or her burden of proof, the employee must demonstrate a link between the alleged reason and the ability to physiologically produce the laboratory result obtained. For example, if an employee shows he has medical condition X, then he must also show a medical/scientific basis for getting from X to a creatinine result below 5 and a specific gravity below 1.001. If the employee shows he had topical exposure to chemical Z, he must also demonstrate medical/scientific evidence that topical exposure to Z in the concentration he experienced leads to the physiological production of the levels of Z in his specimen that the laboratory found. Any such evidence must meet medical/scientific criteria for controls, methodology etc., in order to have credibility.

In any case in which the MRO cancels an adulterated or substituted test result because the employee has established a legitimate medical explanation, the MRO must make a written report to ODAPC. The purpose of this report is to permit ODAPC and HHS to examine the circumstances. This examination could lead to additional guidance to MROs or laboratories concerning the matters that led to the cancellation. ODAPC would not, in such a case, act as a ''court of appeals'' that would overturn the results of the MRO review process.

Under the final rule, the MRO reviewing an adulterated or substituted test result could direct the employee to obtain, within 5 days, a further medical evaluation from someone with expertise in the medical issues raised by the employee's explanation. This individual could be a specialist in a particular field of practice, but need not be. What is important is that the referral physician have enough expertise to deal effectively with the particular issues in the case.

The Department is aware that, in some cases, it may be difficult for an employee to secure, on his or her own, an appointment for this evaluation in a short period of time. Consequently, the Department does not regard it as a refusal to test if the employee is unable, after making good faith efforts, to get the appointment within the 5-day period. However, the MRO and the employer should do everything feasible to assist the employee in finding and getting an appointment with an appropriate physician.

Section 40.149 May the MRO Change a Verified Positive Drug Test Result or Refusal To Test?

This provision is based on proposed § 40.161. There were relatively few comments. A small number of commenters suggested that the employer should be able to change an MRO's action the employer believed to be erroneous, perhaps by referring the matter to another MRO for a second opinion. We do not believe that it would be advisable to authorize this sort of forum shopping. Under the new regulation, MROs will be even better trained in their duties. It would erode the finality of MRO's decisions and the protections the MRO system affords to employees to allow employers a second bite at the apple.

Some commenters also believed the 60-day period during which an MRO could reverse a decision he or she had made was too long. One commenter thought that 14 days was a more reasonable time period. The point of this provision is to allow employees to present evidence that was not originally available. There need be no rush to foreclose this opportunity, which has no adverse safety implications, since the MRO will have already communicated the verification decision to the employer, who will have removed the employee from safety-sensitive duties. We will leave this provision unchanged, except to add a reference to adulteration and substitution cases.

Here is a hypothetical case illustrating how the provision would work, in concert with the five-day extension provision of the §§ 40.137 and 40.145. The MRO interviews the employee, who says she has a legitimate medical explanation. She asks for, and receives, a 3-day extension to find evidence of the explanation, but is unable to do so. The MRO verifies the test as a refusal because of adulteration or substitution. The MRO reports the verified refusal result to the employer, who removes the employee from safety-sensitive duties.

Six weeks later, she returns to the MRO with additional data, including a study performed by the referral physician, acceptable to the MRO, who she has retained. The study, performed under carefully controlled conditions, shows that the employee was able to replicate the laboratory result through physiological means. The MRO determines that this is a legitimate medical explanation and, after discussing the matter with ODAPC, reverses the original verification result. At this point, the employee no longer has an obligation to complete the return-to-duty process before working again in a safety-sensitive position.

Section 40.151 What Are MROs Prohibited From Doing as Part of the Verification Process?

This section is based on § 40.143 of the NPRM. There was little comment. A few comments recommended that MROs should be able to consider evidence extrinsic to the testing process, such as procedural errors not reflected on the CCF, tests of additional specimens (*e.g.,* a hair test), or use of ''medical marijuana'' in a state with a law authorizing such use. The Department is not adopting these suggestions, which would authorize collateral attacks on the validity of the testing process. This regulation prescribes the testing process; if the procedures in a given test meet this part's requirements, that is enough to make the test valid. The MRO should not go beyond the rule's requirements to accept other reasons to cancel a test.

We do not believe it is appropriate to place MROs in the position of having to decide factual disputes between employees and collectors about what did or did not occur at the collection site (*e.g.,* allegations that the collector left the area or left open urine containers where other people could access them) or about whether someone was properly selected for testing. Therefore, this section directs MROs not to become involved in issues extrinsic to the documents in reviewing the CCF. We do not intend, through this provision, to preclude MROs from taking action to cancel a test if the MRO determines that a fatal flaw has occurred in the testing process.

We have, as some commenters suggested, added provisions related to validity testing. Certain substances cannot be produced physiologically in urine, and urine cannot have a zero creatinine content. Likewise, there is no legitimate medical explanation for PCP or 6–AM. The rule specifies that MROs cannot find that a legitimate medical explanation exists in these circumstances. Following a commenter's suggestion, we have also added coca leaf tea explanations to the same category of explanations (along with use of hemp products) that MROs may not accept.

Section 40.153 How Does the MRO Notify Employees of Their Right to a Test of the Split Specimen?

Commenters said that if, as § 40.145 of the NPRM proposed, MROs tell employees with verified positive, adulterated, and substituted tests (1) that they have a right to a test of the split specimen if they make a timely request, and (2) that they are not required to pay for the test from their own funds before the test takes place, then employees will frequently request tests of split specimens. This, in the view of a significant number of commenters, would be a bad thing: Few split specimens fail to reconfirm and testing them is an expensive annoyance that merely serves to delay the inevitable. On the other hand, as one commenter suggested, requiring advance payment from the employee's own funds would have the benefit of eliminating most split specimen tests, since they are most often a ploy used by a guilty employee in the hopes that the split is unavailable for testing or that the specimen will not reconfirm.

The problem with these commenters' analysis is that a test of a split specimen is a right guaranteed to employees by the Omnibus Transportation Employee Testing Act. We agree with commenters that if we do not make employees aware of this right and permit employers to financially deter employees from exercising it, then fewer employees are likely to request a test of the split specimen. However, we must disagree with the proposition that reducing the frequency of requests of a test of the split specimen is an appropriate objective.

When Congress guarantees a right to employees (and we believe we must treat all DOT-regulated employees in our program alike, even if they are not covered by the Omnibus Act), our obligation as a Federal agency is to faithfully execute that legislative decision. The statute provides a series of other protections to employees as a matter of right, such as the use of an HHS-certified laboratory and resort to MRO review for the five HHS drugs. An employer could not say that employees could have their specimen tested at an HHS laboratory only if they paid in advance a higher price to have their specimen tested there instead of a local hospital. Nor could an employer say that it would make MRO review available only if the employee paid in advance for the MRO's services. The same rationale applies to a test of the split specimen. When the statute and rule say that a certain procedure must be made available to an employee, then the employer is responsible for making it happen.

Through collective bargaining or subsequent attempts at securing reimbursement, an employer may seek to have the employee ultimately pay part or all of the cost of a split specimen. But when the employee with a verified positive, adulterated, or substituted test result makes a timely request for a test of the split specimen, it is required that the test take place, and this requirement cannot be made contingent on advance payment by the employee. The Department will retain its NPRM language on this point. (This approach is consistent with the Department's longstanding interpretation of the current rule.)

Another issue in the comments was how to define ''timely.'' The NPRM, like the present rule, says the right to a test of the split specimen is triggered if the employee makes the request within 72 hours of being notified by the MRO of a verified positive test. On request of a number of commenters, we are making explicit that it is the notification of the verified test result that starts this time period running. Some commenters pointed out that RSPA would have to change its rule (which currently permits up to 60 days for such a request) to be consistent with this provision. RSPA will propose such a change as part of its conforming amendments to this rule.

Employers also asked whether they may take action during this 72-hour period. In fact, employers must remove employees from safety-sensitive duties as soon as they are notified of a verified positive, adulterated, or substituted test result. In addition, employers are free to take personnel action once they receive the verified result, although we believe it would be wise to avoid taking final action (*e.g.,* termination) until the 72 hours are up or, where the employee requests a test of the split specimen, until the MRO reports the second

laboratory's split specimen test result to the employer. Nothing requires the employee to be in paid status during this period, in any case.

A number of commenters noted that MROs sometimes authorize tests of the split specimen well after the 72-hour period has elapsed (*e.g.,* weeks or months later). Nothing in the rule precludes an MRO from doing so. However, an employee has a right to a test of the split specimen only if he or she requests it within 72 hours. The employee cannot insist on having the split specimen tested after that time, and the employer is not obligated, financially or otherwise, to make the test happen.

A few commenters suggested that the request for a test of the split specimen should be made in writing. It seems to us that a careful employee would make a written request, in order to have his timely request on the record. But we do not think it is necessary to require this action. Another commenter thought that the rule should not direct the MRO to tell employees that DNA or other tests are not authorized. The Department believes that this provision is beneficial as a means of avoiding unnecessary requests for these tests, and we have retained it.

Section 40.155 What Does the MRO Do When a Negative or Positive Test Result Is Also Dilute?

This section is based on proposed § 40.147 of the NPRM. There was little comment on this section, most of which concerned the issue of whether a dilute specimen should be an occasion for a recollection under direct observation. Such a recollection is not necessary in the case of a test result that is both positive and dilute. For a test that is both negative and dilute, we have decided (see § 40.197(b)) to allow the employer the discretion to conduct an immediate recollection, but not under direct observation, since there can be many innocent reasons for a dilute specimen. This is a change from the existing rule, which permitted tests under direct observation on the next occasion when the individual would be tested (*e.g.,* in the random program).

Section 40.159 What Does the MRO Do When a Drug Test Result Is Invalid?

This section is based on § 40.151 of the NPRM. Consistent with HHS guidelines, we are using the term ''invalid'' rather than ''unsuitable for testing'' to describe such test results. There were a variety of comments on this section. Some commenters thought we should treat invalid tests as refusals to test, the same way we treat adulterated and substituted tests. Another commenter thought it would save time and effort if we simply cancelled invalid tests, with an unannounced recollection under direct observation, rather than going through the MRO inquiry process proposed in the NPRM.

We believe that the Department chose a reasonable middle ground in the NPRM, and we will use this approach in the final rule. When an adulterant has not identified, it has not been conclusively shown that the employee has tampered with the specimen. Recollection under direct observation is an appropriate response to the suspicion of tampering that an invalid result raises. On the other hand, there may be medical reasons for an invalid result. Where these exist, it would be unfair to impose a directly observed collection on the employee.

A commenter suggested that, when an employee admits to adulterating or substituting a specimen, the MRO get a written statement from the employee or make his own contemporaneous written statement of the employee's admission. We think that having the MRO document such admissions is a good idea, and we have added it to paragraph (c).

Section 40.161 What Does the MRO Do When a Drug Test Specimen Is Rejected for Testing?

This section is based on § 40.155 of the NPRM. Most comments were to the effect that it was unnecessary to have the MRO investigate the reason for the rejection, which commenters said was usually obvious. In response, we have removed this requirement and simplified this section. It now just recites the paperwork steps the MRO follows when he or she receives a rejected result.

This section no longer calls for a recollection following a rejected result. There does not seem to be any strong reason for requiring a recollection because of what, in most cases, is an administrative error. Of course, in situations (*e.g.,* pre-employment) where a negative test result is required, there will have to be another test in order to attempt to obtain the negative result.

Section 40.163 How Does the MRO Report Drug Test Results?

Section 40.165 To Whom Does the MRO Transmit Reports of Drug Test Results?

Section 40.167 How Are MRO Reports of Drug Results Transmitted to the Employer?

These sections are all based on proposed § 40.157. We split the proposed section into three parts to make it easier to understand. The greatest number of comments on the proposed section concerned the use of C/TPAs as intermediaries to transmit results from MROs to employers. We discussed this issue in the ''Principal Policy Issues'' portion of the preamble and incorporated our decision in § 40.345. Section 40.165 of the new rule references this decision, by saying that the MRO transmits results either to the DER or to a C/TPA acting as an intermediary. We emphasize that it is the employer's choice that determines whether the MRO transmits the information directly or permits a C/TPA to act as an intermediary.

A number of comments concerned the electronic transmission of results (*e.g.,* by fax or secure computer link). Electronic signature issues were also raised in this context. The Department's advisory committee will take up these issues in greater detail. For now, we will retain the NPRM language that telephone contact is the preferred means for transmitting non-negative results. We also note that one commenter appeared to misunderstand proposed § 40.157(b)(3), which has become § 40.167(c)(3) in the final rule. We do not require the MRO's verbal report to include all the points required in the documentation of the report, which must follow the verbal report. We have also decided to delete the information item concerning the address of the collection site, because we do not believe it is necessary for this report.

Some commenters felt that the report format was too complex and would lead to practical difficulties. In connection with the new CCF, we have simplified these requirements. All reports can be made on a stamped (negatives) or signed (all other results) copy of Copy 2 of the CCF. Otherwise, the MRO must compose a letter with several information items for each result. We prefer that MROs use copies of Copy 2 of the CCF for this purpose, which will result in generating much less paperwork.

Section 40.169 Where is Other Information Concerning the Role of MROs Found in This Regulation?

This is another in the series of sections providing, for readers' convenience, references to other sections of the regulation that concern, in this case, the role and activities of MROs.

Subpart H—Split Specimen Tests

Section 40.171 How Does an Employee Request a Test of a Split Specimen?

There were few comments on this section. A number of commenters wanted to require that requests for tests of split specimens be in writing. One reason given for this request was that some employees, if the split specimen test reconfirmed, would deny asking for the test when the employer asked for reimbursement. We do not think it necessary to require these requests to be in writing, which in some instances could delay or burden the employee's right to have the split specimen retested. However, so that there is a written record of the request, the NPRM and this final rule direct MROs to document the date and time of the employee's request.

Section 40.173 Who Is Responsible for Paying for the Test of a Split Specimen?

This section is related to the provision concerning payment for split specimen tests in § 40.153, and commenters took very similar positions on the issues. Not surprisingly, unions and some service agents liked the proposal better than employers. The Department's rationale for incorporating this provision in the final rule is essentially the same as discussed under § 40.153 above. Employers did want assurance that they could seek reimbursement from employees, and paragraph (c) of both the NPRM and final rule makes that point clear. We added an example of how employers could ensure that testing occurs on time (establishing accounts with laboratories, which they could do on their own or through a C/TPA).

Section 40.175 What Steps Does the First Laboratory Take With a Split Specimen?

There were few comments concerning this section. Some commenters asked that tests be cancelled when a split specimen was unavailable. For reasons discussed above, the Department believes it is better to test the primary specimen in such cases. Some commenters addressed proposed § 40.175(c), which we have deleted because it duplicated laboratory procedure matters in HHS guidance. Laboratories will follow this HHS guidance with respect to specimen retention requirements. Commenters asked for clarification of who gets to choose the laboratory that tests the split specimen. This is an issue on which the Department does not have a position. We are satisfied as long as the parties use an HHS-certified laboratory.

Section 40.177 What Does the Second Laboratory Do With the Split Specimen When It Is Being Tested To Reconfirm the Presence of a Drug or Drug Metabolite?

Section 40.179 What Does the Second Laboratory Do With the Split Specimen When It Is Being Tested To Reconfirm an Adulterated Test Result?

Section 40.181 What Does the Second Laboratory Do With the Split Specimen When It Is Being Tested To Reconfirm a Substituted Test Result?

These sections are all based on proposed § 40.177. Most of the comments on proposed § 40.177 concerned the addition of validity testing to the split specimen portion of the program, discussed in greater detail in the ''Primary Policy Issues'' portion of the preamble.

Existing HHS guidance (Program Documents 35 and 37) establish criteria for testing of the primary specimen for adulteration and substitution. These are the criteria referenced in §§ 40.93 and 40.95. These Program Documents do not, on their face, apply to testing of the split specimen. HHS is planning to incorporate split specimen testing criteria for adulteration in forthcoming mandatory requirements for validity testing. Pending completion of this formal HHS issuance, and because we believe it is important to begin split specimen testing in the validity testing program as soon as possible, the Department in §§ 40.179 and 40.181 is requiring that the split specimen meet exactly the same criteria as the primary specimen in order to be considered reconfirmed. These criteria already exist in HHS guidance (Program Documents 35 and 37) and have a sound technical basis. When HHS issues its final mandatory requirements for split specimen tests in adulteration and substitution cases, the Department will, if necessary, amend these provisions to refer to the HHS issuance.

Section 40.183 What Information Do Laboratories Report to MROs Regarding Split Specimen Results?

This section is based on proposed § 40.181 of the NPRM. There were no substantive comments. We have adopted the section as proposed, except that we have added notations applicable to split specimen tests in adulteration and substitution situations. We also clarified that laboratories must sign and date the appropriate CCF copy.

Section 40.185 Through What Methods and to Whom Must a Laboratory Transmit Split Specimen Results?

This section is based on proposed § 40.179 of the NPRM. Comments focused on two issues: the use of electronic means of transmission and use of service agents as intermediaries between laboratories and MROs. In response to comments favoring greater use of electronic means, the final rule will permit results to be sent by electronic image, as well as other means. However, for the same reasons applicable to transmission of primary specimen test results, we will not permit C/TPAs to receive split specimen results from laboratories.. Laboratories must promptly send split specimen results directly to MROs.

Section 40.187 What Does the MRO Do With Split Specimen Laboratory Results?

This section is based on proposed § 40.183 of the NPRM. Some commenters objected to a retest under direct observation as the consequence of a failure to reconfirm due to the unavailability of the split specimen for testing. As noted above, this situation involves strong evidence of a violation of the rules (*e.g.,* a verified positive test), with the test being cancelled only because of a process problem (*e.g.,* the split leaked away). In this situation, there is a stronger than usual incentive for the employee to attempt to beat the next test, hence the need for direct observation on the recollection.

The Department deleted proposed § 40.185, concerning retests of single specimen collections, since all collections under the new rule will be split specimen collections.

Section 40.189 Where Is Other Information Concerning Split Specimens Found in This Regulation?

This is another in the series of cross-reference sections designed to help readers find related material.

Subpart I—Problems in Drug Tests

Section 40.191 What Is a Refusal To Take a DOT Drug Test, and What Are the Consequences?

If an employee declines to take a drug test or takes a number of other actions that obstruct the drug testing process, the employee is deemed to have refused to test. 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.

Commenters generally agreed with the list of actions in this section that constitute a refusal to test. One commenter wanted refusals on non-DOT tests to count as refusals under this part. They cannot, because this part does not require anyone to take a non-DOT test. A few comments also urged use of alternative testing technologies, such hair testing and on-site testing, in potential refusal situations. The Department will defer to HHS on alternative testing technology issues. HHS has not yet authorized these approaches to testing. We have added a specific reference to verified adulterated or substituted test results as a ground for determining that an employee has refused to test.

Section 40.193 What Happens When an Employee Does Not Provide a Sufficient Amount of Urine for a Drug Test?

This is the so-called ''shy bladder'' provision of the rule. The proposed section would keep the core of the Department's current shy bladder procedures in place, and commenters did not question the direction of this provision. Commenters did address a number of specific issues concerning the section. Some commenters wanted to specify that the physician performing an evaluation of potential medical reasons for a shy bladder situation be a urologist or other specialist, on the theory that a non-specialist was not as well equipped for this function. The Department agrees, and, in parallel with the language concerning MRO review of adulteration and substitution provisions, the final rule calls for the use of a licensed physician with expertise in the medical issues surrounding a failure to provide a sufficient specimen.

Commenters disagreed about who ought to select the physician for this evaluation. Some said the referral physician should be acceptable to the employer. Others said the referral physician should be acceptable to the employee. We take the view that the rule should not specify who makes the selection of the referral physician, but we do think that he or she should be acceptable to the MRO. The MRO is in a better position than either the employee or the employer to determine if a particular referral physician is appropriate to this task.

Under the final rule, the an employee in a shy bladder situation would be directed to obtain within 5 days, a further medical evaluation from someone with expertise in the medical issues raised by the employee's situation. This physician could be a specialist (*e.g.,* a urologist), but need not be. What is important is that the referral physician have sufficient expertise to deal effectively with the medical issues in the employee's case.

The Department is aware that, in some cases, it may be difficult for an employee to secure, on his or her own, an appointment for this evaluation in a short period of time. Consequently, the Department does not regard it as a refusal to test if the employee is unable, after making good faith efforts, to get the appointment within the 5-day period. However, the MRO and the employer should do everything feasible to assist the employee in finding and getting an appointment with an appropriate referral physician.

Commenters raised in this context the issue of whether a refusal to drink fluids in a shy bladder situation should constitute a refusal to test. We do not believe that a refusal to drink fluids should be considered a refusal to test, and we have incorporated this view into the text of this section.

Some commenters suggested that, during the five days that may elapse between an employee's provision of an insufficient specimen and the determination of whether this constitutes a refusal to test, the employee should be stood down from performing safety-sensitive functions. We are not adopting this suggestion. Until and unless a refusal is determined to have occurred, there is no evidence of violation of the rules on which to base a temporary removal from performance of safety-sensitive duties (unlike the situation under a stand-down waiver, where there is the evidence of a confirmed positive test).

A few comments questioned the three-hour waiting/fluid consumption period following an employee's provision of an insufficient specimen. One comment said blood should be drawn after two hours. Other comments said it made more sense to go immediately to an alternative specimen, such as saliva or hair. We believe that the three-hour period is by now well established in the DOT program, and comments did not make a compelling case for changing it. As noted above, we are waiting for HHS action before making any further decisions concerning alternative specimens.

We incorporated in this section an existing DOT interpretation concerning psychological conditions alleged as reasons for a failure to provide a sufficient specimen. The meaning of this interpretation (see paragraph (e)) is that to be regarded as a pre-existing psychological disorder, it is not necessary that the condition be diagnosed before the time of the test, but the symptoms have to have been medically documented before the time of the test. For example, an individual may have brought urination problems to the attention of his urologist over a period of time, but the urologist did not enter a specific diagnosis of a psychological disorder into the medical records. In this situation, the examining physician has the discretion to determine that there was a pre-existing psychological condition, if the physician is convinced that the medically documented symptoms support such a diagnosis.

Section 40.195 What Happens When an Individual Is Unable To Provide a Sufficient Amount of Urine for a Pre-Employment or Return-to-Duty Drug Test Because of a Permanent or Long-Term Medical Condition?

This section is intended to address a rare, but difficult, issue that may arise in these types of testing. In a pre-employment or return-to-duty test, an employee who is not now performing safety-sensitive duties must have a negative test result in order to begin or resume performing safety-sensitive duties. In a ''shy bladder'' situation, if there is an adequate medical reason for the inability to provide a sufficient specimen, the test result is cancelled, not negative. If a permanent or long-term medical condition is the cause of the inability to provide a sufficient specimen, the employee might never be physically capable of obtaining a negative result. This could be very unfair to the employee, and it could raise Americans with Disabilities Act issues as well.

Some commenters expressed the view that this provision should apply to other types of testing as well (*e.g.,* random). We do not believe it is necessary to do so, because employees in these situations do not need a negative test result to perform safety-sensitive functions. A cancelled test is not a violation of DOT rules that compels employers to remove employees from safety-sensitive duties.

In response to a comment, we added language that the MRO can conduct, or cause to be conducted, the further medical evaluation the section requires. We have also clarified that, as part of this evaluation, the physician may use alternative testing methods, including but not limited to blood testing, to help determine whether the employee shows clinical evidence of drug abuse. Particularly given that we do not apply

this procedure to random testing, we do not agree with a suggestion that an individual covered by this section should be taken out of the random testing pool. Doing so would also affect the probability that other individuals would be selected for testing. As in other situations calling for medical evaluations, the rule requires that the physician conducting the evaluation be acceptable to the MRO, rather than to the employer or employee.

Under this section and § 40.193, the referral physician reports to the MRO the basis for any conclusion that the individual has a permanent, long-term disability that prevents providing a sufficient specimen. However, for privacy reasons, neither the referral physician or the MRO passes on to the employer any information about the nature of the disability. The employer is simply told that there is a permanent, long-term condition.

We have not included similar language in the rule concerning alcohol testing, because pre-employment alcohol testing is not mandatory. In the rare situation in which an employee is required to have a negative alcohol test in a return-to-duty or follow-up test situation, and could not produce sufficient breath because of a permanent, long-term disability, we would apply the reasoning of this section to that situation.

Section 40.197 What Happens When an Employer Receives a Report of a Dilute Specimen?

This section is based on §§ 40.147(a) and 40.159(d) of the NPRM. The NPRM, like the existing rule, would have given employers discretion to use direct observation the next time the employee was selected for testing (e.g., in random testing). Comments on this issue and the Department's responses are discussed under ''Collection Issues'' in the ''Principal Policy Issues'' portion of this preamble. It should be noted that, unlike the existing rule and the NPRM, this provision authorizes a new collection immediately following a negative-dilute result, rather than on the next occasion when an employee is selected for testing. This recollection is not conducted under direct observation.

Section 40.199 What Problems Always Cause a Drug Test to be Cancelled?

This section, listing ''fatal flaws'' that invariably result in the cancellation of a test, is based on § 40.197 of the NPRM. The list of fatal flaws in the final rule is somewhat different from that in the proposed rule. Proposed paragraph (b), concerning the lack of a specimen ID number, is really an instance of the flaw cited in paragraph (a), a mismatch between the specimen ID numbers on the specimen bottle and the CCF. The former is included in the latter, so we have deleted the proposed paragraph (b). Consistent with HHS guidelines, we have added a new paragraph (b), concerning a situation in which the printed collector's name and collector's signature are both missing. This section's list of fatal flaws is now consistent with the HHS list of fatal flaws.

A few comments suggested either that fatal flaws automatically cancel a test, without MRO involvement, or that the employer have the authority to cancel a test when a fatal flaw appears. We believe that, as the key ''gatekeeper'' and quality control person in the system, the MRO is the best party to make the actual pronouncement of a cancellation based on a fatal flaw. Another comment suggested that an error in the chain of custody documentation should result in the cancellation of a test. The problem here is that not all errors are created equal. Depending on the seriousness of an error and our ability to fix it, an error on the CCF can be a fatal flaw, a correctable flaw, or a *de minimis* error that does not result in cancellation.

Finally, a commenter asked whether Bottle B may be redesignated as Bottle A, as the final paragraph of this section suggests. This has been an interpretation issue under the existing rule, but we are clear in this final rule that such redesignations can take place.

Section 40.201 What Problems Always Cause a Drug Test To Be Cancelled and May Result in a Requirement for Another Collection?

This section is based on § 40.199 of the NRPM. One commenter suggested treating invalid test results as refusals. As we have discussed above, the Department did not adopt this suggestion. There were no other substantive comments on this section, which we have adopted with some editorial changes and the addition of a paragraph pertaining to the failure of an adulterated or substituted result to reconfirm.

Section 40.203 What Problems Cause a Drug Test To Be Cancelled Unless They are Corrected?

This section is based on § 40.201 of the NPRM and concerns ''correctable flaws.'' Commenters generally approved the proposed provision, but had varied suggestions. As in the case of fatal flaws, one suggestion was to allow employers to cancel tests in the case of an uncorrected flaw. As we said in that case, we believe that MROs are the best party to take all such actions in the drug testing program. Two commenters disagreed concerning the situation of a missing employee signature coupled with a lack of collector notation of the omission: one said it should be a fatal flaw and the other said it need not be even a correctable flaw. We believe that the NPRM formulation of making this situation a correctable flaw makes the most sense, giving due regard both to the need for completeness of the documentation and the ability to work around inadvertent administrative mistakes.

A commenter suggested that an incorrect employee social security number (SSN) or other ID number (*e.g.,* a transposition of numbers) should not be a fatal or correctable flaw. We agree with this comment. We also believe that a minor transposition error is the kind of irregularity that would not cause a test to be cancelled (see § 40.209). If an ID number is completely wrong (*e.g.,* appears to be a different number altogether) is too badly garbled to be useful in establishing the employee's identity, we view the number as having been omitted, which is a correctable flaw under paragraph (c). Another commenter suggested that the combination of a wrong ID number and a missing employee signature should be a fatal flaw. In our view, both of these items independently are correctable flaws, meaning that if either is left uncorrected the test is cancelled. This is a sufficient safeguard, we believe.

Section 40.205 How Are Drug Test Problems Corrected?

This provision is based on proposed § 40.203 and concerns how correctable flaws and other problems are corrected. There were few comments on this section. One commenter said there should be a time limit (*e.g.,* five days) for making corrections, and that errors should be taken into account during verification. We agree that corrections should be timely, and while we do not believe that an absolute ''statute of limitations'' is appropriate, we have added language directing parties to supply this information on the same business day on which they are notified of the problem, transmitting it by fax or courier. Aside from fatal or uncorrected flaws that cause a test to be cancelled, there is no role for consideration of these kinds of mistakes in the verification process, which focuses on whether there is a legitimate medical explanation for a test result.

Another comment suggested that the use of a non-DOT form could be corrected by annotating the remarks

section of the non-DOT form with the needed information. We do not object to this form of correction in the situation where the form was used out of necessity (*e.g.,* only form available for a post-accident test), though we do not think it is necessary to include this point in the rule text. It would obviously be contradictory to use this approach where the non-DOT form was allegedly used ''inadvertently,'' since a collector who noticed the use of the form sufficiently to make the annotation would clearly have been aware of what form he or she was using.

Section 40.207 What Is the Effect of a Cancelled Drug Test?

This section is based on § 40.205 of the NPRM. There was only one comment, which asked for guidance on what to do if an employee with a confirmed positive test had his or her test cancelled because of a fatal or uncorrected flaw. Other provisions of this part determine what action the employer is authorized or required to take. For example, following a cancellation of a verified positive test because a split specimen was unavailable for testing, there must be an immediate recollection under direct observation.

Section 40.209 What is the Effect of Procedural Problems That Are Not Sufficient to Cancel a Drug Test?

There were few comments on this section, which is based on § 40.207 of the NPRM. The NPRM version stated a general principle: tests cannot be cancelled based on an error that does not have a significant adverse effect on the right of the employee to have a fair and accurate test. The point of this proposal was to prevent administrative or judicial decisions invalidating drug tests that were fair and correct, but had certain *de minimis* irregularities. One commenter objected to this principle, saying that tests should be cancelled in these situations. Other commenters were supportive.

Because of comments to other sections of the rule asking for clarification about whether certain mistakes in the process should be the basis for cancellation, and on the basis of the Department's experience in dealing with issues in many drug testing cases, we have decided to add to this section a list of matters that, consistent with this principle, never result in the cancellation of a test. This is not an exclusive or exhaustive list. These matters must be documented, and may result in corrective action for employers or service agents involved, but the proper remedy is not to cancel the test. This is a safety rule, and it is not consistent with safety to permit someone with a positive drug test to continue performing safety-sensitive functions because a collector made a minor paperwork error that does not compromise the fairness or accuracy of the test.

One of the points we make in this section is that a urine collection or an alcohol test must not be cancelled solely because the collector, BAT, or STT has not met training requirements. Such a test would be cancelled only if there were a fatal flaw or other circumstances requiring cancellation. However, an organization that had a pattern or practice of using untrained collectors, BATs, or STTs would be subject to DOT enforcement action (in the case of an employer) or a PIE (in the case of a C/TPA or other service agent).

Subpart J—Alcohol Testing Personnel

Generally speaking, there were far fewer comments on the alcohol testing portions of the rule than on the drug testing and other sections. Throughout much of the alcohol testing portion of the rule, one commenter provided extensive rewrites of the proposed regulatory text. These comments were clearly the product of substantial and thoughtful work on the commenter's part. For the most part, however, the suggested rewrites did not propose significant substantive changes in the proposed text. We will not discuss these rewrites on a paragraph-by-paragraph basis, except where they raise a substantive point that calls for a response.

Section 40.211 Who Conducts DOT Alcohol Tests?

The only comments on this section had to do with the limitation on supervisors serving as BATs or STTs for their own subordinates. Some commenters said that this restriction should be modified, since many supervisors had been trained as BATs and there were some situations, such as ships at sea, where supervisors might be the only BATs or STTs available. We note that the proposed regulation already permitted supervisors to serve as BATs and STTs if no one else were available and DOT agency alcohol testing regulations allowed this practice. As in the case of collectors in the drug testing program, we have used the term ''immediate'' supervisors to indicate that someone higher up in the chain of command was not limited by this restriction.

Section 40.213 What Training Requirements Must STTs and BATs Meet?

The Department has revised this training both in response to comments and to parallel, as much as feasible, the training requirements for collectors in the drug testing program. One comment we adopted in both places was to permit use of a variety of training media (*e.g.,* classroom instruction, internet, video, CD–ROM) for the academic portion of the training. For the proficiency demonstration part of the training, however, absent technological means of real-time monitoring and evaluation of actual proficiency demonstrations, in-person monitoring would be necessary. We also replaced the proposed ''sufficiently knowledgeable'' language referring to trainers, which commenters said was too vague, with a series of criteria relating to experience or course work in the testing field.

One commenter suggested a list of scenarios that should be randomly included in the three consecutive error-free collections needed to demonstrate proficiency for BATs. Without specifically endorsing the commenter's list, we believe that this is a useful suggestion. The Department's guidance on training will include a list of this type for use of persons conducting training.

As in the case of collectors in the drug testing program, BATs and STTs would have to undergo refresher every five years, and error correction training when needed. Most commenters on the subject favored these kinds of training, though some had reservations about what they viewed as the higher costs of the training. In this matter, we believe that insistence on high training standards is no vice, and moderation in the pursuit of a well-trained work force is no virtue. Such a work force is vital to the integrity of the program.

As in the drug testing collector training, some commenters favored waiting until more than one error resulting in cancellation of a test had occurred before requiring error correction training. As in that case, we believe that any such event creates an important training opportunity, to make sure that the individual does not make the same mistake in the future.

Section 40.215 What Information About the DER do Employers Have To Provide to BATs and STTs?

Proposed § 40.215 proposed various record retention and information requirements for organizations employing BATs and STTs. Because we believe it would relieve paperwork

burdens for employers and C/TPAs to have BATs and STTs maintain documentation of their training and qualifications (as § 40.213 provides), the only remaining portion of this section is proposed paragraph (c). This paragraph, on which there were no substantive comments, tells employers to provide to BATs and STTs the name and phone number of a DER.

Section 40.217 Where is Other Information on the Role of STTs and BATs Found in This Regulation?

This is another in the series of cross-reference sections, pointing readers to other sections of the rule relevant to the functions of BATs and STTs.

Subpart K—Testing Sites, Forms, Equipment and Supplies Used in Alcohol Testing

Section 40.221 Where Does an Alcohol Test Take Place?

We adopted this provision without substantive change.

Section 40.223 What Steps Must be Taken To Protect the Security of Alcohol Testing Sites?

We adopted a comment to include ASDs in the requirement to secure testing devices when they are not being used. In response to another comment, we created an exception to the rule that BATs and STTs may not leave the testing site when a test is in progress. The exception is for a situation in which the BAT or STT must notify a supervisor or contact a DER for assistance in the case an employee or other person who obstructs, interferes with, or unnecessarily delays the testing process. Otherwise we have adopted the proposed section without substantive change.

Section 40.225 What Form Is Used for an Alcohol Test?

Most of the comments on this section focused on changes commenters sought in the ATF. The form has been revised, and we have included it at Appendix F. Its use will become mandatory on August 1, 2001. We have also modified the language concerning foreign-language versions of the form to be consistent with the parallel provision concerning the CCF.

Section 40.227 May Employers Use the ATF for non-DOT Tests, or non-DOT Forms for DOT Tests?

This section parallels the requirements for use of the CCF in the drug testing program. The few comments on the section were supportive of the Department's approach.

Section 40.229 What Devices Are Used To Conduct Alcohol Screening Tests?

We adopted one comment, including a clarifying note in § 40.231 that only EBTs listed in the NHTSA CPL *without* an asterisk can be used in the DOT alcohol testing program.

Section 40.231 What Devices Are Used To Conduct Alcohol Confirmation Tests?

We adopted one of several editorial comments we received on this section from a commenter, which is to remove the word ''sequential'' from the requirement that an EBT print a unique number on each copy of the result. As the commenter noted, the important thing is for the same unique test number to be displayed before the test and printed out on the result.

Section 40.233 What Are the Requirements for Proper Use and Care of EBTs?

A number of commenters said it was unclear in the proposed version of this section who was responsible for what. To address this problem, we place responsibility on the user of the EBT, who could be an employer or a service agent. We asked in the preamble to the NPRM whether we should retain the requirement for quality assurance plans (QAPs). Most commenters favored retaining this requirement, and we have done so. We are not specifying in the rule, however, who is authorized to perform various maintenance, calibration, etc., functions, as one commenter suggested. We are not in a good position to determine who can best perform these functions.

Section 40.235 What Are the Requirements for Proper Use and Care of ASDs?

Most of the comments on this section were editorial. One commenter expressed concern that the section appeared to focus on saliva ASDs to the exclusion of breath ASDs. This is not the case. These sections are derived from provisions of the existing regulation that apply to breath devices as well as saliva devices. Because the ''use and care'' requirements for EBTs of § 40.233 also apply to breath ASDs, we have added a cross reference to § 40.233 for clarity.

Subpart L—Alcohol Screening Tests

Section 40.241 What Are the First Steps in Any Alcohol Screening Test?

Many comments on this section were parallel to the comments on § 40.61. In response to the concern about tests not being scheduled in advance, we changed the language to refer to situations in which tests were scheduled. We also added language telling BATs and STTs to begin testing without ''undue'' delay. We did not adopt comments suggesting that it was appropriate for the testing process to wait upon the arrival of employer or employee representatives.

One commenter noted an inconsistency between the way the NPRM treated refusals to sign the certification on the drug and alcohol testing forms, respectively. In the drug testing case, the collector is directed to note the problem in the remarks section of the form and continue with the test. In the alcohol testing case, the BAT or STT is directed to treat the problem as a refusal to test. We agree that these provisions should be consistent, and we have changed the alcohol procedure to be like the drug procedure.

Section 40.243 What Is the Procedure for an Alcohol Screening Test Using an EBT or Non-Evidential Breath ASD?

Commenters had a variety of concerns about this section. One commenter asked if showing the employee the sequential number displayed on the device has been omitted from this provision. It has, and the omission was intended. We do not believe that this action is necessary to maintain the integrity of the process. In addition, these number displays are not available on all devices, such as some types of ASDs.

Another commenter had several suggestions for elaborating on instructions to the BAT or STT as part of the preliminary portion of the testing process. We will consider including these suggestions in guidance. Another commenter asked us to specify the number of times an employee could blow into a breath device. We do not think that this is necessary. The point is to complete the test successfully. If it becomes apparent that the employee cannot provide sufficient breath to activate the device, then we expect the BAT or STT to use good judgment in determining when to begin the ''shy lung'' procedure.

A commenter suggested allowing the result printout to be attached either to the front or the back of the ATF. We will adopt this comment in our pending revision of the ATF. Another suggestion was to use tamper-evident tapes that do not discolor over time. We think that this is a good idea, but not one that we need to mandate in rule text. We have adopted a commenter's suggestion that a self-adhesive label that is tamper-evident can be used to affix a result printout to the ATF.

Section 40.245 What Is the Procedure for an Alcohol Screening Test Using a Saliva ASD?

The Department is adopting the proposed section without substantive change. One commenter asked to include material pertaining to new evidentiary saliva devices. At the time of the publication of this rule, NHTSA is looking at such devices, but NHTSA's review is not complete. NHTSA is considering modifying its model specifications for evidential breath testers to accommodate technologies that measure alcohol in other bodily fluids, such as saliva. If adopted, such changes would also require technical adjustments to Part 40 so that both the NHTSA action and Part 40 requirements worked smoothly in concert. Subsequent to this revision of Part 40, any proposed modifications to NHTSA model specifications or Part 40 to accommodate the above advances in technology would be published in the **Federal Register**, so that the public may comment on them before any changes are made final.

Another commenter said that the ATF can get too sloppy when the STT attempts to use the same form for two separate devices. There is no mandate to use the same form. If one form is getting too cluttered, the STT can use a new form for the part of the process involving the second device. This commenter also said that, in the event the device does not activate on the first try, the STT should not have to place the device in the employee's mouth for the second attempt. We believe that maintaining this requirement is useful to ensure that the second attempt is more likely to succeed (*e.g.,* in a situation in which the employee has used the device incorrectly at first). This commenter also suggested that there may be situations in which it is not possible to conduct a new test on an EBT, when the STT could not successfully follow ASD procedures. We agree with the commenter that the regulation should include language to address this situation, and we have added a provision to § 40.271(a)(3) for this purpose.

Section 40.247 What Procedures Does the BAT or STT Follow After a Screening Test Result?

This section is also substantively unchanged from the NPRM. One commenter preferred splitting the section into several sections, believing that this would make the requirements more clear. Paragraphs (a), (b), and (c) each are devoted to a single situation (test result of less than 0.02, result of 0.02 or greater, invalid result). We believe this organization is sufficiently clear. This commenter also suggested that we clarify that the employee must be observed during the waiting period in all circumstances. We agree, and we have added language to this effect to § 40.251(a)(1). The purpose of this observation is to ensure that the employee remains under the control of responsible personnel during the waiting period and does not take any actions that could interfere with the successful completion of the testing process.

Several comments asked that BATs be able to transmit test results to employers via C/TPAs, acting as intermediaries. Consistent with the Department's decisions in the drug testing part of the rule, the final rule will permit transmission of negative results by this means. (We will not permit positive results to be sent in this way. For safety's sake it is essential that these results be transmitted immediately and directly since, unlike drug test results, positive alcohol test results involve impairment.) Another commenter suggested that the ATF include a provision for a statement or check box to indicate that the employee had received instruction about the waiting period between the screening and confirmation tests. We will consider doing so as part of our pending revision of the ATF.

Subpart M—Alcohol Confirmation Tests

Section 40.251 What Are the First Steps in Any Alcohol Confirmation Test?

One commenter suggested editorial changes to clarify the timing of the waiting period and the confirmation test, in paragraph (a)(1). We have adopted this language. We have not adopted other editorial suggestions for this section, because we believe they are not necessary to clarify the proposed language. We disagree with a comment suggesting that conducting a confirmation test more than 30 minutes after the screening test should not be permitted. While, as paragraph (a)(1) states, it is desirable that the confirmation test begin within 30 minutes, we realize that circumstances (*e.g.,* transportation from the screening test site to a different confirmation test site) could delay the test past this point. Better a delayed test than none at all.

Section 40.253 What Are the Procedures for Conducting an Alcohol Confirmation Test?

At a commenter's suggesting, we added the word ''conducting'' to the first line of this section. Consistent with § 40.243, we have added language saying that a self-adhesive label that is tamper-evident can be used to affix a result printout to the ATF. The section is otherwise unchanged from the NPRM version. We do not believe extensive editorial changes are needed. One commenter said that all test results of 0.02 or greater made on a defective machine before corrective action is taken must be cancelled. This point is covered by § 40.267(c)(5). We will leave the word ''sequential'' in paragraph (f). This section involves the use of EBTs, all of which have sequential test number displays.

Section 40.255 What Happens Next After the Alcohol Confirmation Test Result?

Aside from a few editorial changes and additional requests that C/TPAs be able to act as intermediaries in the transmission of results, there were no comments on this sections. We have addressed the C/TPA transmission issue elsewhere. We have adopted the proposed section without change.

Subpart N—Problems in Alcohol Testing

Section 40.261 What Is a Refusal To Take an Alcohol Test, and What Are Its Consequences?

In response to a comment, we added language clarifying that the failure to remain at a testing site until the testing process was complete constitutes a refusal to test. We have deleted the provision treating refusal of the employee to sign the ATF certification in Step 4 as a refusal to test. Otherwise, the section is substantively unchanged from the NPRM. We have not made extensive editorial changes.

Section 40.263 What Happens When an Employee Does Not Provide a Sufficient Amount of Saliva for an Alcohol Screening Test?

There was no substantive comment on this section, and we have adopted it unchanged from the NPRM.

Section 40.265 What Happens When an Employee Does Not Provide a Sufficient Amount of Breath for an Alcohol Test?

We have revised this provision to be parallel, in many respects, with the ''shy bladder'' procedure in the drug testing portion of the rule. These changes

include providing that the evaluating physician must have expertise in the issues raised by the employee's failure to provide a sufficient amount of breath and that the employee must obtain the evaluation within five days. (The physician could be a specialist, but need not be. What is important is that the physician have sufficient expertise to deal effectively with the issues presented in the employee's case.) Three commenters suggested that this time period should be changed to one, three, or seven days rather than five days. We believe that the five-day period should be generally sufficient and is consistent with other medical evaluation provisions of the rule.

However, the Department is aware that, in some cases, it may be difficult for an employee to secure, on his or her own, an appointment for this evaluation in a short period of time. Consequently, the Department does not regard it as a refusal to test if the employee is unable, after making good faith efforts, to get the appointment within the 5-day period. However, the employer should do everything feasible to assist the employee in finding and getting an appointment with an appropriate physician.

A commenter suggested giving employees additional attempts to provide a sufficient amount of breath to complete a test. We have modified this section to permit an additional attempt, if the BAT or STT believes that it would be useful (*e.g.,* because the employee came close on the second attempt or made a mistake in using the device that could be readily corrected). It is not mandatory for the BAT or STT to provide this third attempt. At this commenter's suggestion, we have also added language telling the BAT or STT to instruct the employee on the proper use of the device.

Section 40.267 What Problems Always Cause an Alcohol Test To Be Cancelled?

One commenter disliked the use of the word ''cancelled,'' preferring ''invalid.'' The term ''invalid'' has a specific meaning in the drug testing part of the rule, so we think it better to avoid the word here. ''Cancelled'' has the same meaning here as it does in drug testing, and should not cause any confusion. A commenter suggested adding rule text requiring BATs and STTs to notify DERs within 48 hours of the discovery of a fatal flaw. We agree that prompt notification is important, and we have added language to § 40.273 to this effect. We put this provision into § 40.273 so that it applies to all cancellations.

Section 40.269 What Problems Cause an Alcohol Test To Be Cancelled Unless They Are Corrected?

There were no substantive comments on this section, which is unchanged from the NPRM.

Section 40.271 How Are Alcohol Testing Problems Corrected?

As discussed above, we have added a new paragraph (a)(3) to this section, concerning situations in which a new testing device is not available at the testing site. We have also added a new paragraph (c), clarifying that when a correctable flaw cannot be corrected, the test must be cancelled. We did not receive substantive comments on this section, which is otherwise unchanged from the NPRM.

Section 40.273 What Is the Effect of a Cancelled Alcohol Test?

There were no substantive comments on this section, the proposed text of which is unchanged from the NPRM. We have added new paragraphs (c) and (d), which respectively call for notification of the DER and state that a cancelled test is not intended to provide a basis for a subsequent test under company policy,

Section 40.275 What Is the Effect of Procedural Problems That Are Not Sufficient To Cancel an Alcohol Test?

Section 40.277 Are Alcohol Tests Other Than Saliva or Breath for Screening and Breath for Confirmation Permitted Under These Regulations?

There were no substantive comments on these sections, which are unchanged from the NPRM.

Subpart O—Substance Abuse Professionals and the Return-to-Duty Process

Section 40.281 Who Is Qualified To Act as a SAP?

Section 40.283 How Does a Certification Organization Obtain Recognition for Its Members as SAPs?

These sections were both based on proposed § 40.281. We received extensive comment on the question of who should be viewed as eligible to perform SAP functions. Many individuals, professional organizations, and certification organizations (*e.g.,* for drug and alcohol counselors, marriage and family therapists, licensed professional counselors) asserted that their qualifications were as appropriate, if not more so, than groups and professions which the rule views as eligible. Without denigrating the qualifications of any individuals, professions, and organizations, the Department believes that the proposed rule continues to identify those professions and organizations that currently are best equipped to perform the SAP function in the DOT drug and alcohol testing program.

This is a program that is national in scope, and we believe that, for persons who wish to act as SAPs based on membership in a licensed or certified profession, it is reasonable to require that the licensure or certification be available in all U.S. states. For persons who wish to act as SAPs based on an organizational certification, the Department has set forth criteria in Appendix E for the requirements that must lie behind such certifications. The Department developed these criteria under the existing rule as a means of evaluating applications to the Department for SAP eligibility, and they are consistent with the requirements of certification organizations that are already part of the SAP program.

The NPRM proposed to require organizations that certify counselors to obtain National Commission for Certifying Agencies (NCCA) accreditation before submitting their requests to have the Department consider their certified counselors for inclusion in the SAP definition. The NPRM also proposed that the two certifying organizations whose counselors are already in the SAP definition (*i.e.,* the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC) and the International Certification Reciprocity Consortium/ Alcohol and Other Drug Abuse (ICRC)) would not be required to have NCCA accreditation because they have already been through a rigorous Department process prior to their inclusion.

Commenters overwhelmingly supported the concept of having certification organizations obtain NCCA accreditation prior to submitting their requests to have their certified counselors considered for inclusion to the Department. A few organizations opposed any type of review by any organization, including the Department, prior to having their certified counselors added to the SAP definition. A few commenters wanted the Department to maintain total control of the review process—a process that proved entirely too burdensome and time consuming for us. Still other commenters wanted us to clarify that the NCCA accreditation requirement (and Appendix F of Part 40) applied solely to certifying organizations wishing to have their counselors included in the SAP definition and not to physicians, social

workers, psychologists, and employee assistance professionals; and not to NAADAC and ICRC. Those who commented on NAADAC and ICRC, did not believe NCCA accreditation was necessary for those two groups.

Part 40 will require certification organizations wishing to have their certified counselors included in the SAP definition to meet the requirements (which includes NCCA accreditation) at Appendix F of Part 40 prior to asking the Department to review their inclusion proposals. The Department will still receive and review all proposals for inclusion based upon Appendix F standards. It is important to note that NCCA accreditation is simply one of the prerequisites for inclusion, but it represents an area of review that the Department found to be the largest barrier to our streamlining the process for reviewing certification groups' application materials and for evaluating the quality of those groups' certification testing processes.

Because NAADAC and ICRC excelled in the Department's previous review process, they will be compelled neither to have NCCA accreditation nor to complete the process again. Physicians, social workers, psychologists, and employee assistance professionals were never intended to have NCCA accreditation. This requirement is not for them: it is only for certification organizations wishing to have their certified counselors added to those of NAADAC and ICRC.

A few commenters suggested that all SAPs be certified by the Department. One suggested that we support any future proposals by the Substance Abuse and Mental Health Services Administration to certify drug and alcohol counselors. While we support efforts to ensure that SAPs are better trained (and Part 40 has new training requirements for SAPs), the Department lacks the expertise, personnel, and time needed to establish and operate a SAP counselor certification effort. Like the lone commenter mentioned in this paragraph, we would support efforts by HHS to develop certification standards and subsequently certify all drug and alcohol counselors.

As was the case with commenters on MRO training, most commenters on SAP training thought that self-certification was not adequate. Many comments favored more formal training requirements for SAPs, like those proposed for MROs. Some of these comments mentioned situations in which they believed SAPs had made poor decisions based on an incomplete understanding of their role under the DOT rules.

The Department is persuaded that more formal SAP training is appropriate. Like MROs, SAPs are highly-qualified professionals. They play a key role in the return-to-duty process, which has important safety implications. In addition to their professional qualifications, they need to be very aware of their role in implementing DOT agency drug and alcohol testing rules. Consequently, the Department is revising SAP training requirements to parallel the training requirements for MROs. The Department is aware that there are not currently an array of SAP courses analogous to the MRO courses that medical groups currently present. For this reason, the SAP qualification training deadline has been extended to December 2003. However, the Department anticipates that, in the time permitted for new and current SAPs to meet this requirement (see § 40.281(c)(3)), the demand for training will lead to a supply becoming available. We believe that organizations will take the opportunity to create appropriate training courses and materials.

Like qualification training for MROs, SAP qualification training includes a requirement for an examination. However, the Department does not believe that this examination need be a formally designed and validated examination. SAP functions are narrower in scope and less complex than MRO functions, and the examination can therefore be simpler, in our view. The purpose of SAP training and the examination is not to teach people how to be clinicians, but rather to help SAPs learn how to operate in their specialized role within the DOT regulatory framework.

As with MROs, we have added a continuing education requirement to keep SAPs current on program requirements and issues. This continuing education must involve a test or other assessment tool to help SAPs determine whether they have successfully learned the material.

Section 40.285 When Is a SAP Evaluation Required?

This section is based on § 40.283 of the NPRM. Consistent with other provisions of the rule, we have added adulteration and substitution results to the situations requiring SAP evaluations. We disagree with a commenter who said that an alcohol test result of 0.04 or greater was not a violation of DOT agency alcohol regulations. It is a violation, and a SAP evaluation is a necessary part of the return-to-duty process following such a violation. Some comments questioned whether a SAP evaluation was necessary in all cases (*e.g.,* including pre-employment tests) following a violation. It is, and we have added some clarifying language to this effect. In the case of a pre-employment test violation, the employer to whom the individual had applied would be responsible for providing the individual information about SAP resources and the return-to-duty process, even if the employer wanted no further relationship with the individual.

A commenter asked whether a SAP evaluation would be needed for an employee who had a DUI/DWI charge against him or her in a private automobile. The answer is no: under Part 40 only a violation of DOT agency drug and alcohol testing rules triggers the requirement for a SAP evaluation (though DOT agency rules may impose additional requirements in some cases). Another commenter recommended that applicants who test positive on pre-employment tests should be required to present evidence of having completed the return-to-duty process before being able to work in a safety-sensitive position for another employer. We have addressed this issue in § 40.25, concerning inquiries about previous test results.

Section 40.287 What Information Is an Employer Required To Provide Concerning SAP Services to an Employee Who Has a DOT Drug and Alcohol Regulation Violation?

This section is based on proposed § 40.285 of the NPRM. There were few comments. One asked whether the employer or the employee was to select the SAP. This section does not address selection of a SAP: it just says that the employer has to provide the employee a list of SAPs and how to reach them. The provision does clarify that this requirement applies to all violation situations, including pre-employment tests. If an applicant fails a pre-employment test, the employer must provide this information even if the employer intends not to hire the applicant.

Section 40.289 Are Employers Required To Provide SAP and Treatment Services to Employees?

This provision is based on proposed § 40.287 of the NPRM. Paragraphs (a) and (c) emphasize the employer's provision of SAP services. An employer may or may not provide SAP-related services to employees. An employer may or may not pay for such services. These are matters the Department leaves to employer discretion or labor-

management negotiations. One commenter suggested that employers be required to cover these services in their health plans. We believe that, as the commenter acknowledged, imposing coverage requirements on health care providers or insurers is outside the Department's jurisdiction.

The proposed § 40.287 included two paragraphs telling employers that they must ensure the SAPs used to evaluate employees before they return to duty meet certain qualifications. In view of the SAP training and qualification provisions of § 40.281 of the final rule, we believe these paragraphs are duplicative, and we have deleted them. This section continues to emphasize that, before an employee who has violated a DOT agency drug and alcohol testing regulation may return to safety-sensitive duties, the employee must successfully complete the SAP evaluation/return-to-duty process.

Section 40.291 What Is the Role of the SAP in the Evaluation, Referral, and Treatment Process of an Employee Who Has Violated DOT Agency Drug and Alcohol Testing Regulations?

The content of proposed § 40.291 has been moved to § 40.355(a). This section now concerns a different subject, stating the general duties of SAPs.

Section 40.293 What is the SAP's Function in Conducting the Initial Evaluation of an Employee?

The final rule has no equivalent to proposed § 40.289, the content of which duplicates other provisions in this subpart. There were few comments concerning § 40.293, and they were mostly supportive. Some comments did favor allowing C/TPAs to transmit SAP reports to employers. As discussed in the ''Principal Policy Issues'' section of the preamble, we have chosen not to permit this, as a means of preventing anyone from having the opportunity to alter the SAP's report and recommendations.

We have added three new points to this section. First, as discussed in the ''Principal Policy Issues'' section of the preamble, we believe that there are no circumstances in which it is appropriate for a SAP to find that a violator of our regulations is not in need of education and/or treatment. Therefore, paragraph (b) requires that SAPs make a recommendation for education and/or treatment in every case. Second, we have become concerned that we have not previously given SAPs guidance with respect to employees' stories that minimize the seriousness of their violations, analogous to the guidance we give MROs with respect to legitimate medical explanations. Therefore, paragraph (f) specifically forbids SAPs from taking certain kinds of factors into account in making their recommendations.

Third, while we are not making quantitations routinely available to SAPs in drug testing cases (see discussion in ''Principal Policy Issues''), we believe it is very important for MROs and SAPs to have good communications about employees. Paragraph (g) explicitly authorizes SAPs to consult with MROs, and tells MROs they must cooperate with SAPs in these consultations.

Section 40.295 Can Employees or Employers Seek a Second SAP Evaluation if They Disagree With the First SAP's Recommendations?

The purpose of this section is to prevent employers and employees from forum shopping until they get a SAP evaluation they like. Most comments supported the proposed prohibition on second opinions, though one commenter thought this should be permitted if the original SAP does a bad job. The difficulty with this suggestion is that a party's perception of the quality of the SAP's work is likely to be influenced on whether the SAP made a recommendation the party feels is in its interest. We believe that a prohibition on second opinions is the only way to prevent forum shopping.

One commenter suggested that we remove the reference to the SAP being suitable to the employer. We believe the proposed language in this section is unnecessary, and we have deleted it. Also, to tighten the provision, we have added a sentence saying that if, notwithstanding the regulatory prohibition, an employee gets an evaluation from a second SAP, the employer must not pay any attention to it.

Section 40.297 Does Anyone Have the Authority To Change a SAP's Initial Evaluation?

Several commenters noted that the language of the proposed section appeared to prevent even the SAP who originally made the recommendation from modifying his or her own recommendation. We did not intend to prevent SAPs from modifying their own recommendations, and we have added clarifying language that permits SAPs to do so when they receive new or additional information.

Section 40.299 What Is the SAP's Role and What Are the Limits on a SAP's Discretion in Referring Employees for Treatment and Education?

A number of commenters appeared to prefer stating one of the exceptions to the rule against self-referral in terms of SAPs located in ''rural and remote areas'' rather than the NPRM's ''general commuting area'' language. The Department does not believe that this would improve the clarity of the section, since ''rural'' and ''remote'' are rather subjective terms. The exception is intended to apply, in any case, to a situation in which there is no other source of services reasonably available in the vicinity. For example, if an employee had to make an overnight trip to get to another source of services, we would not consider it reasonably available.

One commenter wanted to consider referrals to spouses as prohibited by this section. We believe this is covered by the prohibition on referrals to people with whom the SAP shares a financial interest. Another commenter wanted to create a fifth exception for in-house corporate SAPs. We believe that the second and third exceptions are adequate to cover this situation. We also received a suggestion to delete the signed statement requirement of proposed paragraph (d). Given the specificity of the other requirements of the section, we do not believe that this signed statement adds much of substance, and we have deleted it in the interest of reducing paperwork.

Section 40.301 What Is the SAP's Function in the Follow-Up Evaluation of an Employee?

Comments were generally supportive of this section. A few comments pointed out that some current DOT agency regulations do not make use of the SAP process. This is true. However, DOT agencies will amend their regulations to conform to Part 40 before the effective date of this part. Another commenter asked for clarification of who makes a return-to-duty determination. SAPs simply determine whether an employee has successfully demonstrated compliance with the SAP's recommendations. As this section and § 40.305 make clear, only the employer decides whether, after all prerequisites have been met, the employee returns to safety-sensitive duties. In response to comments that employers should be notified if the SAP process is taking longer than expected (*e.g.,* because the employee has not made expected progress in treatment), we have added a provision requiring the SAP to provide

written notice to the employer when the employee has not demonstrated successful compliance on follow-up evaluation.

The Department understands that not every employee will make strides in dealing with a drug or alcohol problem sufficient to receiving a SAP follow-up report indicating that he or she has demonstrated successful compliance with the SAP's recommendation. When this happens, we believe that it is important that the employer receive a SAP follow-up report outlining the reason(s) why the employee has not demonstrated successful compliance. We understand that some employees may be actively involved in carrying out their education and/or treatment plan and simply need additional time to complete the work. Others may have been non-participants in a SAP-recommended program. Therefore, when the SAP determines that the employee has failed to demonstrate successful compliance, we have no objection to having the employer deciding to allow an additional SAP follow-up evaluation to be made consistent with the employee's progress (or lack of progress) and with employer policy and/or labor-management agreements. Nor will the Department object if the employer chooses instead to take other personnel actions consistent with employer policy and/or labor-management agreements.

Section 40.303 What Happens if the SAP Believes the Employee Needs Additional Treatment, Aftercare, or Support Group Services Even After the Employee Returns to Safety-Sensitive Duties?

As discussed in the ''Principal Policy Issues'' section of the preamble, we have deleted a proposed requirement that employers ''monitor'' returned employees'' aftercare. This was the subject of the bulk of the comments on this section. The section now gives discretion to employers concerning their monitoring and enforcement of SAP aftercare recommendations. We strongly recommend that employers play an active role in ensuring that employees who have returned to work following a violation comply with aftercare recommendations. This is very important both for safety and the welfare of the employees. The rule also states that employees are obligated to comply with these SAP recommendations and are subject to employer discipline if they do not.

Section 40.305 How Does the Return-to-Duty Process Conclude?

This section underlines the point that it is the employer, and the employer alone, who is responsible for deciding whether an employee who has violated DOT agency drug and alcohol testing rules will return to work. A determination by the SAP that the employee has successfully complied with the SAP's recommendations is a prerequisite to the employee's return to duty. So is a negative result on a subsequent return-to-duty test. But only the employer can decide whether or not to put the person back to work. SAPs do not make ''fitness for duty'' decisions, and employers should not ask them to do so. Commenters asked that we make these points clear. We think this section is as clear on this point as we can make it.

Section 40.307 What Is the SAP's Function in Prescribing the Employee's Follow-up Tests?

Section 40.309 What Are the Employer's Responsibilities With Respect to the SAP's Directions for Follow-up Tests?

As discussed in the ''Principal Policy Issues'' section of the preamble, the Department has decided to retain the ''at least six follow-up tests in the first 12 months'' formulation for follow-up testing. In response to requests from commenters, we have clarified that this follow-up testing requirement ''follows the employee'' through job changes and breaks in safety-sensitive service. The six tests must occur during the first 12 months of safety-sensitive service after return-to-duty, regardless of for whom or when that service is performed.

Of course, SAPs have the discretion to require more follow-up tests than the minimum. One commenter suggested that SAPs negotiate the number of follow-up tests over the minimum with the employer. We did not adopt this suggestion, because this is intended to be a clinical determination, not subject to economic or policy give-and-take. Employers are obligated to follow the SAP's follow-up testing plan. All parties involved should be aware that, under this rule, all employees who return to work after a violation will have a follow-up testing requirement with which employers and employees must comply.

Section 40.311 What Are Requirements Concerning SAP Reports?

Most of the comment on this section concerned the issue of C/TPAs acting as intermediaries in the transmission of SAP reports to employers. As discussed above, the Department is not permitting C/TPAs to act in this capacity. SAPs must send their reports directly to the DER. The report must be on the SAP's own letterhead, not that of a C/TPA or another service agent.

In response to a comment on the content of the SAP report, we have used the term ''date(s)'' rather than ''date'' to cover the possibility that assessments will happen over a period of time longer than a single meeting. We have also clarified that ''reason for the assessment'' refers to the date and nature of the violation of DOT rules, as a commenter requested, and as DOT's SAP Guidelines outline.

Section 40.313 Where Is Other Information on SAP Functions Found in This Regulation?

This is the last of the regulation's sections providing informational cross-references to other provisions concerning, in this case, SAP functions.

Subpart P—Confidentiality and Release of Information

Section 40.321 What Is the General Confidentiality Rule for Drug and Alcohol Test Information?

Several commenters disagreed with the proposal to continue the Department's ban on blanket releases. These commenters believed that permitting blanket releases would facilitate the flow of information among parties who needed to know, for example, whether an applicant for a job had previously violated a DOT regulation. Other commenters favored retaining this proposal in order to protect employee privacy. The Department believes that the principle of specific written consent for any release of test result or medical information to third parties is critical to protect employees' legitimate expectations of privacy and confidentiality in the testing program. Permitting blanket releases is directly contrary to this principle. The Department will include the proposed provision in the final rule.

Section 40.323 May Program Participants Release Drug or Alcohol Test Information in Connection With Legal Proceedings?

The existing rule and the NPRM both provide that in a proceeding brought by, or on behalf of, an employee, resulting from a positive test (*e.g.,* a lawsuit or grievance), the employer may release employee test result information without the employee's consent. One commenter suggested that we add references to substituted and

adulterated tests and other refusals to test. We have done so.

Another commenter raised the issue of a different kind of legal proceeding. The commenter asked whether otherwise confidential information could be released in a personal injury lawsuit where the employee's conduct was an issue (*e.g.,* a truck or bus driver involved in a collision). We believe that, if a court orders the production of such information because it is relevant in such a proceeding, it is reasonable for the employer to provide it without getting the employee's consent. In this situation, the requirements of justice in the litigation outweigh the employee's privacy interest. We have added a paragraph to this effect. We also added a paragraph telling a service agent who is holding this information to provide it to the employer when the employer requests it for use in a legal proceeding covered by this section.

Section 40.327 When Must the MRO Report Medical Information Gathered in the Verification Process?

This section provides that, under certain circumstances, MROs must provide certain otherwise confidential information to employers and certain other parties. The purpose of providing this information is to enhance safety. Commenters had a variety of concerns about this section. One comment suggested that the medical information be provided in writing in all cases. We think that a prudent MRO may choose to do so, but we do not believe that a regulatory requirement is needed.

Some commenters objected to the paragraph that allows MROs to consult with the employee's own physician to see if alternate medication might be available that would be less likely to adversely affect safety, saying that MROs should stay out of what looks like a doctor-patient relationship with employees. A few commenters supported this proposal. Under the proposal, the MRO would take this step only with the employee's consent, and for the purpose of helping the employee find medication that would be compatible with safe job performance. From both the point of view of employee interests and safety, we believe that this proposal is sound, and we have retained it.

One commenter said that Canadian law would preclude a doctor from releasing this information to an employer. We have added a provision saying that if the law of a foreign country, such as Canada, prohibits MROs from providing medical information to the employer, the MROs may comply with that prohibition.

Another commenter pointed out that not only physicians, but also other medical professionals, may make determinations about whether an employee meets physical qualification standards. We have adopted the commenter's suggestion that the MRO can release information to the ''health care provider'' involved in this activity. Consistent with the SAP provisions of the rule, we have included SAPs who are evaluating employees as part of the return-to-duty process as a party to whom the MRO can provide information under this section.

Finally, as some commenters requested, we have made it mandatory for MROs to release information under this section if the information is likely to result in the employee being medically unqualified for performance of safety-sensitive duties under a DOT regulation or if the information indicates that continued performance by the employee of his or her safety-sensitive function is likely to pose a significant safety risk. In this case, the Department believes that the safety interest served by the information release outweighs the confidentiality interest of the employee.

We point out that the medical information described in this section cannot be transmitted to employers or other parties using a C/TPA or other service agent as an intermediary. MROs must transmit this information directly to the employer.

Section 40.329 What Information Must Laboratories and Other Service Agents Release to Employees?

Proposed § 40.329, concerning release of information by MROs to third-party employers, has been deleted, for the reasons given in the ''Principal Policy Issues'' section of the preamble. This section is based on proposed § 40.331 of the NPRM.

One commenter requested that the Department require that laboratories provide all records requested by an employee, as well as a laboratory person to testify in a legal proceeding who has firsthand knowledge of the laboratory, its records, and operating procedures. This commenter also requested that the rule require the laboratory to make records available within 10 days, rather than waiting for payment from the employee. This section does require that laboratories and other service agents provide a ''data package'' (sometimes referred to as a ''litigation package'') upon the employee's request. We do require that they provide it within 10 business days. The rule also limits the charge the service agent can make for the cost of copying and preparation. We believe these provisions adequately protect employee interests. We do not believe it is necessary, as another commenter suggested, to list the contents of a litigation package, which is quite standard and well understood among laboratories.

We have not adopted the suggestion that laboratories be required to produce witnesses for appearances at legal proceedings. Such an open-ended requirement would impose, in our view, unnecessary costs and burdens on laboratories and other service agents. There are adequate means (*e.g.,* documentary evidence) through which employees can raise issues about the testing process.

The NPRM proposed that laboratories provide to employees, on written request, information relating to the results of relevant HHS certification reviews. One comment supported this proposal, which is consistent with long-standing DOT interpretation of the existing Part 40, while another commenter proposed that the laboratory's obligation be limited to the latest HHS **Federal Register** notice listing the laboratory as certified. Based on conversations with HHS staff, we have decided to delete this provision. HHS staff believe that providing this information would unnecessarily intrude on the HHS-laboratory relationship and could result in the introduction of misleading information about the laboratory certification process in legal proceedings involving drug test results.

Section 40.331 To What Additional Parties Must Employers and Service Agents Release Information?

This section is based on § 40.333 of the NPRM. Some commenters objected to being required to permit DOT representatives to see a broad array of drug and alcohol testing information. DOT has significant safety responsibilities for transportation industries, of which our drug and alcohol testing rules are an important part. As part of its safety mandate, DOT must be able to inspect regulated employers and those who carry out their drug and alcohol testing program responsibilities. DOT cannot do this job unless we have access to all relevant information. We believe it is vital to maintain this provision in the final rule. We would point out, particularly in response to a comment that Canadian MROs could not legally release certain information, that this paragraph focuses on the inspection and review of documents as part of the DOT oversight process, not on release of information to third parties.

Commenters pointed out that, in some jurisdictions, state laws or rules require employers or service agents to provide drug test result information to state law enforcement or safety agencies. To ensure that there is no conflict between Part 40 and these state laws or rules, we have added language (already found in some DOT agency rules) to this section. It says that if requested by a state or local safety agency with regulatory authority over the employer or employee, employers and service agents must provide drug and alcohol test records concerning the employee to the agency. This paragraph also covers Federal agency requests (including requests by DOT, HHS, and the National Transportation Safety Board) for drug and alcohol test records. It should be noted that this paragraph applies only to testing records. It does not authorize provision of specimens.

We have also added a paragraph stating in rule text the advice we have frequently given to employers and service agents faced with subpoenas or other orders directing them, contrary to Part 40 requirements, to produce specimens where Part 40 does not permit. What is a laboratory or other party to do if it gets a request to produce a urine specimen or aliquot for an unauthorized test? The first thing the laboratory should do is to ''just say no,'' giving this DOT regulatory mandate as the reason. If someone seeks a subpoena or other court order directing the production of the specimen, the laboratory's attorneys should seek to quash or resist the action, asserting on the basis of this section that such an order is contrary to Federal law and subject to Federal pre-emption (under the existing pre-emption provisions of DOT agency drug and alcohol regulations). In such cases, we suggest that laboratories call the Department to consult about the matter. If a court ultimately issues a binding order requiring the production of the specimen, the laboratory may comply (we do not seek to make laboratories subject to contempt citations). However, as noted above, employers must continue to implement all consequences of a verified positive test required by DOT rules, regardless of the outcome of the unauthorized test or any personnel process decisions flowing from it.

Section 40.333 What Records Must Employers Keep?

This section is based on § 40.335 of the NPRM. In response to a number of comments and consistent with decisions reflected elsewhere in this document, proposed requirements for the retention of records concerning training of service agents and signed agreements with service agents have been deleted. Under the final rule, collectors, BATs, MROs etc. will maintain their own training records, and employers will not have this responsibility. The requirement to have signed agreements among employers and all service agents has been deleted.

In response to a comment, we have deleted the word ''secure'' from paragraph (c), since we agree that control of access is the key point. One comment suggested that service agents should have up to five business days to get information to employers who are being audited. In our view, each DOT agency's rules and inspection practices should determine how quickly an employer must produce records. The service agent is responsible for meeting the employer's need to comply with DOT agency requirements.

Subpart Q—Roles and Responsibilities of Service Agents

Section 40.341 Must Service Agents Comply With DOT Drug and Alcohol Testing Requirements?

There was only one comment on the proposed § 40.341. AC/TPA wanted C/TPAs to be authorized to act as a DER and to be required to have a certified MRO or administrator in charge. For reasons we have discussed elsewhere, we are not permitting C/TPAs to act as DERs. While we think that training and certification programs for program administrators are a good idea, we do not believe that it is necessary to make them mandatory at this point.

Section 40.343 What Tasks May a Service Agent Perform for An Employer?

This is a new section that makes the basic point that service agents can perform for employers those functions authorized by DOT rules. Proposed § 40.343 dealt with a different issue. DOT has become aware of reports that, particularly in some industries, service agents have imposed requirements on covered entities that exceed the requirements of DOT rules. Some service agents have made compliance with these extra requirements a condition of approval of an employer's DOT drug and alcohol testing program. The proposed section was intended specifically to prevent excesses of this kind.

There were few comments on the proposed section. One said that service agents work for employers in capacities other than compliance with DOT rules. This is doubtless true, but is an issue outside the scope of this rulemaking. One commenter suggested that there was a reverse problem, in that sometimes employers asked service agents (*e.g.*, SAPs) to perform tasks beyond what DOT rules require (*e.g.*, make fitness for duty decisions). We have strengthened language elsewhere in Part 40 to emphasize that it is inappropriate to call on SAPs to make these decisions for employers. A third commenter was concerned that the section might inhibit the ability of service agents to advise employers to recommend provisions not covered by DOT rules. Service agents can recommend provisions not covered by DOT rules, but they cannot make adoption of these recommendations a condition of approving employers' plans for DOT compliance purposes.

The Department has relocated this provision to § 40.355(l).

Section 40.345 In What Circumstances May a C/TPA Act as an Intermediary in the Transmission of Drug and Alcohol Testing Information to Employers?

The proposed § 40.345 made the point that a service agent that did not comply with DOT regulations was subject to PIE proceedings. Comments to this proposal were along the lines of comments on the PIE proposal itself, to which we responded in the ''Principal Policy Issues'' section of the preamble. The substance of this proposed section has been incorporated in § 40.341 of the final rule.

The new § 40.345 incorporates the Department's decision, discussed at length under ''Principal Policy Issues,'' to permit employers to use C/TPAs for a variety of information transmission functions, such as passing drug and alcohol test results from MROs or BATs to employers. We emphasize four points. First, with respect to any and all of the functions that C/TPAs may perform, the employer has the choice of using a C/TPA as an intermediary or getting the information directly from the party (*e.g.*, the MRO) who generates the information. Second, we direct readers' attention to Appendix F. C/TPAs may act as intermediaries *only* with respect to the functions listed in Appendix F.

Third, when C/TPAs act as an intermediary, they must meet all requirements (*e.g.*, concerning confidentiality and timing) that would apply if the party generating the information (*e.g.*, an MRO or collector) sent the information directly to the employer. For example, if a C/TPA transmits the MRO's drug testing results to DERs, it must transmit each drug test result to the DER in compliance with the requirements for MROs set forth in § 40.167. Fourth, as noted in connection with § 40.15, employers remain fully

responsible for receiving all information and taking all actions required under Part 40 and other DOT agency rule.

Section 40.347 What Functions May C/TPAs Perform With Respect to Administering Testing?

One comment on this section suggested that it refer to C/TPAs specifically, rather than service agents generally, because the content of the section covered functions that C/TPAs perform and other service agents (*e.g.*, MROs, laboratories) either should not or typically do not perform. We agree with this comment, and we have changed the language of the section accordingly. Another commenter appeared to be confused about the provision telling service agents not to select employees randomly for testing from a ''follow-up'' pool. This point—which applies to employers as well as C/TPAs—is that follow-up tests are scheduled individually for employees who have returned to safety-sensitive duties after a violation, consistent with the SAP's plan. It is never appropriate to put returned employees into a pool and select them randomly for follow-up testing. Employees never get advance notice of the time of a follow-up test, but follow-up testing is in no way random. On the other hand, in addition to being subject to follow-up testing, returned employees must be in the regular random testing pool, and are subject to selection for random testing on the same basis as all other covered employees.

Section 40.349 What Records May a Service Agent Receive and Maintain?

Some commenters on this section were concerned that because the proposed rule used the general term ''service agent'' in this section, the section glossed over restrictions on the activities of MROs and laboratories. They suggested that, as in the case of § 40.347, we limit the section to C/TPAs. While we agree that C/TPAs perform many record management functions, it does not appear to us that the provisions of this section apply only to C/TPAs. However, in response to the commenters' concerns, we are prefacing this section with an ''except where otherwise specified in this part'' statement (we did the same in § 40.347). The import of this language is that, where MRO, laboratory, or other provisions of the rule impose requirements or restrictions beyond those of this section, those requirements or restrictions control.

Another comment suggested clarifying that DOT access to service agent records and facilities does not apply to records and facilities not involved in the DOT drug and alcohol testing program. This point seems clear on the face of the proposed and final provisions, so we will not restate the obvious. Another comment objected to requiring this access, and asked for a justification. This is equally obvious: in order to maintain proper oversight of an important safety program, the Department needs access to the records and facilities of those who actually perform program tasks.

Section 40.351 What Confidentiality Requirements Apply to Service Agents?

This section is also based on parts of proposed § 40.349. A number of comments pertained to proposed § 40.349(e), relating to handling of the CCF. There is no equivalent to this proposed paragraph in the final rule. A few comments also supported allowing ''blanket'' releases of information. As under the present rule, we believe that blanket releases compromise the confidentiality of employee-specific records and are subject to abuse. The final rule continues this prohibition.

§ 40.353 What Principles Govern the Interaction Between MROs and Other Service Agents?

This section is based on § 40.351 of the NPRM. Much of the comment concerned the discretion of C/TPAs, acting as an intermediary, to transmit laboratory results to MRO and MRO verification decisions to the employer. As discussed in ''Principal Policy Issues'' and in connection with § 40.345, the final rule permits the latter and prohibits the former.

Some commenters appeared to believe that the proposed section required MROs to exercise full-time, in-person, over-the-shoulder supervision of their staffs. This is not the case. As long as MROs really supervise their staff, this supervision need not always take place at the same site. We are aware that MRO operations may have more than one site and that an MRO cannot be everywhere at once. On the other hand, the rule is intended to prohibit C/TPA staff, working on their own or under C/TPA rather than MRO supervision, from performing MRO staff functions.

To reduce paperwork, we have deleted a proposed requirement for written agreements between MROs and other service agents.

§ 40.355 What Limitations Apply to the Activities of Service Agents?

Some commenters on this section favored allowing C/TPAs to act as DERs and to act as an intermediary in transmitting results from laboratories to MROs. Another commenter opposed any ''firewalls'' between C/TPAs and MROs. As we have explained above, the final rule does not permit C/TPAs to act as DERs or to transmit laboratory results to MROs. In our view, some firewalls between MROs and other participants in the testing process are essential to maintaining the necessary independence of MROs.

Another commenter said that employers, not SAPs, should make follow-up testing determinations. SAPs are used in the return-to-duty process because of their expertise in evaluating individuals with drug and alcohol problems. We believe that their expertise should be used to determine follow-up testing requirements. Employers may know their workers, of course, but they are not typically experts in drug and alcohol abuse evaluation and treatment.

One commenter suggested adding a sentence specifying that MROs could determine that an individual had refused a test, in the context of an adulteration or substitution finding. We agree, and we have added this language.

We have added a paragraph concerning a problem that the Department has occasionally encountered. It states that service agents must not intentionally delay the transmission of drug or alcohol testing-related documents because of a payment dispute or other reasons. Parties can work out disputes among themselves, but it is essential to the safety purposes of this program that drug and alcohol testing results and other information flow freely. As a safety matter, this information must not be held hostage to business disagreements.

Subpart R—Public Interest Exclusions

The Department discussed PIEs extensively in the ''Principal Policy Issues'' portion of the preamble. We will not repeat this discussion here, focusing instead on points in the individual sections of Subpart R that should be highlighted.

§ 40.361 What Is The Purpose of a Public Interest Exclusion (PIE)?

Section 40.363 On What Basis May the Department Issue a PIE?

Section 40.365 What Is the Department's Policy Concerning Starting a PIE Proceeding?

These sections emphasize that the basic purpose of PIEs is to protect the public from serious noncompliance on the part of service agents. PIEs are not an exclusive remedy: We can take other actions (*e.g.*, sanctions against employers, referral to the DOT Inspector

General) if circumstances warrant. The basic grounds for issuing a PIE are serious noncompliance with Part 40 or DOT agency drug and alcohol testing regulations and failure to cooperate with DOT oversight and enforcement efforts.

Section 40.365 includes a list illustrating the kinds of misconduct that we believe warrant initiating a PIE proceeding. We emphasize that this is not an exhaustive or exclusive list. We can and will initiate PIEs on the basis of other fact situations, if warranted. However, this list should give interested persons a good idea of the Department's policy concerning the level of seriousness that we intend to be the basis for PIE actions. The items on the list all concern such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives. Many of the items are drawn from problems the Department has noted under the existing Part 40.

We note that the PIE provisions of the rule are not intended to have retroactive effect. That is, the Department would not initiate a PIE proceeding on the basis of conduct that occurred before the PIE provisions took effect.

Section 40.367 Who Initiates a PIE Proceeding?

Section 40.369 What Is the Discretion of an Initiating Official in Starting a PIE Proceeding?

Section 40.371 On What Information Does an Initiating Official Rely in Deciding Whether To Start a PIE Proceeding?

Section 40.411 What Is the Role of the DOT Inspector General's Office?

These sections concern the Department's decision about whether to begin a PIE proceeding. Only selected DOT officials are authorized to begin such a proceeding: DOT agency drug and alcohol program managers, an official of ODAPC other than the Director (who, as the decisionmaker, is precluded from any role in initiating or prosecuting a PIE proceeding), or the designee of these officials. We emphasize that individual inspectors and subordinate staff members, while they may provide information to initiating officials, are not themselves authorized to initiate PIE proceedings.

Initiating officials have broad discretion in deciding whether to start a PIE proceeding, though this discretion must be exercised with the policy expressed § 40.365 in mind. DOT is never required to start a PIE proceeding. An initiating official can take into account such factors as his or her judgment of the seriousness of the matter and the availability of resources to investigate and prosecute a matter adequately.

An initiating official can rely on credible information from any source in deciding whether to start a proceeding. As many commenters requested, the initiating official will make an informal contact with the service agent before sending a correction notice, in an attempt to determine if the service agent has any information that would help the initiating official make his or her decision to initiate a proceeding.

While the DOT inspector general (IG) is not an initiating official in the PIE process, the IG can investigate complaints concerning waste, fraud, and abuse in the drug and alcohol testing program. The initiating official can use information from IG investigations and audits as the basis to begin a PIE proceeding. The IG can also take action leading to criminal or civil action against a service agent or employer if the facts warrant.

Section 40.373 Before Starting a PIE Proceeding, Does the Initiating Official Give the Service Agent an Opportunity To Correct Problems?

Section 40.375 How Does the Initiating Official Start a PIE Proceeding?

These sections describe the first formal steps in any PIE proceeding. Before taking other action, the initiating official sends a correction notice, outlining the compliance problem and giving the service agent 60 days to correct it. If the service agent documents correction of the problem in this period, the official does not pursue a PIE proceeding. If not, the official sends a notice of proposed exclusion (NOPE) to the service agent, detailing the basis for the proposed exclusion and informing the service agent of the next procedural steps.

There may be some problems that cannot be corrected, or some misconduct so serious that subsequent corrective steps are insufficient to make up for the effects of noncompliance. For example, an MRO who has counterfeit medical credentials probably cannot correct this problem. A laboratory that has demonstrated a significant lack of business integrity by falsifying evidence or a pattern or practice of careless conduct resulting in the cancellation of numerous tests might have great difficulty demonstrating that it has made adequate changes to make up for the problems it caused. The Department is not limited, in deciding whether to initiate a PIE proceeding, to purely prospective considerations (*e.g.,* analogous to the ''imminent [future] harm'' standard HHS uses in deciding to take certification action against a laboratory). Nor is the Department required to accept, on face value, assurances from a service agent that it has learned its lesson and will comply in the future. The Department will make judgments of this kind on a case-by-case basis.

Section 40.377 Who Decides Whether To Issue a PIE?

This sections focuses on the role of the ODAPC Director as decisionmaker. Section 40.377 articulates the firewall between the Director and the initiating official, to ensure impartiality. The Director can delegate the decisionmaking role to another official (*e.g.,* in a case where the Director would be unavailable to decide the case or recused himself or herself because of a potential conflict of interest), who would then be subject to the same firewall requirements.

Section 40.379 How Do You Contest the Issuance of a PIE?

Section 40.381 What Information Do You Present to Contest the Proposed Issuance of a PIE?

Section 40.383 What Procedures Apply if You Contest the Issuance of a PIE?

Section 40.385 Who Bears the Burden of Proof in a PIE Proceeding?

These sections cover an important part of the administrative due process protections built into the PIE provisions of the rule. Within 30 days of getting a NOPE, a service agent must contact the Director and make arrangements to present information and arguments. If the service agent asks to meet with the Director, the Director will schedule a meeting. At this meeting, or in a written presentation, the service agent may provide any arguments or factual information it believes relevant to the proposed issuance of a PIE, its scope and duration. We emphasize that the opportunity to meet with the Director is not a ''hearing'' or ''trial,'' with formal rules of evidence. The Director will consider any relevant evidence and listen to any witnesses the initiating official or the service agent presents. Because the initiating official is the proponent of the PIE action, he or she bears the burden of proof (by a preponderance of the evidence) on all issues. To justify issuing a PIE, the Director must find that the service agent failed or refused to perform drug and/or alcohol testing services as required by this part or is in serious noncompliance

with a DOT agency drug and alcohol regulation.

Section 40.387 What Matters Does the Director Decide Concerning a Proposed PIE?

Section 40.389 What Factors May the Director Consider?

Section 40.391 What Is the Scope of a PIE?

Section 40.393 How Long Does a PIE Stay in Effect?

Section 40.407 May a Service Agent Ask To Have a PIE Reduced or Terminated?

These sections concern what decisions the Director makes and which factors the Director considers in deciding on whether to issue a PIE, as well as the scope and duration of a PIE. When the Director receives the NOPE and the service agent's response to it, the Director can dismiss the proceeding (*e.g.,* for not raising a sufficiently serious noncompliance issue to warrant issuing a PIE), remand it to the initiating official for more fact finding, or continue with the proceeding. Whenever a proceeding does go to decision, the Director would make determinations concerning disputed factual issues, whether the facts support issuing a PIE, and the scope and duration of a PIE. The factors the Director considers in making these decisions include the seriousness of the noncompliance, the pervasiveness of the noncompliance within the service agent's organization, and the compliance disposition of the service agent.

The scope of a PIE was the subject of many comments. In the final rule, the initiating official proposes a scope for the PIE, the service agent can contest the proposal, and the Director decides what the scope should be. The general rule is that a PIE applies to parts of an organization or types of services that are affected by the service agent's noncompliance. The more pervasive the misconduct, the broader the scope of the PIE. The rule text provides several examples of the Department's thinking on how to view the proper scope of a PIE.

There are also situations in which the PIE can apply to individual officers or employees of the service agent, if they are responsible for the noncompliance that formed the basis for the PIE. This provision is intended to prevent individuals from going into business under a different business or corporate name while a PIE remains in effect against the service agent they worked for. The same is true of businesses affiliated with the service agent concerning which the Department issued a PIE.

A PIE stays in effect from one to five years. Like the scope of a PIE, the duration of a PIE is proposed by the initiating official, may be contested by the service agent, and is decided upon by the ODAPC Director. The Director's decision is based on such factors as the seriousness of the noncompliance on which the PIE is based and the continued need to protect employers and employees from the service agent's noncompliance. The Director considers factors such as those listed in § 40.387 in making this decision.

After a PIE has been in effect for nine months, the service agent can apply to have its duration shortened. If the Director verifies that the sources of noncompliance have been eliminated and that all drug or alcohol testing-related services the service agent would provide to DOT-regulated employers will be consistent with the requirements of this part, the Director may issue a notice terminating or reducing the PIE. We emphasize that this process is limited to the issues of duration and scope: it is not an appeal or reconsideration of the decision to issue the PIE.

Section 40.395 Can You Settle a PIE Proceeding?

Section 40.397 When Does the Director Make a PIE Decision?

Section 40.399 How Does the Department Notify Service Agents of Its Decision?

Section 40.401 How Does the Department Notify Employers and the Public About a PIE?

Section 40.403 Must a Service Agent Notify Its Clients When the Department Issues a PIE?

Section 40.405 May the Federal Courts Review PIE Decisions?

Section 40.413 How Are Notices Sent to Service Agents?

The next group of provisions concern the mechanics of making PIE decisions and informing people about them. The initiating official and the service agent can settle a PIE proceeding at any time before the Director issues a decision. The Director must concur in the settlement, which could include, for example, provisions to ensure compliance or a period of voluntary exclusion during which the service agent agrees not to provide certain services to DOT-regulated employers while it fixes noncompliance problems.

The Director is normally responsible for making a decision within 60 days of the record of the proceeding being completed. The Director can extend this normal decision period for 30 days at a time for good cause. It is the Department's policy to expedite these important decisions, however. Once the Director issues a decision, it is a final administrative action of the Department, subject, like all such actions, to judicial review under the Administrative Procedure Act.

The Director must provide written notice of a PIE to the service agent, including a statement of the basis for his or her decision and the scope and duration of the PIE. The Department also informs the public about the PIE though a web site posting and a **Federal Register** notice. We also anticipate informing employer and testing industry groups about the action, so that they can inform their members. The service agent also has an affirmative responsibility to inform customers about the PIE, so that they can obtain services from and transfer records to other service agents. Finally, § 40.113 concerns the mechanics of how notices are sent to service agents and when they are deemed to have been received. As a policy matter, the initiating official will make reasonable efforts to follow up with the service agent to ensure that the service agent has received and understood the notice.

Section 40.409 What Does the Issuance of a PIE Mean to Transportation Employers?

Employers have an affirmative responsibility to stop using the services of a service agent that is subject to a PIE. This obligation begins 90 days *after* the Director issues the PIE, to give the employer time to find another service provider. The obligation applies to services provided through an affiliate of the service agent subject to the PIE as well as the service agent itself, and it applies to employers in all DOT-regulated industries. It is important to note that a PIE does not invalidate otherwise proper drug and alcohol tests in which the service agent was involved before, and for 90 days after, the issuance of the PIE. The rule text spells out the operation of this provision in more detail.

Appendices

Appendix A

During the last decade of drug testing, the Department has not regulated nor standardized the materials (*i.e.,* collection containers, specimen bottles, etc.) used in DOT-mandated drug

testing. During the first few years of drug testing, only one specimen bottle was required. Subsequent to the Omnibus Act, split specimen collections became a requirement for four of the six DOT agencies. In general, each laboratory provided to the collection site or the employer laboratory specific collection kits, many of which differed in composition.

The introduction of the split, the fact that in the pipeline and maritime industry split collection was an employer option, and the wide variance among the laboratories' kits, resulted in significant problems and numerous tests had to be cancelled based on collector error that, at times, was due to the differences in the makeup of the kits.

Several years ago, the Department requested all laboratories to provide samples of their urine collection kits. These were reviewed against the then current regulatory requirements (*e.g.,* tamper-evident seals on the bottles, availability and use of shipping container seals, collection instructions), and a majority of kits did not meet the regulatory requirements. Laboratories were notified and corrective action was recommended, but the Department did not take any specific action to standardize these kits at that time.

The Department is convinced that the new requirement for all DOT agencies to use splits, and the development of a standard kit, will result in fewer mistakes and cancellations of drug tests. In that light, Appendix A spells out broad criteria for the composition of urine collection kits.

The requirement for a collection container should minimize the need to give the employee both bottles, when there is no collection container in the kit, and request the employee to urinate into only one bottle. In some cases, employees fill both bottles and collectors submit these, resulting in splits that do not reconfirm. In some cases, the two bottles contained urine of different colors, but collectors submitted them anyway.

The requirement that the collection container and the bottles be wrapped or sealed in a plastic bag was established earlier to prevent accusations by the employee that either the collector or someone at the collection site introduced some foreign substance into the containers, causing a positive result. The standards specifically spell out that the collection container needs to be securely wrapped separately from the specimen bottles and that the bottles must be either shrink wrapped or sealed in plastic bags or may be secured with other methodology provided that the tamper-evident mechanism is effective and easily discernable to the employee.

For example, the use of a tiny filament between the bottle and the cap which breaks when the bottle is first opened may be effective in determining if the bottle was opened, but only if the employee has this pointed out to him or her. Even at that, the employee would have to look very closely to see if the filament is or is not attached. Most collectors will not spend the time to go through this process and employees can say they were not really able to tell if the filament was in place. It is much easier to defend and remember that a bottle was wrapped in a plastic bag, rather than argue that the employee was or was not specifically shown the filament or that he or she actually did or did not see the filament. Conversely, a bottle that has a paper label.

The use of a leak-resistant plastic bag has been in place for a number of years, driven primarily by U.S. Postal Service and courier and shipping services requirements as a safety issue related to transportation of biological specimens. Under the new standards, the plastic bags must not only be leak-resistant (no zip locked bags), but must also be tamper-evident. In other words, once the bag is sealed it cannot be opened without the opening becoming obvious.

Under current rules, there is a requirement that the shipping container be sealed with a shipping container seal that is initialed or signed and dated by the collector. In the NPRM, we proposed to use a tamper-evident seal on the plastic bag instead of the shipping container, since in many cases, collectors may collect several specimens in plastic bags and hold or store them until they have several which can then be placed into a shipping contained which is subsequently sealed. There were few comments related to the kit, but laboratories did indicate that when a shipping container, usually a box, arrives at the laboratory with a broken seal, the specimens are tested provided the specimen bottle seals are intact. To date, the Department is not aware of any problems related to this practice. However, it does call into question the purpose of the second (shipping container) seal. The Department's position is that if the leak-resistant plastic bag is tamper-evident, that serves as the secondary protection, which is currently ensured by the shipping seal.

The primary concern is, and always has been, the integrity of the specimen bottle seals. As long as the integrity of the specimen bottle seals is intact, the condition of the shipping container seal is not relevant. The standards listed in Appendix A, therefore, do not include a requirement for a shipping container or plastic bag seal.

The current regulatory requirement is that the ''specimens shall be placed in shipping containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes and/or padded mailers)''. In many cases, kits contain cardboard boxes designed to hold only two bottles for shipment. In some cases, collection sites may, and do, place a number of specimens in plastic bags and then into one large shipping container or box, and transport the specimens in that manner. With the advent of stronger plastics, some laboratories are requesting collection sites to transport bottles wrapped in leak-resistant plastic bags which are placed into larger plastic envelopes, contending that because the specimen bottles are constructed of stronger plastic, this is an acceptable practice.

The Department has discussed this issue of transporting specimens with two of the largest courier services and both have expressed their concerns about leakage of urine specimens in transit and concern for the safety of their employees. Both courier services require a watertight primary receptacle (bottle) and a secondary watertight container, which in this case would be the leak-resistant plastic bag. One courier requires a sturdy outer package consisting of corrugated fiberboard, wood, metal, or rigid plastic; Styrofoam boxes, plastic bags, and paper envelopes are not acceptable as outer packaging. The second major courier requires that the primary container (bottle) meet a 150-pound crush test. If it meets that test, it may be placed in a leak-resistant plastic bag or container and then may be placed in a secondary leak-resistant plastic envelope without further packaging. Conversely, if the bottle(s) does not meet the crush test, it must be placed into a secondary package, which meets the 150-pound crush test. The secondary package may then be placed into a plastic shipping envelope.

The Department has determined that current shipping regulations and requirements are sufficient to ensure that specimens are shipped in a manner that will protect them from damage. Therefore, the standards direct that the specimen bottles be shipped in containers that can sufficiently protect them from damage; the standards do not specify the type of material or the extent of weight (crush test) that the shipping containers should meet. The standards also permit the specimens to be transported to a laboratory in the leak-resistant plastic bag provided they are hand-carried by a laboratory courier. In other words, the courier picks the

specimens up in whatever is a convenient shipping or carrying container and does not subsequently place them into a system (automated transportation, another delivery courier, or on a plane, railroad, or truck), but personally delivers them to the laboratory.

Appendix B

Appendix B is simply a list of the data elements and format for the semi-annual laboratory report provided to employers. Laboratories should follow this format when they compose these reports.

Appendix D

This appendix identifies the format and type of information that the MRO needs to submit to DOT when a split specimen test fails to reconfirm the presence of the drug/drug metabolite, adulterant, or the substitution finding found in the primary specimen.

There has been a long-standing practice under the current rule that when the employee requests a test of the split specimen and the test of the split fails to reconfirm the presence of the drug/drug metabolite that was found in the primary specimen, or if the split was not available (*i.e.,* not collected or leaked in transit), the MRO was required to report this result to the Department. The purpose of this report was to determine if this was an administrative or collection error (*e.g.,* the primary bottle and the split bottle were not the same urine) or if the failure to reconfirm was one of a technical nature, requiring review by HHS. Although the majority of ''failures to reconfirm'' have been due to the unavailability of the split specimen, some of the technical problems led to the discovery of the various adulterants that are currently used to circumvent the testing process. Based on this, the Department will continue to require this reporting by the MRO.

The Department has also decided to permit an employee to request the test of the split specimen when the primary specimen is reported as adulterated or substituted. Based on that decision, we have determined that should the split fail to indicate the adulterant or the substitution is not supported by the test of the split or the MRO cancels the test based on medical evidence, the MRO needs to report this cancellation to the Department in the same manner as if it was a positive result which failed to reconfirm.

There is not a standard ''report'' that the MRO needs to fill out. However, for consistency of information, Appendix D provides the format for the information that the Department needs to fully assess if there are any technical problems in the testing process. For ease of use, the same format can be used for reporting cancellation of a positive as well as for adulteration and substitution.

Appendix E

This Appendix lists the 12 criteria the Department examines in determining whether certification organizations should be accepted under §§ 40.281–40.283 for participation in the SAP program. The first eleven items are the same criteria the Department has used in evaluating other certification organizations that are already part of the program (*e.g.,* ICRC). The twelfth item is NCCA accreditation, discussed in the preamble to § 40.281.

Appendix F

This Appendix is a list of the drug and alcohol testing information transmission functions that C/TPAs are authorized to perform (see § 40.345) C/TPAs may, acting as an intermediary, transmit the information in the listed regulatory sections to the DER for an employer, if the employer chooses to have the C/TPA do so. These are the only items that C/TPAs are permitted to transmit to the employer as an intermediary. The use of service agent intermediaries is prohibited in all other cases, such as transmission of laboratory drug test results to MROs, the transmission of SAP reports to employers, and the transmission of positive alcohol test results.

In every case, the C/TPA must ensure that, in transmitting the information, it meets all requirements (*e.g.,* concerning confidentiality and timing) that would apply if the party originating the information (*e.g.,* an MRO or collector) sent the information directly to the employer. For example, if a C/TPA transmits MROs' drug testing results to DERs, you must transmit each drug test result to the DER in compliance with the requirements for MROs set forth in § 40.157.

Appendix G

The ATF included in Appendix G is a slight modification of the existing alcohol testing form. One commenter suggested that a new alcohol testing form be developed that incorporated requirements proposed by the NPRM (*e.g.,* the name of the DER, whether an STT used a saliva device). We believe that a revised form will serve the program better by allowing us to capture the necessary information. At the same time, it will no longer require the employee to sign in Step 4 if the alcohol concentration is less than 0.02. This signature will only be necessary if the alcohol concentration is 0.02 or higher on the confirmation test. Consistent with the CCF, all pages of the form may be white, with the distribution legend at the bottom of pages 2 and 3 following the colors of the current form. The OMB control number of the new form will be OMB 2105–0529, the same as for the current form. Program participants may start using the form January 18, 2001. Use of the form will become mandatory on August 1, 2001.

Regulatory Analyses and Notices

Executive Order 12866 and DOT Regulatory Policies and Procedures

This rule is a significant rule for purposes of Executive Order 12866. It is significant because of its policy importance and its impact upon sizeable industries. It is not, however, an economically significant regulation. It is a reworking of existing requirements, imposing few new mandates, and should not have significant incremental costs. Because of its multimodal impact and policy interest to regulated parties and service agents, it is a significant rule for purposes of the DOT Regulatory Policies and Procedures. Throughout this regulation, we have attempted to balance the costs of new requirements with the cost savings accrued through the elimination of some current requirements.

Economic Impacts

There are two features of the regulation that would add new requirements having economic impacts. The first is the requirement for validity testing. As the result of work by HHS and the laboratories, these protocols are already in place and are being used by most laboratories, so we expect the incremental costs of this requirement to be modest. The Department believes that public safety is well-served by these steps to identify and hold accountable employees in safety-sensitive positions who attempt to tamper with the testing process.

Second, the rule includes additional training requirements for some service agents. Errors in the testing process resulting from lack of training can lead to increased employer program costs and increased paperwork required to document the errors and repeat the testing process. The rule upgrades requirements for collectors, MROs, and SAPs. Well-attended training courses for MROs already exist, as do some collector and SAP courses.

At the same time, the Department anticipates cost savings from some provisions of the regulation, such as the

reductions in blind specimen requirements and mitigation of some reporting requirements. The additional training requirements discussed in the previous paragraphs will help to reduce costs from errors in the system. For example, every time a better-trained collector conducts a collection properly instead of making a mistake, the costs of developing memorandums for correction, preparing laboratory litigation packages, arbitration or court proceedings, and reversing personnel actions are avoided.

The Department has estimated cost increases and decreases that could be expected if the proposed rule's provisions are made final. It is important to understand that this is a big program, touching some 8.34 million employees working for about 673,413 employers. Around 30,000 individuals and organizations work as service agents.

In terms of new costs, the Department estimates an annual cost of about $1.4 million for validity testing. With respect to training for SAPs. MROs, BATs, STTs, and collectors, we anticipate that annual costs will run about $4 million. In addition, we estimate that there will be one-time costs for a variety of administrative requirements in the first year of implementation of approximately $1.93 million.

On the other hand, we anticipate saving at least $4.3 million per year from the reduction in blind specimen testing (the savings will probably be somewhat greater, because fewer organizations will be required to submit blind specimens). By changing the current quarterly laboratory report requirement to require a semiannual report, we anticipate saving another $2.5 million annually. By permitting positive, adulterated, and substituted test results to be faxed rather than sent by overnight express, we project an annual $3.3 million saving. These annual savings are greater than the additional annual costs we anticipate for the proposed rule. In total, then, we estimate that the new rule will result in about $7.4 million in incremental costs versus $10.1 million in incremental savings, compared to the existing rule.

The Department has placed in the docket for this rulemaking a document describing the basis for these estimates in greater detail.

Executive Order 13132 and Federalism

This final rule does not have sufficient Federalism impacts to warrant further action under Executive Order 13132. The Department notes that the provisions of Part 40 are incorporated by reference in the other DOT agency drug and alcohol testing regulations, which have existing pre-emption provisions in them. Consequently, for example, a provision of a state or local law or regulation that conflicted with a provision of Part 40 could be subject to pre-emption on the basis of this existing operating administration authority.

Regulatory Flexibility Act

With respect to the Regulatory Flexibility Act, the Department certifies that this rule does not have a significant economic impact on a substantial number of small entities, so a Regulatory Flexibility analysis has not been prepared. It is clear that the rule affects large numbers of small entities. Many thousands of covered employers are small businesses (*e.g.,* small trucking companies, small transit authorities), as are many service agents (*e.g.,* occupational health clinics). Given the small, and overall favorable, net change in regulatory costs compared to the present rule, spread over these thousands of small entitites, the cost impact per entity is expected to be negligible.

We have also taken some steps, such as the reduction in blind specimens, the reduced frequency of some reports, and the discretion we have given C/TPAs to act as intermediaries in some situations, that should assist small entities in complying and reduce their burdens. For the smallest entities (*e.g.,* owner-operators), we have also permitted C/TPAs to perform some additional functions. The PIE provision should reduce costs to small employers as the result of noncompliance by service agents. Our ability to create special provisions for small entities is limited by the need to have uniform requirements to ensure safety and fairness to employees. There must be a single standard for the accuracy and integrity of the program and the protection of legitimate employee interests that cannot vary with the size of the employer or service agent.

This rulemaking resulted from a ''610 Review'' under the Regulatory Flexibility Act. We have reviewed the existing program to identify areas in which the rule can be improved with the effect of assisting small businesses to comply in a rational and cost-effective manner. In addition to the general clarification of the program this rule provides, we have identified some specific areas (*e.g.,* blind specimen requirements, the addition of the public interest exclusion provision, the reduction in reporting frequencies, the discretionary use of C/TPAs to transmit information) that should be particularly helpful to small regulated employers.

Paperwork Reduction Act

Since the inception of the Department's drug and alcohol testing program, each individual DOT agency has complied with the requirements of the Paperwork Reduction Act (PRA) by submitting a justification to the Office of Management and Budget (OMB). These PRA submissions reflected requirements derived from the respective DOT agency drug and alcohol regulations as well as from Part 40. The submissions were never presented to OMB in a coordinated fashion, nor were they reviewed together to ensure that all drug and alcohol program requirements were reflected in a manner that was consistent, accurate, and non-duplicative.

In January 2000, the Department began an effort to evaluate prior PRA submissions in an attempt to address disparities between DOT agency estimates as well as the aggregate burden and cost estimates. A One-DOT group was formed. Its goals were to bring consistency and simplicity to DOT's PRA submissions; eliminate PRA submission duplication between and among DOT agencies, OST, and other Federal agencies; eliminate PRA submission discrepancies; and, more importantly perhaps, ensure accuracy of submissions. In addition, the group decided to standardize cost, hour, and wage indicators, where possible, and to identify task commonalities in DOT agency regulations and standardize how they are reported to OMB. The group sought to determine where program PRA responsibilities for specific drug and alcohol program elements lie—with the DOT agencies, OST, or other Federal agencies.

The group identified a total of 37 PRA tasks contained in one or more of the regulations of six DOT agencies (*i.e.,* that properly reside in the operating administration rules rather than in Part 40). Some tasks were shared by all or some DOT agencies, while other tasks were peculiar to only one DOT agency. The operating administrations subsequently made PRA submissions to OMB for these items, which OMB approved. These submissions resulted in a reduction in the paperwork burden attributable to operating administration rules, both because Part 40-related burdens were kept separate and because a significant overestimate of the burden connected with one of the operating administration programs was corrected. The total reduction was over 50 million hours.

Next, the Department constructed a baseline for the information collection burden attributable to the existing Part

40 (most of which had not previously been accounted for in PRA submissions or had been subsumed under operating administration submissions). This baseline is approximately 2.23 million hours. The Department submitted a PRA request to OMB concerning this material, which OMB has approved.

Third, the Department compared the information collection burden of the existing Part 40 baseline to the estimated burden for the new Part 40. Comparing the existing rule to the new rule, there are some items that increase (*e.g.,* obtaining test results from previous employers, MRO review of negative test documentation, employer SAP lists being provided to employees), in part because they previously were accounted for under operating administration rules. Other items decreased (*e.g.,* changing from quarterly to semi-annual laboratory reports). The largest decrease resulted from the drug testing form's burden hours being accounted for under the PRA responsibility of HHS. Cumulatively, the new Part 40's information collection burden is approximately about 842 thousand hours, or about 1.39 million hours less than that of the existing Part 40.

For informational purposes, the Department has placed its entire Paperwork Reduction Act package on the internet, on the same Docket Management System web site on which comments on this rulemaking are posted. Interested persons may review this material electronically. The following web address provides instructions and access to the DOT electronic docket: *http://dms.dot.gov/search/.* To find the material on the Part 40 rulemaking, just enter the number 6578 in the ''docket number'' search dialog box.

In addition, we note that § 40.25, which requires employers to obtain information from applicants about previous drug and alcohol test results, was not previously the subject of PRA-related comment. While this section is part of the PRA package OMB has approved in connection with Part 40, you may comment about the information collection aspects of the section. Please send any comments to Jim L. Swart, Drug and Alcohol Policy Advisor, Office of Drug and Alcohol Policy and Compliance (ODAPC), 400 7th Street, SW., Room 10403, Washington, DC 20590, 202–366–3784 (voice), 202–366–3897 (fax), or *jim.swart@ost.dot.gov* (e-mail).

Other Executive Orders

There are a number of other Executive Orders that can affect rulemakings. These include Executive Orders 13084 (Consultation and Coordination with Indian Tribal Governments), 12988 (Civil Justice Reform), 12875 (Enhancing the Intergovernmental Partnership), 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights), 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations), 13045 (Protection of Children from Environmental Health Risks and Safety Risks), and 12889 (Implementation of North American Free Trade Agreement). We have considered these Executive Orders in the context of this rule, and we believe that the rule does not directly affect the matters that the Executive Orders cover. We have prepared this rulemaking in accordance with the Presidential Directive on Plain Language.

List of Subjects in 49 CFR Part 40

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

Issued this 1st day of December 2000, at Washington, DC.

Rodney E. Slater,

Secretary of Transportation.

For the reasons set forth in the preamble, the Department of Transportation amends 49 CFR subtitle A as follows:

1. Effective January 18, 2001, amend the current 49 CFR part 40 as follows:

PART 40—[AMENDED]

a. The authority citation for Part 40 is revised to read as follows:

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

b. Add Subparts E and F to read as follows:

Subpart E—Additional Administrative Provisions and Validity Testing

Sec.

Subpart F—Public Interest Exclusions

Subpart E—Additional Administrative Provisions and Validity Testing

§ 40.201 Additional definitions.

The following definitions apply to the provisions of this subpart E and subpart F of this part:

Adulterated specimen. A specimen that contains a substance that is not expected to be present in human urine, or contains a substance expected to be present but is at a concentration so high that it is not consistent with human urine.

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 F of this part.

Confirmation (or confirmatory) validity test. A second test performed on a urine specimen to further support a validity test result.

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

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

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.

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.

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

§ 40.203 Who issues authoritative interpretations of this regulation?

ODAPC and the DOT Office of General Counsel (OGC) provide written interpretations of the provisions of this part. These written DOT interpretations are the only official and authoritative interpretations concerning the provisions of this part. DOT agencies may incorporate ODAPC/OGC interpretations in written guidance they issue concerning drug and alcohol testing matters.

§ 40.205 What is validity testing, and are laboratories authorized to conduct it?

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

(b) As a laboratory, you are authorized to conduct validity testing.

§ 40.207 What validity tests must laboratories conduct on primary specimens?

As a laboratory, if you conduct validity testing under the authorization of § 40.205(b), you must conduct it in accordance with the requirements of this section.

(a) You must test each primary specimen for creatinine. You must also determine its specific gravity if you find that the creatinine concentration is less than 20 mg/dL.

(b) You must measure the pH of each primary specimen.

(c) You must test each primary specimen to determine if it contains substances that may be used to adulterate the specimen. Your tests must have the capability of determining whether any substance identified in current HHS requirements or specimen validity guidance is present in the specimen.

(d) If you suspect the presence of an interfering substance/adulterant that could make a test result invalid, but you are unable to identify it (*e.g.,* a new adulterant), you may, as the first laboratory, send the specimen to another HHS certified laboratory that has the capability of doing so.

(e) If you identify a substance in a specimen that appears to be an adulterant, but which is not listed in current HHS requirements or guidance, you must report the finding in writing to ODAPC and the Division of Workplace Programs, HHS, within three business days. You must also complete testing of the specimen for drugs, to the extent technically feasible.

(f) You must conserve as much as possible of the specimen for possible future testing.

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

(a) As a laboratory you must consider the primary specimen to be dilute if the creatinine concentration is less than 20 mg/dL *and* the specific gravity is less than 1.003, unless the criteria for a substituted specimen are met.

(b) As a laboratory you must consider the primary specimen to be substituted if the creatinine concentration is less than or equal to 5 mg/dL *and* the specific gravity is less than or equal to 1.001 or greater than or equal to 1.020.

§ 40.211 What criteria do laboratories use to establish that a specimen is adulterated?

(a) As a laboratory, you must consider the primary specimen to be adulterated if you determine that—

(1) A substance that is not expected to be present in human urine is identified in the specimen;

(2) A substance that is expected to be present in human urine is identified at a concentration so high that it is not consistent with human urine; or

(3) The physical characteristics of the specimen are outside the normal expected range for human urine.

(b) In making your determination under paragraph (a) of this section, you must apply the criteria in current HHS requirements or specimen validity guidance.

§ 40.213 How long does the laboratory retain specimens after testing?

(a) As a laboratory testing the primary specimen, you must retain a specimen that was reported with positive, adulterated, substituted, or invalid results for a minimum of one year.

(b) You must keep such a specimen in secure, long-term, frozen storage in accordance with HHS requirements.

(c) Within the one-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain a specimen for an additional period of time (*e.g.,* for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the specimen at the end of the year.

(d) If you have not sent the split specimen to another laboratory for testing, you must retain the split specimen for an employee's test for the same period of time that you retain the primary specimen and under the same storage conditions.

(e) As the laboratory testing the split specimen, you must meet the requirements of paragraphs (a) through (c) of this section with respect to the split specimen.

§ 40.215 On what basis does the MRO verify test results involving adulteration or substitution?

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive test for a drug or drug metabolite.

(b) You must follow the same procedures used for verification of a confirmed positive test for a drug or drug except as otherwise provided in this section.

(c) In the verification interview, you must explain the laboratory findings to the employee and address technical questions or issues the employee may raise.

(d) You must offer the employee the opportunity to present a legitimate medical explanation for the laboratory findings with respect to presence of the adulterant in, or the creatinine and specific gravity findings for, the specimen.

(e) The employee has the burden of proof that there is a legitimate medical explanation.

(1) To meet this burden in the case of an adulterated specimen, the employee must demonstrate that the adulterant found by the laboratory entered the specimen through physiological means.

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine, through physiological means, meeting the creatinine and specific gravity criteria of § 40.209(b).

(3) The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the specimen, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence supporting a legitimate medical explanation within that time.

(f) As the MRO or the employer, you are not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

(g) As the MRO, you must exercise your best professional judgment in deciding whether the employee has established a legitimate medical explanation.

(1) If you determine that the employee's explanation does not present a reasonable basis for concluding that there may be a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution, as applicable.

(2) If you believe that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, you must direct the employee to obtain, within the five-day period set forth in paragraph (e)(3) of this section, a further medical evaluation. This evaluation must be performed by a licensed physician (the ''referral physician''), acceptable to you, with expertise in the medical issues raised by the employee's explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(i) As the MRO or employer, you are not responsible for finding or paying a referral physician. However, on request of the employee, you must provide reasonable assistance to the employee's efforts to find such a physician. The final choice of the referral physician is the employee's, as long as the physician is acceptable to you.

(ii) As the MRO, you must consult with the referral physician, providing guidance to him or her concerning his or her responsibilities under this section. As part of this consultation, you must provide the following information to the referral physician:

(A) That the employee was required to take a DOT drug test, but the laboratory reported that the specimen was adulterated or substituted, which is treated as a refusal to test;

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

(C) That the referral physician must agree to follow the requirements of paragraphs (g)(3) through (g)(4) of this section; and

(D) That the referral physician must provide you with a signed statement of his or her recommendations.

(3) As the referral physician, you must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. You may conduct additional tests to determine whether there is a legitimate medical explanation. Any additional urine tests must be performed in an HHS-certified laboratory.

(4) As the referral physician, you must then make a written recommendation to the MRO about whether the MRO should determine that there is a legitimate medical explanation. As the MRO, you must seriously consider and assess the referral physician's recommendation in deciding whether there is a legitimate medical explanation.

(5) As the MRO, if you determine that there is a legitimate medical explanation, you must cancel the test and inform ODAPC in writing of the determination and the basis for it (*e.g.,* referral physician's findings, evidence produced by the employee).

(6) As the MRO, if you determine that there is not a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution.

(h) The following are examples of types of evidence an employee could present to support an assertion of a legitimate medical explanation for a substituted result:

(1) Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of § 40.209(b).

(i) To be regarded as medically valid, the evidence must have been gathered using appropriate methodology and controls to ensure its accuracy and reliability.

(ii) Assertion by the employee that his or her personal characteristics (*e.g.,* with respect to race, gender, weight, diet, working conditions) are responsible for the substituted result does not, in itself, constitute a legitimate medical explanation. To make a case that there is a legitimate medical explanation, the employee must present evidence showing that the cited personal characteristics actually result in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.209 (b).

(2) Information from a medical evaluation under paragraph (g) of this section that the individual has a medical condition that has been demonstrated to cause the employee to physiologically produce urine meeting the creatinine and specific gravity criteria of § 40.209(b).

(i) A finding or diagnosis by the physician that an employee has a medical condition, in itself, does not constitute a legitimate medical explanation.

(ii) To establish there is a legitimate medical explanation, the employee must demonstrate that the cited medical condition actually results in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.209(b).

§ 40.217 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen using the same criteria that were used for the primary specimen or HHS guidance, as applicable. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.219 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing the split specimen, you must test the split specimen using the criteria of § 40.209(b), just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.221 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, and you are using the Federal Testing Custody and Control Form (CCF) issued by HHS on June 23, 2000, you must report split specimen test results in adulteration and substitution situations by checking the ''Reconfirmed'' box or the ''Failed to Reconfirm'' box (Step 5(b)) on Copy 1 of the CCF.

(b) If you check the ''Failed to Reconfirm'' box, one of the following statements must be included (as appropriate) on the ''Reason'' line (Step 5(b)):

(1) Drug(s)/metabolite(s) not detected.''

(2) ''Adulterant not found within criteria.''

(3) ''Specimen not consistent with substitution criteria [specify creatinine, specific gravity, or both]''

(4) ''Specimen not available for testing.''

(c) If you are using the CCF issued by HHS prior to June 23, 2000, enter the information referenced in paragraph (b) (2), (3), or (4) of this section on the ''remarks'' line.

(d) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

§ 40.223 What does the MRO do with split specimen laboratory results?

As an MRO, you must take the following actions when a laboratory reports the following results of split specimen tests concerning adulterated or substituted specimens:

(a) *Reconfirmed.* (1) In the case of a reconfirmed positive test for a drug or drug metabolite, report the reconfirmation to the DER and the employee.

(2) In the case of a reconfirmed adulterated or substituted result, report to the DER and the employee that the specimen was adulterated or substituted, either of which constitutes a refusal to test. Therefore, ''refusal to test'' is the final result.

(b) *Failed to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Inform ODAPC of the failure to reconfirm.

(c) *Failed to Reconfirm: Adulterated or Substituted (as appropriate); Criteria Not Met.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Inform ODAPC of the failure to reconfirm.

(d) *Failed to Reconfirm: Specimen not Available for Testing.* (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) Inform ODAPC of the failure to reconfirm.

(e) Enter your name, sign and date the appropriate copy of the CCF.

(f) Send a legible copy of the appropriate copy of the CCF (or a signed and dated letter) to the employer and keep a copy for your records.

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

(a) [Reserved]

(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) [Reserved]

(e) [Reserved]

Subpart F—Public Interest Exclusions

§§ 40.301–40.359 [Reserved]

§ 40.361 What is the purpose of a public interest exclusion (PIE)?

(a) To protect the public interest, including protecting transportation employers and employees from serious noncompliance with DOT drug and alcohol testing rules, the Department's policy is to ensure that employers conduct business only with responsible service agents.

(b) The Department therefore uses PIEs to exclude from participation in DOT's drug and alcohol testing program any service agent who, by serious noncompliance with this part or other DOT agency drug and alcohol testing regulations, has shown that it is not currently acting in a responsible manner.

(c) A PIE is a serious action that the Department takes only to protect the public interest. We intend to use PIEs only to remedy situations of serious noncompliance. PIEs are not used for the purpose of punishment.

(d) Nothing in this subpart precludes a DOT agency or the Inspector General from taking other action authorized by its regulations with respect to service agents or employers that violate its regulations.

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

(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.

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

(a) It is the Department's policy to start a PIE proceeding only in cases of serious, uncorrected noncompliance with the provisions of this part, affecting such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives.

(b) The following are examples of the kinds of serious noncompliance that, as a matter of policy, the Department views as appropriate grounds for starting a PIE proceeding. These examples are not intended to be an exhaustive or exclusive list of the grounds for starting a PIE proceeding. We intend them to illustrate the level of seriousness that the Department believes supports starting a PIE proceeding. The examples follow:

(1) For an MRO, verifying tests positive without interviewing the

employees as required by this part or providing MRO services without meeting the qualifications for an MRO required by this part;

(2) For a laboratory, refusing to provide information to the Department, an employer, or an employee as required by this part; or a pattern or practice of testing errors that result in the cancellation of tests. (As a general matter of policy, the Department does not intend to initiate a PIE proceeding concerning a laboratory with respect to matters on which HHS initiates certification actions under its laboratory guidelines.);

(3) For a collector, a pattern or practice of directly observing collections when doing so is unauthorized, or failing or refusing to directly observe collections when doing so is mandatory;

(4) For collectors, BATs, or STTs, a pattern or practice of using forms, testing equipment, or collection kits that do not meet the standards in this part;

(5) For a collector, BAT, or STT, a pattern or practice of ''fatal flaws'' or other significant uncorrected errors in the collection process;

(6) For a laboratory, MRO or C/TPA, failing or refusing to report tests results as required by this part or DOT agency regulations;

(7) For a laboratory, falsifying, concealing, or destroying documentation concerning any part of the drug testing process, including, but not limited to, documents in a ''litigation package'';

(8) For SAPs, providing SAP services while not meeting SAP qualifications required by this part or performing evaluations without face-to-face interviews;

(9) For any service agent, maintaining a relationship with another party that constitutes a conflict of interest under this part (*e.g.,* a laboratory that derives a financial benefit from having an employer use a specific MRO);

(10) For any service agent, representing falsely that the service agent or its activities is approved or certified by the Department or a DOT agency;

(11) For any service agent, disclosing an employee's test result information to any party this part or a DOT agency regulation does not authorize, including by obtaining a ''blanket'' consent from employees or by creating a data base from which employers or others can retrieve an employee's DOT test results without the specific consent of the employee;

(12) For any service agent, interfering or attempting to interfere with the ability of an MRO to communicate with the Department, or retaliating against an MRO for communicating with the Department;

(13) For any service agent, directing or recommending that an employer fail or refuse to implement any provision of this part; or

(14) With respect to noncompliance with a DOT agency regulation, conduct that affects important provisions of Department-wide concern (*e.g.,* failure to properly conduct the selection process for random testing).

§ 40.367 Who initiates a PIE proceeding?

The following DOT officials may initiate a PIE proceeding:

(a) The drug and alcohol program manager of a DOT agency;

(b) An official of ODAPC, other than the Director; or

(c) The designee of any of these officials.

§ 40.369 What is the discretion of an initiating official in starting a PIE proceeding?

(a) Initiating officials have broad discretion in deciding whether to start a PIE proceeding.

(b) In exercising this discretion, the initiating official must consider the Department's policy regarding the seriousness of the service agent's conduct (see § 40.365) and all information he or she has obtained to this point concerning the facts of the case. The initiating official may also consider the availability of the resources needed to pursue a PIE proceeding.

(c) A decision not to initiate a PIE proceeding does not necessarily mean that the Department regards a service agent as being in compliance or that the Department may not use other applicable remedies in a situation of noncompliance.

§ 40.371 On what information does an initiating official rely in deciding whether to start a PIE proceeding?

(a) An initiating official may rely on credible information from any source as the basis for starting a PIE proceeding.

(b) Before sending a correction notice (see § 40.373), the initiating official informally contacts the service agent to determine if there is any information that may affect the initiating official's determination about whether it is necessary to send a correction notice. The initiating official may take any information resulting from this contact into account in determining whether to proceed under this subpart.

§ 40.373 Before starting a PIE proceeding, does the initiating official give the service agent an opportunity to correct problems?

(a) If you are a service agent, the initiating official must send you a correction notice before starting a PIE proceeding.

(b) The correction notice identifies the specific areas in which you must come into compliance in order to avoid being subject to a PIE proceeding.

(c) If you make and document changes needed to come into compliance in the areas listed in the correction notice to the satisfaction of the initiating official within 60 days of the date you receive the notice, the initiating official does not start a PIE proceeding. The initiating official may conduct appropriate fact finding to verify that you have made and maintained satisfactory corrections. When he or she is satisfied that you are in compliance, the initiating official sends you a notice that the matter is concluded.

§ 40.375 How does the initiating official start a PIE proceeding?

(a) As a service agent, if your compliance matter is not correctable (see § 40.373(a)), or if have not resolved compliance matters as provided in § 40.373(c), the initiating official starts a PIE proceeding by sending you a notice of proposed exclusion (NOPE). The NOPE contains the initiating official's recommendations concerning the issuance of a PIE, but it is not a decision by the Department to issue a PIE.

(b) The NOPE includes the following information:

(1) A statement that the initiating official is recommending that the Department issue a PIE concerning you;

(2) The factual basis for the initiating official's belief that you are not providing drug and/or alcohol testing services to DOT-regulated employers consistent with the requirements of this part or are in serious noncompliance with a DOT agency drug and alcohol regulation;

(3) The factual basis for the initiating official's belief that your noncompliance has not been or cannot be corrected;

(4) The initiating official's recommendation for the scope of the PIE;

(5) The initiating official's recommendation for the duration of the PIE; and

(6) A statement that you may contest the issuance of the proposed PIE, as provided in § 40.379.

(c) The initiating official sends a copy of the NOPE to the ODAPC Director at the same time he or she sends the NOPE to you.

§ 40.377 Who decides whether to issue a PIE?

(a) The ODAPC Director, or his or her designee, decides whether to issue a PIE. If a designee is acting as the

decisionmaker, all references in this subpart to the Director refer to the designee.

(b) To ensure his or her impartiality, the Director plays no role in the initiating official's determination about whether to start a PIE proceeding.

(c) There is a ''firewall'' between the initiating official and the Director. This means that the initiating official and the Director are prohibited from having any discussion, contact, or exchange of information with one another about the matter, except for documents and discussions that are part of the record of the proceeding.

§ 40.379 How do you contest the issuance of a PIE?

(a) If you receive a NOPE, you may contest the issuance of the PIE.

(b) If you want to contest the proposed PIE, you must provide the Director information and argument in opposition to the proposed PIE in writing, in person, and/or through a representative. To contest the proposed PIE, you must take one or more of the steps listed in this paragraph (b) within 30 days after you receive the NOPE.

(1) You may request that the Director dismiss the proposed PIE without further proceedings, on the basis that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in § 40.365.

(2) You may present written information and arguments, consistent with the provisions of § 40.381, contesting the proposed PIE.

(3) You may arrange with the Director for an informal meeting to present your information and arguments.

(c) If you do not take any of the actions listed in paragraph (b) of this section within 30 days after you receive the NOPE, the matter proceeds as an uncontested case. In this event, the Director makes his or her decision based on the record provided by the initiating official (*i.e.,* the NOPE and any supporting information or testimony) and any additional information the Director obtains.

§ 40.381 What information do you present to contest the proposed issuance of a PIE?

(a) As a service agent who wants to contest a proposed PIE, you must present at least the following information to the Director:

(1) Specific facts that contradict the statements contained in the NOPE (see § 40.375(b)(2) and (3)). A general denial is insufficient to raise a genuine dispute over facts material to the issuance of a PIE;

(2) Identification of any existing, proposed or prior PIE; and

(3) Identification of your affiliates, if any.

(b) You may provide any information and arguments you wish concerning the proposed issuance, scope and duration of the PIE (see § 40.375(b)(4) and (5).

(c) You may provide any additional relevant information or arguments concerning any of the issues in the matter.

§ 40.383 What procedures apply if you contest the issuance of a PIE?

(a) DOT conducts PIE proceedings in a fair and informal manner. The Director may use flexible procedures to allow you to present matters in opposition. The Director is not required to follow formal rules of evidence or procedure in creating the record of the proceeding.

(b) The Director will consider any information or argument he or she determines to be relevant to the decision on the matter.

(c) You may submit any documentary evidence you want the Director to consider. In addition, if you have arranged an informal meeting with the Director, you may present witnesses and confront any person the initiating official presents as a witness against you.

(d) In cases where there are material factual issues in dispute, the Director or his or her designee may conduct additional fact-finding.

(e) If you have arranged a meeting with the Director, the Director will make a transcribed record of the meeting available to you on your request. You must pay the cost of transcribing and copying the meeting record.

§ 40.385 Who bears the burden of proof in a PIE proceeding?

(a) As the proponent of issuing a PIE, the initiating official bears the burden of proof.

(b) This burden is to demonstrate, by a preponderance of the evidence, that the service agent was in serious noncompliance with the requirements of this part for drug and/or alcohol testing-related services or with the requirements of another DOT agency drug and alcohol testing regulation.

§ 40.387 What matters does the Director decide concerning a proposed PIE?

(a) Following the service agent's response (see § 40.379(b)) or, if no response is received, after 30 days have passed from the date on which the service agent received the NOPE, the Director may take one of the following steps:

(1) In response to a request from the service agent (see § 40.379(b)(1)) or on his or her own motion, the Director may dismiss a PIE proceeding if he or she determines that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in § 40.365.

(i) If the Director dismisses a proposed PIE under this paragraph (a), the action is closed with respect to the noncompliance alleged in the NOPE.

(ii) The Department may initiate a new PIE proceeding against you on the basis of different or subsequent conduct that is in noncompliance with this part or other DOT drug and alcohol testing rules.

(2) If the Director determines that the initiating official's submission does not have complete information needed for a decision, the Director may remand the matter to the initiating official. The initiating official may resubmit the matter to the Director when the needed information is complete. If the basis for the proposed PIE has changed, the initiating official must send an amended NOPE to the service agent.

(b) The Director makes determinations concerning the following matters in any PIE proceeding that he or she decides on the merits:

(1) Any material facts that are in dispute;

(2) Whether the facts support issuing a PIE;

(3) The scope of any PIE that is issued; and

(4) The duration of any PIE that is issued.

§ 40.389 What factors may the Director consider?

This section lists examples of the kind of mitigating and aggravating factors that the Director may consider in determining whether to issue a PIE concerning you, as well as the scope and duration of a PIE. This list is not exhaustive or exclusive. The Director may consider other factors if appropriate in the circumstances of a particular case. The list of examples follows:

(a) The actual or potential harm that results or may result from your noncompliance;

(b) The frequency of incidents and/or duration of the noncompliance;

(c) Whether there is a pattern or prior history of noncompliance;

(d) Whether the noncompliance was pervasive within your organization, including such factors as the following:

(1) Whether and to what extent your organization planned, initiated, or carried out the noncompliance;

(2) The positions held by individuals involved in the noncompliance, and

whether your principals tolerated their noncompliance; and

(3) Whether you had effective standards of conduct and control systems (both with respect to your own organization and any contractors or affiliates) at the time the noncompliance occurred;

(e) Whether you have demonstrated an appropriate compliance disposition, including such factors as the following:

(1) Whether you have accepted responsibility for the noncompliance and recognize the seriousness of the conduct that led to the cause for issuance of the PIE;

(2) Whether you have cooperated fully with the Department during the investigation. The Director may consider when the cooperation began and whether you disclosed all pertinent information known to you;

(3) Whether you have fully investigated the circumstances of the noncompliance forming the basis for the PIE and, if so, have made the result of the investigation available to the Director;

(4) Whether you have taken appropriate disciplinary action against the individuals responsible for the activity that constitutes the grounds for issuance of the PIE; and

(5) Whether your organization has taken appropriate corrective actions or remedial measures, including implementing actions to prevent recurrence;

(f) With respect to noncompliance with a DOT agency regulation, the degree to which the noncompliance affects matters common to the DOT drug and alcohol testing program;

(g) Other factors appropriate to the circumstances of the case.

§ 40.391 What is the scope of a PIE?

(a) The scope of a PIE is the Department's determination about the divisions, organizational elements, types of services, affiliates, and/or individuals (including direct employees of a service agent and its contractors) to which a PIE applies.

(b) If, as a service agent, the Department issues a PIE concerning you, the PIE applies to all your divisions, organizational elements, and types of services that are involved with or affected by the noncompliance that forms the factual basis for issuing the PIE.

(c) In the NOPE (see § 40.375(b)(4)), the initiating official sets forth his or her recommendation for the scope of the PIE. The proposed scope of the PIE is one of the elements of the proceeding that the service agent may contest (see § 40.381(b)) and about which the Director makes a decision (see § 40.387(b)(3)).

(d) In recommending and deciding the scope of the PIE, the initiating official and Director, respectively, must take into account the provisions of paragraphs (e) through (j) of this section.

(e) The pervasiveness of the noncompliance within a service agent's organization (see § 40.389(d)) is an important consideration in determining the scope of a PIE. The appropriate scope of a PIE grows broader as the pervasiveness of the noncompliance increases.

(f) The application of a PIE is not limited to the specific location or employer at which the conduct that forms the factual basis for issuing the PIE was discovered.

(g) A PIE applies to your affiliates, if the affiliate is involved with or affected by the conduct that forms the factual basis for issuing the PIE.

(h) A PIE applies to individuals who are officers, employees, directors, shareholders, partners, or other individuals associated with your organization in the following circumstances:

(1) Conduct forming any part of the factual basis of the PIE occurred in connection with the individual's performance of duties by or on behalf of your organization; or

(2) The individual knew of, had reason to know of, approved, or acquiesced in such conduct. The individual's acceptance of benefits derived from such conduct is evidence of such knowledge, acquiescence, or approval.

(i) If a contractor to your organization is solely responsible for the conduct that forms the factual basis for a PIE, the PIE does not apply to the service agent itself unless the service agent knew or should have known about the conduct and did not take action to correct it.

(j) PIEs do not apply to drug and alcohol testing that DOT does not regulate.

(k) The following examples illustrate how the Department intends the provisions of this section to work:

Example 1 to § 40.391. Service Agent P provides a variety of drug testing services. P's SAP services are involved in a serious violation of this Part 40. However, P's other services fully comply with this part, and P's overall management did not plan or concur in the noncompliance, which in fact was contrary to P's articulated standards. Because the noncompliance was isolated in one area of the organization's activities, and did not pervade the entire organization, the scope of the PIE could be limited to SAP services.

Example 2 to § 40.391. Service Agent Q provides a similar variety of services. The conduct forming the factual basis for a PIE concerns collections for a transit authority. As in Example 1, the noncompliance is not pervasive throughout Q's organization. The PIE would apply to collections at all locations served by Q, not just the particular transit authority or not just in the state in which the transit authority is located.

Example 3 to § 40.391. Service Agent R provides a similar array of services. One or more of the following problems exists: R's activities in several areas—collections, MROs, SAPs, protecting the confidentiality of information—are involved in serious noncompliance; DOT determines that R's management knew or should have known about serious noncompliance in one or more areas, but management did not take timely corrective action; or, in response to an inquiry from DOT personnel, R's management refuses to provide information about its operations. In each of these three cases, the scope of the PIE would include all aspects of R's services.

Example 4 to § 40.391. Service Agent W provides only one kind of service (*e.g.,* laboratory or MRO services). The Department issues a PIE concerning these services. Because W only provides this one kind of service, the PIE necessarily applies to all its operations.

Example 5 to § 40.391. Service Agent X, by exercising reasonably prudent oversight of its collection contractor, should have known that the contractor was making numerous ''fatal flaws'' in tests. Alternatively, X received a correction notice pointing out these problems in its contractor's collections. In neither case did X take action to correct the problem. X, as well as the contractor, would be subject to a PIE with respect to collections.

Example 6 to § 40.391. Service Agent Y could not reasonably have known that one of its MROs was regularly failing to interview employees before verifying tests positive. When it received a correction notice, Y immediately dismissed the erring MRO. In this case, the MRO would be subject to a PIE but Y would not.

Example 7 to § 40.391. The Department issues a PIE with respect to Service Agent Z. Z provides services for DOT-regulated transportation employers, a Federal agency under the HHS-regulated Federal employee testing program, and various private businesses and public agencies that DOT does not regulate. The PIE applies only to the DOT-regulated transportation employers with respect to their DOT-mandated testing, not to the Federal agency or the other public agencies and private businesses. The PIE does not prevent the non-DOT regulated entities from continuing to use Z's services.

§ 40.393 How long does a PIE stay in effect?

(a) In the NOPE (see § 40.375(b)(5)), the initiating official proposes the duration of the PIE. The duration of the PIE is one of the elements of the proceeding that the service agent may contest (see § 40.381(b)) and about which the Director makes a decision (see § 40.387(b)(4)).

(b) In deciding upon the duration of the PIE, the Director considers the

seriousness of the conduct on which the PIE is based and the continued need to protect employers and employees from the service agent's noncompliance. The Director considers factors such as those listed in § 40.389 in making this decision.

(c) The duration of a PIE will be between one and five years, unless the Director reduces its duration under § 40.407.

§ 40.395 Can you settle a PIE proceeding?

At any time before the Director's decision, you and the initiating official can, with the Director's concurrence, settle a PIE proceeding.

§ 40.397 When does the Director make a PIE decision?

The Director makes his or her decision within 60 days of the date when the record of a PIE proceeding is complete (including any meeting with the Director and any additional fact-finding that is necessary). The Director may extend this period for good cause for additional periods of up to 30 days.

§ 40.399 How does the Department notify service agents of its decision?

If you are a service agent involved in a PIE proceeding, the Director provides you written notice as soon as he or she makes a PIE decision. The notice includes the following elements:

(a) If the decision is not to issue a PIE, a statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute.

(b) If the decision is to issue a PIE—

(1) A reference to the NOPE;

(2) A statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute;

(3) A statement of the scope of the PIE; and

(4) A statement of the duration of the PIE.

§ 40.401 How does the Department notify employers and the public about a PIE?

(a) The Department maintains a document called the ''List of Excluded Drug and Alcohol Service Agents.'' This document may be found on the Department's web site (http://www.dot.gov/ost/dapc). You may also request a copy of the document from ODAPC.

(b) When the Director issues a PIE, he or she adds to the List the name and address of the service agent, and any other persons or organizations, to whom the PIE applies and information about the scope and duration of the PIE.

(c) When a service agent ceases to be subject to a PIE, the Director removes this information from the List.

(d) The Department also publishes a **Federal Register** notice to inform the public on any occasion on which a service agent is added to or taken off the List.

§ 40.403 Must a service agent notify its clients when the Department issues a PIE?

(a) As a service agent, if the Department issues a PIE concerning you, you must notify each of your DOT-regulated employer clients, in writing, about the issuance, scope, duration, and effect of the PIE. You may meet this requirement by sending a copy of the Director's PIE decision or by a separate notice. You must send this notice to each client within three working days of receiving from the Department the notice provided for in § 40.399(b).

(b) As part of the notice you send under paragraph (a) of this section, you must offer to transfer immediately all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it.

§ 40.405 May the Federal courts review PIE decisions?

The Director's decision is a final administrative action of the Department. Like all final administrative actions of Federal agencies, the Director's decision is subject to judicial review under the Administrative Procedure Act (5 U.S.C. 551 *et seq.*).

§ 40.407 May a service agent ask to have a PIE reduced or terminated?

(a) Yes, as a service agent concerning whom the Department has issued a PIE, you may request that the Director terminate a PIE or reduce its duration and/or scope. This process is limited to the issues of duration and scope. It is not an appeal or reconsideration of the decision to issue the PIE.

(b) Your request must be in writing and supported with documentation.

(c) You must wait at least nine months from the date on which the Director issued the PIE to make this request.

(d) The initiating official who was the proponent of the PIE may provide information and arguments concerning your request to the Director.

(e) If the Director verifies that the sources of your noncompliance have been eliminated and that all drug or alcohol testing-related services you would provide to DOT-regulated employers will be consistent with the requirements of this part, the Director may issue a notice terminating or reducing the PIE.

§ 40.409 What does the issuance of a PIE mean to transportation employers?

(a) As an employer, you are deemed to have notice of the issuance of a PIE when it appears on the List mentioned in § 40.401(a) or the notice of the PIE appears in the **Federal Register** as provided in § 40.401(d). You should check this List to ensure that any service agents you are using or planning to use are not subject to a PIE.

(b) As an employer who is using a service agent concerning whom a PIE is issued, you must stop using the services of the service agent no later than 90 days after the Department has published the decision in the **Federal Register** or posted it on its web site. You may apply to the ODAPC Director for an extension of 30 days if you demonstrate that you cannot find a substitute service agent within 90 days.

(c) Except during the period provided in paragraph (b) of this section, you must not, as an employer, use the services of a service agent that are covered by a PIE that the Director has issued under this subpart. If you do so, you are in violation of the Department's regulations and subject to applicable DOT agency sanctions (*e.g.,* civil penalties, withholding of Federal financial assistance).

(d) You also must not obtain drug or alcohol testing services through a contractor or affiliate of the service agent to whom the PIE applies.

Example to Paragraph (d). Service Agent R was subject to a PIE with respect to SAP services. As an employer, not only must you not use R's own SAP services, but you also must not use SAP services you arrange through R, such as services provided by a subcontractor or affiliate of R or a person or organization that receives financial gain from its relationship with R.

(e) This section's prohibition on using the services of a service agent concerning which the Director has issued a PIE applies to employers in all industries subject to DOT drug and alcohol testing regulations.

Example to Paragraph (e). The initiating official for a PIE was the FAA drug and alcohol program manager, and the conduct forming the basis of the PIE pertained to the aviation industry. As a motor carrier, transit authority, pipeline, railroad, or maritime employer, you are also prohibited from using the services of the service agent involved in connection with the DOT drug and alcohol testing program.

(f) The issuance of a PIE does not result in the cancellation of drug or alcohol tests conducted using the service agent involved before the

issuance of the Director's decision or up to 90 days following its publication in the **Federal Register** or posting on the Department's web site, unless otherwise specified in the Director's PIE decision or the Director grants an extension as provided in paragraph (b) of this section.

Example to Paragraph (f). The Department issues a PIE concerning Service Agent N on September 1. All tests conducted using N's services before September 1, and through November 30, are valid for all purposes under DOT drug and alcohol testing regulations, assuming they meet all other regulatory requirements.

§ 40.411 What is the role of the DOT Inspector General's office?

(a) Any person may bring concerns about waste, fraud, or abuse on the part of a service agent to the attention of the DOT Office of Inspector General.

(b) In appropriate cases, the Office of Inspector General may pursue criminal or civil remedies against a service agent.

(c) The Office of Inspector General may provide factual information to other DOT officials for use in a PIE proceeding.

§ 40.413 How are notices sent to service agents?

(a) If you are a service agent, DOT sends notices to you, including correction notices, notices of proposed exclusion, decision notices, and other notices, in any of the ways mentioned in paragraph (b) or (c) of this section.

(b) DOT may send a notice to you, your identified counsel, your agent for service of process, or any of your partners, officers, directors, owners, or joint venturers to the last known street address, fax number, or e-mail address. DOT deems the notice to have been received by you if sent to any of these persons.

(c) DOT considers notices to be received by you—

(1) When delivered, if DOT mails the notice to the last known street address, or five days after we send it if the letter is undeliverable;

(2) When sent, if DOT sends the notice by fax or five days after we send it if the fax is undeliverable; or

(3) When delivered, if DOT sends the notice by e-mail or five days after DOT sends it if the e-mail is undeliverable.

2. Effective August 1, 2001, revise 49 CFR Part 40 to read as follows:

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

Subpart A—Administrative Provisions

Sec.

Subpart B—Employer Responsibilities

Subpart C—Urine Collection Personnel

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

Subpart E—Urine Specimen Collections

Subpart F—Drug Testing Laboratories

Subpart G—Medical Review Officers and the Verification Process

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

Subpart A—Administrative Provisions

§ 40.1 Who does this regulation cover?

(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).

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

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

Adulterated specimen. A specimen that contains a substance that is not expected to be present in human urine, or contains a substance expected to be present but is at a concentration so high that it is not consistent with human urine.

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.

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.

Confirmation (or confirmatory) drug test. A second analytical procedure performed on a urine specimen to identify and quantify the presence of a specific drug or drug metabolite.

Confirmation (or confirmatory) validity test. A second test performed on a 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 medical review officers (MROs) and substance abuse professionals (SAPs) who have completed qualification training and are performing MRO or SAP functions, designed to keep MROs and 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 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 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 Research and Special Programs Administration (RSPA), 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. The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

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

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. (The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs are available on the internet at *http://www.health.org/workpl.htm* or from the Division of Workplace Programs, 5600 Fishers Lane, Rockwall II Building, Suite 815, Rockville, MD 20857.)

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.

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.

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).

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).

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.

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 specimen with creatinine and specific gravity values that are so diminished that they are not consistent with 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.

§ 40.5 Who issues authoritative interpretations of this regulation?

ODAPC and the DOT Office of General Counsel (OGC) provide written interpretations of the provisions of this part. These written DOT interpretations are the only official and authoritative interpretations concerning the provisions of this part. DOT agencies may incorporate ODAPC/OGC interpretations in written guidance they issue concerning drug and alcohol testing matters. Only Part 40 interpretations issued after August 1, 2001, are considered valid.

§ 40.7 How can you get an exemption from a requirement in this regulation?

(a) If you want an exemption from any provision of this part, you must request it in writing from the Office of the Secretary of Transportation, under the provisions and standards of 49 CFR part 5. You must send requests for an exemption to the following address: Department of Transportation, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, Washington, DC 20590.

(b) Under the standards of 49 CFR part 5, we will grant the request only if the request documents special or exceptional circumstances, not likely to be generally applicable and not contemplated in connection with the rulemaking that established this part, that make your compliance with a specific provision of this part impracticable.

(c) If we grant you an exemption, you must agree to take steps we specify to comply with the intent of the provision from which an exemption is granted.

(d) We will issue written responses to all exemption requests.

Subpart B—Employer Responsibilities

§ 40.11 What are the general responsibilities of employers under this regulation?

(a) As an employer, you are responsible for meeting all applicable requirements and procedures of this part.

(b) You are responsible for all actions of your officials, representatives, and agents (including service agents) in carrying out the requirements of the DOT agency regulations.

(c) All agreements and arrangements, written or unwritten, between and among employers and service agents concerning the implementation of DOT drug and alcohol testing requirements are deemed, as a matter of law, to require compliance with all applicable provisions of this part and DOT agency drug and alcohol testing regulations. Compliance with these provisions is a material term of all such agreements and arrangements.

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

(a) DOT tests must be completely separate from non-DOT tests in all respects.

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

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

(d) The single exception to paragraph (c) of this section is when a DOT drug test collection is conducted as part of a physical examination required by DOT agency regulations. It is permissible to conduct required medical tests related to this physical examination (*e.g.,* for glucose) on any urine remaining in the collection container after the drug test urine specimens have been sealed into the specimen bottles.

(e) No one is permitted to change or disregard the results of DOT tests based on the results of non-DOT tests. For example, as an employer you must not disregard a verified positive DOT drug test result because the employee presents a negative test result from a blood or urine specimen collected by the employee's physician or a DNA test result purporting to question the identity of the DOT specimen.

(f) As an employer, you must not use the CCF or the ATF in your non-DOT drug and alcohol testing programs. This prohibition includes the use of the DOT forms with references to DOT programs and agencies crossed out. You also must always use the CCF and ATF for all your DOT-mandated drug and alcohol tests.

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

(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.

§ 40.17 Is an employer responsible for obtaining information from its service agents?

Yes, as an employer, you are responsible for obtaining information required by this part from your service agents. This is true whether or not you choose to use a C/TPA as an intermediary in transmitting information to you. For example, suppose an applicant for a safety-sensitive job takes a pre-employment drug test, but there is a significant delay in your receipt of the test result from an MRO or C/TPA. You must not assume that ''no news is good news'' and permit the applicant to perform safety-sensitive duties before receiving the result. This is a violation of the Department's regulations.

§ 40.19 [Reserved]

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

(a) As an employer, you are prohibited from standing employees down, except consistent with a waiver a DOT agency grants under this section.

(b) You may make a request to the concerned DOT agency for a waiver from the prohibition of paragraph (a) of this section. Such a waiver, if granted, permits you to stand an employee down following the MRO's receipt of a laboratory report of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test pertaining to the employee.

(1) For this purpose, the concerned DOT agency is the one whose drug and alcohol testing rules apply to the majority of the covered employees in your organization. The concerned DOT agency uses its applicable procedures for considering requests for waivers.

(2) Before taking action on a waiver request, the concerned DOT agency coordinates with other DOT agencies that regulate the employer's other covered employees.

(3) The concerned DOT agency provides a written response to each employer that petitions for a waiver, setting forth the reasons for the agency's decision on the waiver request.

(c) Your request for a waiver must include, as a minimum, the following elements:

(1) Information about your organization:

(i) Your determination that standing employees down is necessary for safety in your organization and a statement of your basis for it, including any data on safety problems or incidents that could have been prevented if a stand-down procedure had been in place;

(ii) Data showing the number of confirmed laboratory positive, adulterated, and substituted test results for your employees over the two calendar years preceding your waiver request, and the number and percentage of those test results that were verified positive, adulterated, or substituted by the MRO;

(iii) Information about the work situation of the employees subject to stand-down, including a description of the size and organization of the unit(s) in which the employees work, the process through which employees will be informed of the stand-down, whether there is an in-house MRO, and whether your organization has a medical disqualification or stand-down policy for employees in situations other than drug and alcohol testing; and

(iv) A statement of which DOT agencies regulate your employees.

(2) Your proposed written company policy concerning stand-down, which must include the following elements:

(i) Your assurance that you will distribute copies of your written policy to all employees that it covers;

(ii) Your means of ensuring that no information about the confirmed positive, adulterated, or substituted test result or the reason for the employee's temporary removal from performance of safety-sensitive functions becomes available, directly or indirectly, to anyone in your organization (or subsequently to another employer) other than the employee, the MRO and the DER;

(iii) Your means of ensuring that all covered employees in a particular job category in your organization are treated the same way with respect to stand-down;

(iv) Your means of ensuring that a covered employee will be subject to stand-down only with respect to the actual performance of safety-sensitive duties;

(v) Your means of ensuring that you will not take any action adversely affecting the employee's pay and benefits pending the completion of the MRO's verification process. This includes continuing to pay the employee during the period of the stand-down in the same way you would have paid him or her had he or she not been stood down;

(vi) Your means of ensuring that the verification process will commence no later than the time an employee is temporarily removed from the performance of safety-sensitive functions and that the period of stand-down for any employee will not exceed five days, unless you are informed in writing by the MRO that a longer period is needed to complete the verification process; and

(vii) Your means of ensuring that, in the event that the MRO verifies the test negative or cancels it—

(A) You return the employee immediately to the performance of safety-sensitive duties;

(B) The employee suffers no adverse personnel or financial consequences as a result; and

(C) You maintain no individually identifiable record that the employee had a confirmed laboratory positive, adulterated, or substituted test result (*i.e.,* you maintain a record of the test only as a negative or cancelled test).

(d) The Administrator of the concerned DOT agency, or his or her designee, may grant a waiver request only if he or she determines that, in the context of your organization, there is a high probability that the procedures you propose will effectively enhance safety and protect the interests of employees in fairness and confidentiality.

(1) The Administrator, or his or her designee, may impose any conditions he or she deems appropriate on the grant of a waiver.

(2) The Administrator, or his or her designee, may immediately suspend or revoke the waiver if he or she determines that you have failed to protect effectively the interests of employees in fairness and confidentiality, that you have failed to comply with the requirements of this section, or that you have failed to comply with any other conditions the DOT agency has attached to the waiver.

(e) You must not stand employees down in the absence of a waiver, or inconsistent with the terms of your waiver. If you do, you are in violation

of this part and DOT agency drug testing regulations, and you are subject to enforcement action by the DOT agency just as you are for other violations of this part and DOT agency rules.

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

(a) As an employer who receives a verified positive drug test result, you must immediately remove the employee involved from performing safety-sensitive functions. You must take this action upon receiving the initial report of the verified positive test result. Do not wait to receive the written report or the result of a split specimen test.

(b) As an employer who receives a verified adulterated or substituted drug test result, you must consider this a refusal to test and immediately remove the employee involved from performing safety-sensitive functions. You must take this action on receiving the initial report of the verified adulterated or substituted test result. Do not wait to receive the written report or the result of a split specimen test.

(c) As an employer who receives an alcohol test result of 0.04 or higher, you must immediately remove the employee involved from performing safety-sensitive functions. If you receive an alcohol test result of 0.02—0.39, you must temporarily remove the employee involved from performing safety-sensitive functions, as provided in applicable DOT agency regulations. Do not wait to receive the written report of the result of the test.

(d) As an employer, when an employee has a verified positive, adulterated, or substituted test result, or has otherwise violated a DOT agency drug and alcohol regulation, you must not return the employee to the performance of safety-sensitive functions until or unless the employee successfully completes the return-to-duty process of Subpart O of this part.

(e) As an employer who receives a drug test result indicating that the employee's specimen was dilute, take action as provided in § 40.197.

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

(1) You must immediately direct the employee to provide a new specimen under direct observation.

(2) You must not attach consequences to the finding that the test was invalid other than collecting a new specimen under direct observation.

(3) You must not give any advance notice of this test requirement to the employee.

(4) You must instruct the collector to note on the CCF the same reason (*e.g.* random test, post-accident test) as for the original collection.

(g) As an employer who receives a cancelled test result when a negative result is required (*e.g.*, pre-employment, return-to-duty, or follow-up test), you must direct the employee to provide another specimen immediately.

(h) As an employer, you may also be required to take additional actions required by DOT agency regulations (*e.g.*, FAA rules require some positive drug tests to be reported to the Federal Air Surgeon).

(i) As an employer, you must not alter a drug or alcohol test result transmitted to you by an MRO, BAT, or C/TPA.

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

(a) Yes, as an employer, you must, after obtaining an employee's written consent, request the information about the employee listed in paragraph (b) of this section. This requirement applies only to employees seeking to begin performing safety-sensitive duties for you for the first time (*i.e.*, a new hire, an employee transfers into a safety-sensitive position). If the employee refuses to provide this written consent, you must not permit the employee to perform safety-sensitive functions.

(b) You must request the information listed in this paragraph (b) from DOT-regulated employers who have employed the employee during any period during the two years before the date of the employee's application or transfer:

(1) Alcohol tests with a result of 0.04 or higher alcohol concentration;

(2) Verified positive drug tests;

(3) Refusals to be tested (including verified adulterated or substituted drug test results);

(4) Other violations of DOT agency drug and alcohol testing regulations; and

(5) With respect to any employee who violated a DOT drug and alcohol regulation, documentation of the employee's successful completion of DOT return-to-duty requirements (including follow-up tests). If the previous employer does not have information about the return-do-duty process (*e.g.*, an employer who did not hire an employee who tested positive on a pre-employment test), you must seek to obtain this information from the employee.

(c) The information obtained from a previous employer includes any drug or alcohol test information obtained from previous employers under this section or other applicable DOT agency regulations.

(d) If feasible, you must obtain and review this information before the employee first performs safety-sensitive functions. If this is not feasible, you must obtain and review the information as soon as possible. However, you must not permit the employee to perform safety-sensitive functions after 30 days from the date on which the employee first performed safety-sensitive functions, unless you have obtained or made and documented a good faith effort to obtain this information.

(e) If you obtain information that the employee has violated a DOT agency drug and alcohol regulation, you must not use the employee to perform safety-sensitive functions unless you also obtain information that the employee has subsequently complied with the return-to-duty requirements of Subpart O of this part and DOT agency drug and alcohol regulations.

(f) You must provide to each of the employers from whom you request information under paragraph (b) of this section written consent for the release of the information cited in paragraph (a) of this section.

(g) The release of information under this section must be in any written form (*e.g.*, fax, e-mail, letter) that ensures confidentiality. As the previous employer, you must maintain a written record of the information released, including the date, the party to whom it was released, and a summary of the information provided.

(h) If you are an employer from whom information is requested under paragraph (b) of this section, you must, after reviewing the employee's specific, written consent, immediately release the requested information to the employer making the inquiry.

(i) As the employer requesting the information required under this section, you must maintain a written, confidential record of the information you obtain or of the good faith efforts you made to obtain the information. You must retain this information for three years from the date of the employee's first performance of safety-sensitive duties for you.

(j) As the employer, you must also ask the employee whether he or she has tested positive, or refused to test, on any pre-employment drug or alcohol test administered by an employer to which the employee applied for, but did not obtain, safety-sensitive transportation work covered by DOT agency drug and alcohol testing rules during the past two years. If the employee admits that he or she had a positive test or a refusal to

test, you must not use the employee to perform safety-sensitive functions for you, until and unless the employee documents successful completion of the return-to-duty process (see paragraphs (b)(5) and (e) of this section).

§ 40.27 Where is other information on employer responsibilities found in this regulation?

You can find other information on the responsibilities of employers in the following sections of this part:

§ 40.3—Definition.
§ 40.35—Information about DERs that employers must provide collectors.
§ 40.45—Modifying CCFs, Use of foreign-language CCFs.
§ 40.47—Use of non-Federal forms for DOT tests or Federal CCFs for non-DOT tests.
§ 40.67—Requirements for direct observation.
§§ 40.103–40.105—Blind specimen requirements.
§ 40. 173—Responsibility to ensure test of split specimen.
§ 40.193—Action in ''shy bladder'' situations.
§ 40.197—Actions following report of a dilute specimen.
§ 40.207—Actions following a report of a cancelled drug test.
§ 40.209—Actions following and consequences of non-fatal flaws in drug tests.
§ 40.215—Information about DERs that employers must provide BATs and STTs.
§ 40.225—Modifying ATFs; use of foreign-language ATFs.
§ 40.227—Use of non-DOT forms for DOT tests or DOT ATFs for non-DOT tests.
§ 40.235 (c) and (d)—responsibility to follow instructions for ASDs.
§ 40.255 (b)—receipt and storage of alcohol test information.
§ 40.265 (c)–(e)—actions in ''shy lung'' situations.
§ 40.267—Cancellation of alcohol tests.
§ 40.271—Actions in ''correctable flaw'' situations in alcohol tests.
§ 40.273—Actions following cancelled tests in alcohol tests.
§ 40.275—Actions in ''non-fatal flaw'' situations in alcohol tests.
§§ 40.287–40.289—Responsibilities concerning SAP services.
§§ 40.295–40.297—Prohibition on seeking second SAP evaluation or changing SAP recommendation.
§ 40.303—Responsibilities concerning aftercare recommendations.
§ 40.305—Responsibilities concerning return-to-duty decision.
§ 40.309—Responsibilities concerning follow-up tests.
§ 40.321—General confidentiality requirement.
§ 40.323—Release of confidential information in litigation.
§ 40.331—Other circumstances for the release of confidential information.
§ 40.333—Record retention requirements.
§ 40.345—Choice of who reports drug testing information to employers.

Subpart C—Urine Collection Personnel

§ 40.31 Who may collect urine specimens for DOT drug testing?

(a) Collectors meeting the requirements of this subpart are the only persons authorized to collect urine specimens for DOT drug testing.

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

(c) As the immediate supervisor of an employee being tested, you may not act as the collector when that employee is tested, unless no other collector is available and you are permitted to do so under DOT agency drug and alcohol regulations.

(d) You must not act as the collector for the employee being tested if you work for a HHS-certified laboratory (*e.g.,* as a technician or accessioner) and could link the employee with a urine specimen, drug testing result, or laboratory report.

§ 40.33 What training requirements must a collector meet?

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, 400 7th Street, SW., 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 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 an individual 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.

(i) 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.

(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.

§ 40.35 What information about the DER must employers provide to collectors?

As an employer, you must provide to collectors the name and telephone number of the appropriate DER (and C/TPA, where applicable) to contact about any problems or issues that may arise during the testing process.

§ 40.37 Where is other information on the role of collectors found in this regulation?

You can find other information on the role and functions of collectors in the following sections of this part:

§ 40.3—Definition.
§ 40.43—Steps to prepare and secure collection sites.
§§ 40.45–40.47—Use of CCF.
§§ 40.49–40.51—Use of collection kit and shipping materials.
§§ 40.61–40.63—Preliminary steps in collections.
§ 40.65—Role in checking specimens.
§ 40.67—Role in directly observed collections.
§ 40.69—Role in monitored collections.
§ 40.71—Role in split specimen collections.
§ 40.73—Chain of custody completion and finishing the collection process.
§ 40.103—Processing blind specimens.
§ 40.191—Action in case of refusals to take test.
§ 40.193—Action in ''shy bladder'' situations.
§ 40.199–40.205—Collector errors in tests, effects, and means of correction.

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

§ 40.41 Where does a urine collection for a DOT drug test take place?

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

(b) If you are operating a collection site, you must ensure that it meets the security requirements of § 40.43.

(c) If you are operating a collection site, you must have all necessary personnel, materials, equipment, facilities and supervision to provide for the collection, temporary storage, and shipping of urine specimens to a laboratory, and a suitable clean surface for writing.

(d) Your collection site must include a facility for urination described in either paragraph (e) or paragraph (f) of this section.

(e) The first, and preferred, type of facility for urination that a collection site may include is a single-toilet room, having a full-length privacy door, within which urination can occur.

(1) No one but the employee may be present in the room during the collection, except for the observer in the event of a directly observed collection.

(2) You must have a source of water for washing hands, that, if practicable, should be external to the closed room where urination occurs. If an external source is not available, you may meet this requirement by securing all sources of water and other substances that could be used for adulteration and substitution (*e.g.,* water faucets, soap dispensers) and providing moist towelettes outside the closed room.

(f) The second type of facility for urination that a collection site may include is a multistall restroom.

(1) Such a site must provide substantial visual privacy (*e.g.,* a toilet stall with a partial-length door) and meet all other applicable requirements of this section.

(2) If you use a multi-stall restroom, you must either—

(i) 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

(ii) Conduct all collections in the facility as monitored collections (see § 40.69 for procedures). This is the only circumstance in which you may conduct a monitored collection.

(3) No one but the employee may be present in the multistall restroom during the collection, except for the monitor in the event of a monitored collection or the observer in the event of a directly observed collection.

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

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

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

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

(1) 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 is blue;

(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) Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;

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

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

(8) Recheck items in paragraphs (b)(1) through (7) of this section following each collection to ensure the site's continued integrity.

(c) If the collection site uses a facility normally used for other purposes, like a public rest room or hospital examining room, you must, as a collector, 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.

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

(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only one employee at a time. However, during the time one employee is in the period for drinking fluids in a ''shy bladder''

situation (see § 40.193(b)), you may conduct a collection for another employee.

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

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

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

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

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

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

(2) Except for the observer in a directly observed collection or the monitor in the case of a monitored collection, you must not permit anyone to enter the urination facility in which employees provide specimens.

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

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

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

§ 40.45 What form is used to document a DOT urine collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) 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. You may view this form on the Department's web site (http://www.dot.gov/ost/dapc) or the HHS web site (http://www.health.org/workpl.htm).

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

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

(2) The CCF must include the names, addresses, telephone numbers and fax numbers of the employer and the MRO, which may be preprinted, typed, or handwritten. The MRO information must include the specific physician's name and address, as opposed to only a generic clinic, health care organization, or company name. This information is required, and it is prohibited for an employer, collector, service agent or any other party to omit it. In addition, a C/TPA's name, address, fax number, and telephone number may be included, but is not required.

(3) As an employer, you may add the name of the DOT agency under whose authority the test occurred as part of the employer information.

(4) As a collector, you may use a CCF with your name, address, telephone number, and fax number preprinted, but under no circumstances may you sign the form before the collection event.

(c) Under no circumstances may the CCF transmit personal identifying information about an employee (other than a social security number (SSN) or other employee identification (ID) number) to a laboratory.

(d) As an employer, you may use an equivalent foreign-language version of the CCF approved by ODAPC. You may use such a non-English language form only in a situation where both the employee and collector understand and can use the form in that language.

§ 40.47 May employers use the CCF for non-DOT collections or non-Federal forms for DOT collections?

(a) No, as an employer, you are prohibited from using the CCF for non-DOT urine collections. You are also prohibited from using non-Federal forms for DOT urine collections. Doing either subjects you to enforcement action under DOT agency regulations.

(b) (1) In the rare case where the collector, either by mistake or as the only means to conduct a test under difficult circumstances (*e.g.*, post-accident or reasonable suspicion test with insufficient time to obtain the CCF), uses a non-Federal form for a DOT collection, the use of a non-Federal form does not present a reason for the laboratory to reject the specimen for testing or for an MRO to cancel the result.

(2) The use of the non-DOT form is a ''correctable flaw.'' As an MRO, to correct the problem you must follow the procedures of § 40.205(b)(2).

§ 40.49 What materials are used to collect urine specimens?

For each DOT drug test, you must use a collection kit meeting the requirements of Appendix A of this part.

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

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

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

Subpart E—Urine Specimen Collections

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

As the collector, you must take the following steps before actually beginning a collection:

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

(b) Ensure that, when the employee enters the collection site, you begin the testing process without undue delay. For example, you must not wait because the employee says he or she is not ready or is unable to urinate or because an authorized employer or employee representative is delayed in arriving.

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

Example to Paragraph (b)(1): An employee enters the test site for both a drug and an alcohol test. Normally, the collector would wait until the BAT had completed the alcohol test process before beginning the drug test process. However, there are some situations in which an exception to this normal practice would be reasonable. One

such situation might be if several people were waiting for the BAT to conduct alcohol tests, but a drug testing collector in the same facility were free. Someone waiting might be able to complete a drug test without unduly delaying his or her alcohol test. Collectors and BATs should work together, however, to ensure that post-accident and reasonable suspicion alcohol tests happen as soon as possible (*e.g.*, by moving the employee to the head of the line for alcohol tests).

(2) If the employee needs medical attention (*e.g.,* an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to collect a specimen.

(3) You must not collect, by catheterization or other means, urine from an unconscious employee to conduct a drug test under this part. Nor may you catheterize a conscious employee. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner.

(4) If, as an employee, you normally void through self-catheterization, and decline to do so, this constitutes a refusal to test.

(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employed individual) or a Federal, state, or local government (*e.g.,* a driver's license). You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(d) If the employee asks, provide your identification to the employee. Your identification must include your name and your employer's name, but does not have to include your picture, address, or telephone number.

(e) Explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF.

(f) Direct the employee to remove outer clothing (*e.g.,* coveralls, jacket, coat, hat) that could be used to conceal items or substances that could be used to tamper with a specimen. You must also direct the employee to leave these garments and any briefcase, purse, or other personal belongings with you or in a mutually agreeable location. You must advise the employee that failure to comply with your directions constitutes a refusal to test.

(1) If the employee asks for a receipt for any belongings left with you, you must provide one.

(2) You must allow the employee to keep his or her wallet.

(3) You must not ask the employee to remove other clothing (*e.g.,* shirts, pants, dresses, underwear), to remove all clothing, or to change into a hospital or examination gown (unless the urine collection is being accomplished simultaneously with a DOT agency-authorized medical examination).

(4) You must direct the employee to empty his or her pockets and display the items in them to ensure that no items are present which could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee can place the items back into his or her pockets. As the employee, you must allow the collector to make this observation.

(5) If, in your duties under paragraph (f)(4) of this section, you find any material that could be used to tamper with a specimen, you must:

(i) Determine if the material appears to be brought to the collection site with the intent to alter the specimen, and, if it is, conduct a directly observed collection using direct observation procedures (see § 40.67); or

(ii) Determine if the material appears to be inadvertently brought to the collection site (*e.g.,* eye drops), secure and maintain it until the collection process is completed and conduct a normal (*i.e.,* unobserved) collection.

(g) You must instruct the employee not to list medications that he or she is currently taking on the CCF. (The employee may make notes of medications on the back of the employee copy of the form for his or her own convenience, but these notes must not be transmitted to anyone else.)

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

As the collector, you must take the following steps before the employee provides the urine specimen:

(a) Complete Step 1 of the CCF.

(b) Instruct the employee to wash and dry his or her hands at this time. You must tell the employee not to wash his or her hands again until after delivering the specimen to you. You must not give the employee any further access to water or other materials that could be used to adulterate or dilute a specimen.

(c) Select, or allow the employee to select, an individually wrapped or sealed collection container from collection kit materials. Either you or the employee, with both of you present, must unwrap or break the seal of the collection container. You must not unwrap or break the seal on any specimen bottle at this time. You must not allow the employee to take anything from the collection kit into the room used for urination except the collection container.

(d) Direct the employee to go into the room used for urination, provide a specimen of at least 45 mL, not flush the toilet, and return to you with the specimen as soon as the employee has completed the void.

(1) Except in the case of an observed or a monitored collection (see §§ 40.67 and 40.69), neither you nor anyone else may go into the room with the employee.

(2) As the collector, you may set a reasonable time limit for voiding.

(e) You must pay careful attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute). If you detect such conduct, you must require that a collection take place immediately under direct observation (see § 40.67) and note the conduct and the fact that the collection was observed in the ''Remarks'' line of the CCF (Step 2). You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

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

As a collector, you must check the following when the employee gives the collection container to you:

(a) *Sufficiency of specimen.* You must check to ensure that the specimen contains at least 45 mL of urine.

(1) If it does not, you must follow ''shy bladder'' procedures (see § 40.193(b)).

(2) When you follow ''shy bladder'' procedures, you must discard the original specimen, unless another problem (*i.e.,* temperature out of range, signs of tampering) also exists.

(3) You are never permitted to combine urine collected from separate voids to create a specimen.

(4) You must discard any excess urine.

(b) *Temperature.* You must check the temperature of the specimen no later than four minutes after the employee has given you the specimen.

(1) The acceptable temperature range is 32–38 °C/90–100 °F.

(2) You must determine the temperature of the specimen by reading the temperature strip attached to the collection container.

(3) If the specimen temperature is within the acceptable range, you must mark the ''Yes'' box on the CCF (Step 2).

(4) If the specimen temperature is outside the acceptable range, you must mark the ''No'' box and enter in the ''Remarks'' line (Step 2) your findings about the temperature.

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

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

(7) In a case where the employee refuses to provide another specimen (see § 40.191(a)(3)) or refuses to provide another specimen under direct observation (see § 40.191(a)(4)), you must notify the DER. As soon as you have notified the DER, you must discard any specimen the employee has provided previously during the collection procedure.

(c) *Signs of tampering.* You must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering (*e.g.,* if you notice any unusual odor).

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

(2) In a case where a specimen is collected under direct observation because of showing signs of tampering, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but it shows signs of tampering. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(3) In a case where the employee refuses to provide another specimen (see § 40.191(a)(3)) or refuses to provide a specimen under direct observation (see § 40.193(a)(4)), you must notify the DER. As soon as you have notified the DER, you must discard any specimen the employee has provided previously during the collection procedure.

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

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

(1) The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to you that there was not an adequate medical explanation for the result; or

(2) The MRO reported to you that the original positive, adulterated, or substituted test result had to be cancelled because the test of the split specimen could not be performed.

(b) As an employer, you may direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.

(c) As a collector, you must immediately conduct a collection under direct observation if:

(1) You are directed by the DER to do so (see paragraphs (a) and (c) of this section); or

(2) You observed materials brought to the collection site or the employee's conduct clearly indicates an attempt to tamper with a specimen (see §§ 40.61(f)(5)(i) and 40.63(e)); or

(3) The temperature on the original specimen was out of range (see § 40.65(b)(5)); or (4) The original specimen appeared to have been tampered with (see § 40.65(c)(1)).

(d)(1) As the employer, you must explain to the employee the reason for a directly observed collection under paragraph (a) or (b) of this section.

(2) As the collector, you must explain to the employee the reason under this part for a directly observed collection under paragraphs (c)(2) through (4) of this section.

(e) As the collector, you must complete a new CCF for the directly observed collection.

(1) You must mark the ''reason for test'' block (Step 1) the same as for the first collection.

(2) You must check the ''Observed, (Enter Remark)'' box and enter the reason (see § 40.67(b)) in the ''Remarks'' line (Step 2).

(f) In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the specimen at the collection site, enter 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 specimen ID number of the other specimen.

(g) As the collector, you must ensure that the observer is the same gender as the employee. You must never permit an opposite gender person to act as the observer. The observer can be a different person from the collector and need not be a qualified collector.

(h) As the collector, if someone else is to observe the collection (*e.g.,* in order to ensure a same gender observer), you must verbally instruct that person to follow procedures at paragraphs (i) and (j) of this section. If you, the collector, are the observer, you too must follow these procedures.

(i) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to watch the urine go from the employee's body into the collection container.

(j) As the observer but not the collector, you must not take the collection container from the employee, but you must observe the specimen as the employee takes it to the collector.

(k) As the collector, when someone else has acted as the observer, you must include the observer's name in the ''Remarks'' line of the CCF (Step 2).

(l) As the employee, if you decline to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.

§ 40.69 How is a monitored collection conducted?

(a) As the collector, you 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.

(b) As the collector, you must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant). The monitor can be a different person from the collector and need not be a qualified collector.

(c) As the collector, if someone else is to monitor the collection (*e.g.,* in order to ensure a same gender monitor), you must verbally instruct that person to follow procedures at paragraphs (d) and (e) of this section. If you, the collector, are the observer, you too must follow these procedures.

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

(e) As the monitor, you must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) As the collector, when someone else has acted as the monitor, you must note that person's name in the ''Remarks'' line of the CCF (Step 2).

(g) As the employee being tested, if you decline to permit a collection authorized under this section to be monitored, it is a refusal to test.

§ 40.71 How does the collector prepare the specimens?

(a) All collections under DOT agency drug testing regulations must be split specimen collections.

(b) As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you. You must take these steps in the presence of the employee.

(1) Check the box on the CCF (Step 2) indicating that this was a split specimen collection.

(2) You, not the employee, must first pour at least 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.

(3) You, not the employee, must then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.

(4) You, not the employee, must place and secure (*i.e.,* tighten or snap) the lids/caps on the bottles.

(5) You, not the employee, must seal the bottles by placing the tamper-evident bottle seals over the bottle caps/lids and down the sides of the bottles.

(6) You, not the employee, must then write the date on the tamper-evident bottle seals.

(7) You must then ensure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the specimens he or she provided. If the employee fails or refuses to do so, you must note this in the ''Remarks'' line of the CCF (Step 2) and complete the collection process.

§ 40.73 How is the collection process completed?

(a) As the collector, you must do the following things to complete the collection process. You must complete the steps called for in paragraphs (a)(1) through (a)(7) of this section in the employee's presence.

(1) Direct the employee to read and sign the certification statement on Copy 2 (Step 5) of the CCF and provide date of birth, printed name, and day and evening contact telephone numbers. If the employee refuses to sign the CCF or to provide date of birth, printed name, or telephone numbers, you must note this in the ''Remarks'' line (Step 2) of the CCF, and complete the collection. If the employee refuses to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

(2) Complete the chain of custody on the CCF (Step 5) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory,

(3) Ensure that all copies of the CCF are legible and complete.

(4) Remove Copy 5 of the CCF and give it to the employee.

(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(6) Secure both pouches of the plastic bag.

(7) Advise the employee that he or she may leave the collection site.

(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(i) Place the sealed plastic bag in a shipping container (*e.g.,* standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

(9) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations.

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

Subpart F—Drug Testing Laboratories

§ 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.

(b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory certification standards or deemed your laboratory fully equivalent to a laboratory meeting HHS laboratory certification standards for all testing required under this part; or

(2) The DOT, based on a written recommendation from HHS, has recognized a Canadian or Mexican certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your laboratory under those equivalent standards and procedures.

(c) As a laboratory participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.

(d) If DOT determines that you are in noncompliance with this part, you could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to you, you are ineligible to participate in the DOT drug testing program even if you continue to meet the requirements of paragraph (a) or (b) of this section.

§ 40.83 How do laboratories process incoming specimens?

As the laboratory, you must do the following when you receive a DOT specimen:

(a) You are authorized to receive only the laboratory copy of the CCF. You are not authorized to receive other copies of the CCF nor any copies of the alcohol testing form.

(b) You must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing urine drug specimens.

(c) You must inspect each specimen and CCF for the following ''fatal flaws:''

(1) The specimen ID numbers on the specimen bottle and the CCF do not match;

(2) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (g) of this section);

(3) The collector's printed name *and* signature are omitted from the CCF; and

(4) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be

redesignated (see paragraph (g) of this section).

(d) When you find a specimen meeting the criteria of paragraph (c) of this section, you must document your findings and stop the testing process. Report the result in accordance with § 40.97(a)(3) .

(e) You must inspect each specimen and CCF for the following ''correctable flaws'':

(1) The specimen temperature was not checked and the ''Remarks'' line did not contain an entry regarding the temperature being outside of range; and

(2) The collector's signature is omitted on the certification statement on the CCF.

(f) Upon finding that a specimen meets the criteria of paragraph (e) of this section, document the flaw and continue the testing process.

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the flaw.

(2) You must then attempt to correct the flaw by following the procedures of § 40.205(b).

(3) If the flaw is not corrected, report the result in accordance with § 40.97(a)(3).

(g) If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, you must still test the primary specimen and follow appropriate procedures outlined in § 40.175(b) regarding the unavailability of the split specimen for testing.

(1) The primary specimen and the split specimen can be redesignated (*i.e.,* Bottle B is redesignated as Bottle A, and vice-versa) if:

(i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(ii) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

(iii) The laboratory opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing.

(2) In situations outlined in paragraph (g)(1) of this section, the laboratory shall mark through the ''A'' and write ''B,'' then initial and date the change. A corresponding change shall be made to the other bottle by marking through the ''B'' and writing ''A,'' and initialing and dating the change.

(h) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

§ 40.85 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test ''DOT specimens'' for any other drugs.

(a) Marijuana metabolites.

(b) Cocaine metabolites.

(c) Amphetamines.

(d) Opiate metabolites.

(e) Phencyclidine (PCP).

§ 40.87 What are the cutoff concentrations for initial and confirmation tests?

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

Type of drug or metabolite	Initial test	Confirmation test
(1) Marijuana metabolites	50	
(i) Delta-9-tetrahydrocanna-binol-9-carboxylic acid (THC)		15
(2) Cocaine metabolites (Benzoylecgonine)	300	150
(3) Phencyclidine (PCP)	25	25
(4) Amphetamines	1000	
(i) Amphetamine		500
(ii) Methamphetamine		500 (Specimen must also contain amphetamine at a concentration of greater than or equal to 200 ng/mL.)
(5) Opiate metabolites	2000	
(i) Codeine		2000
(ii) Morphine		2000
(iii) 6-acetylmorphine (6–AM)		10 (Test for 6–AM in the specimen. Conduct this test only when specimen contains morphine at a concentration greater than or equal to 2000 ng/mL.)

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.

(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

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

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

(b) As a laboratory, you must conduct validity testing.

§ 40.91 What validity tests must laboratories conduct on primary specimens?

As a laboratory, when you conduct validity testing under § 40.89, you must conduct it in accordance with the requirements of this section.

(a) You must test each primary specimen for creatinine. You must also determine its specific gravity if you find that the creatinine concentration is less than 20 mg/dL.

(b) You must measure the pH of each primary specimen.

(c) You must test each primary specimen to determine if it contains

substances that may be used to adulterate the specimen. Your tests must have the capability of determining whether any substance identified in current HHS requirements or specimen validity guidance is present in the specimen.

(d) If you suspect the presence of an interfering substance/adulterant that could make a test result invalid, but you are unable to identify it (*e.g.,* a new adulterant), you must, as the first laboratory, send the specimen to another HHS certified laboratory that has the capability of doing so.

(e) If you identify a substance in a specimen that appears to be an adulterant, but which is not listed in current HHS requirements or guidance, you must report the finding in writing to ODAPC and the Division of Workplace Programs, HHS, within three business days. You must also complete testing of the specimen for drugs, to the extent technically feasible.

(f) You must conserve as much as possible of the specimen for possible future testing.

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

(a) As a laboratory you must consider the primary specimen to be dilute if the creatinine concentration is less than 20 mg/dL and the specific gravity is less than 1.003, unless the criteria for a substituted specimen are met.

(b) As a laboratory you must consider the primary specimen to be substituted if the creatinine concentration is less than or equal to 5 mg/dL *and* the specific gravity is less than or equal to 1.001 or greater than or equal to 1.020.

§ 40.95 What criteria do laboratories use to establish that a specimen is adulterated?

(a) As a laboratory, you must consider the primary specimen to be adulterated if you determine that—

(1) A substance that is not expected to be present in human urine is identified in the specimen;

(2) A substance that is expected to be present in human urine is identified at a concentration so high that it is not consistent with human urine; or

(3) The physical characteristics of the specimen are outside the normal expected range for human urine.

(b) In making your determination under paragraph (a) of this section, you must apply the criteria in current HHS requirements or specimen validity guidance.

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

(a) As a laboratory, you must report the results for each primary specimen tested as one of the following:

(1) Negative;

(2) Negative—dilute;

(3) Rejected for testing, with remark(s);

(4) Positive, with drug(s)/metabolite(s) noted;

(5) Positive, with drug(s)/metabolite(s) noted—dilute;

(6) Adulterated, with remark(s);

(7) Substituted, with remark(s); or

(8) Invalid result, with remark(s).

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

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

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

(A) Laboratory name;

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

(C) Specimen I.D. number;

(D) Donor's SSN or employee I.D. number, if provided; '

(E) Reason for test, if provided;

(F) Date of the collection;

(G) Date received at the laboratory;

(H) Date certifying scientist released the results;

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

(J) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) The laboratory results report may be released only after review and approval by the certifying scientist and must reflect the same test result information as contained on the CCF signed by the certifying scientist.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage.

(2) Non-negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.

(c) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax, the fax connection must have a fixed telephone number accessible only to authorized individuals.

(d) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(e) You must provide quantitative values for confirmed positive drug, adulterated, and substituted test results to the MRO when the MRO requests you to do so in writing. The MRO's request may either be a general request covering all such results you send to the MRO or a specific case-by-case request.

(f) You must provide quantitative values for confirmed opiate results for morphine or codeine at 15,000 ng/mL or above, even if the MRO has not requested quantitative values for the test result.

§ 40.99 How long does the laboratory retain specimens after testing?

(a) As a laboratory testing the primary specimen, you must retain a specimen that was reported with positive, adulterated, substituted, or invalid results for a minimum of one year.

(b) You must keep such a specimen in secure, long-term, frozen storage in accordance with HHS requirements.

(c) Within the one-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain a specimen for an additional period of time (*e.g.,* for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the specimen at the end of the year.

(d) If you have not sent the split specimen to another laboratory for testing, you must retain the split specimen for an employee's test for the same period of time that you retain the primary specimen and under the same storage conditions.

(e) As the laboratory testing the split specimen, you must meet the requirements of paragraphs (a) through (d) of this section with respect to the split specimen.

§ 40.101 What relationship may a laboratory have with an MRO?

(a) As a laboratory, you may not enter into any relationship with an MRO that creates a conflict of interest or the appearance of a conflict of interest with the MRO's responsibilities for the employer. You may not derive any financial benefit by having an employer use a specific MRO.

(b) The following are examples of relationships between laboratories and MROs that the Department regards as creating conflicts of interest, or the appearance of such conflicts. This following list of examples is not intended to be exclusive or exhaustive:

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the employer a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

§ 40.103 What are the requirements for submitting blind specimens to a laboratory?

(a) As an employer or C/TPA with an aggregate of 2000 or more DOT-covered employees, you must send blind specimens to laboratories you use. If you have an aggregate of fewer than 2000 DOT-covered employees, you are not required to provide blind specimens.

(b) To each laboratory to which you send at least 100 specimens in a year, you must transmit a number of blind specimens equivalent to one percent of the specimens you send to that laboratory, up to a maximum of 50 blind specimens in each quarter (*i.e.,* January–March, April–June, July–September, October–December). As a C/TPA, you must apply this percentage to the total number of DOT-covered employees' specimens you send to the laboratory. Your blind specimen submissions must be evenly spread throughout the year. The following examples illustrate how this requirement works:

Example 1 to Paragraph (b). You send 2500 specimens to Lab X in Year 1. In this case, you would send 25 blind specimens to Lab X in Year 1. To meet the even distribution requirement, you would send 6 in each of three quarters and 7 in the other.

Example 2 to Paragraph (b). You send 2000 specimens to Lab X and 1000 specimens to Lab Y in Year 1. In this case, you would send 20 blind specimens to Lab X and 10 to Lab Y in Year 1. The even distribution requirement would apply in a similar way to that described in Example 1.

Example 3 to Paragraph (b). Same as Example 2, except that you also send 20 specimens to Lab Z. In this case, you would send blind specimens to Labs X and Y as in Example 2. You would not have to send any blind specimens to Lab Z, because you sent fewer than 100 specimens to Lab Z.

Example 4 to Paragraph (b). You are a C/TPA sending 2000 specimens to Lab X in Year 1. These 2000 specimens represent 200 small employers who have an average of 10 covered employees each. In this case you—not the individual employers—send 20 blind specimens to Lab X in Year 1, again ensuring even distribution. The individual employers you represent are not required to provide any blind specimens on their own.

Example 5 to Paragraph (b). You are a large C/TPA that sends 40,000 specimens to Lab Y in Year 1. One percent of that figure is 400. However, the 50 blind specimen per quarter ''cap'' means that you need send only 50 blind specimens per quarter, rather than the 100 per quarter you would have to send to meet the one percent rate. Your annual total would be 200, rather than 400, blind specimens.

(c) Approximately 75 percent of the specimens you submit must be blank (*i.e.,* containing no drugs, nor adulterated or substituted). Approximately 15 percent must be positive for one or more of the five drugs involved in DOT tests, and approximately 10 percent must either be adulterated with a substance cited in HHS guidance or substituted (*i.e.,* having specific gravity and creatinine meeting the criteria of § 40.93(b)).

(1) The blind specimens that you submit that contain drugs, that are adulterated with a substance cited in HHS guidance, or that are substituted must be validated as to their contents by the supplier using initial and confirmatory tests.

(2) The supplier must provide information regarding the shelf life of the blind specimens.

(3) If the blind specimen is drug positive, the concentration of drug it contains must be between 1.5 and 2 times the initial drug test cutoff concentration.

(4) If the blind specimen is adulterated with nitrite, the concentration of nitrite it contains must be between 1.5 and 2 times the initial validity test cutoff concentration.

(5) If the blind specimen is adulterated by altering pH, the pH must be less than or equal to 2, or greater than or equal to 12.

(6) If the blind specimen is substituted, the creatinine must be less than or equal to 2, and the specific gravity must be 1.000.

(d) You must ensure that each blind specimen is indistinguishable to the laboratory from a normal specimen.

(1) You must submit blind specimens to the laboratory using the same channels (*e.g.,* via a regular collection site) through which employees' specimens are sent to the laboratory.

(2) You must ensure that the collector uses a CCF, places fictional initials on the specimen bottle label/seal, indicates for the MRO on Copy 2 that the specimen is a blind specimen, and discards Copies 4 and 5 (employer and employee copies).

(3) You must ensure that all blind specimens include split specimens.

§ 40.105 What happens if the laboratory reports a result different from that expected for a blind specimen?

(a) If you are an employer, MRO, or C/TPA who submits a blind specimen, and if the result reported to the MRO is different from the result expected, you must investigate the discrepancy.

(b) If the unexpected result is a false negative, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy.

(c) If the unexpected result is a false positive, you must provide the laboratory with the expected results (obtained from the supplier of the blind specimen), and direct the laboratory to determine the reason for the discrepancy. You must also notify ODAPC of the discrepancy by telephone (202–366–3784) or e-mail (addresses are listed on the ODAPC web site, http://www.dot.gov/ost/dapc). ODAPC will notify HHS who will take appropriate action.

§ 40.107 Who may inspect laboratories?

As a laboratory, you must permit an inspection, with or without prior notice, by ODAPC, a DOT agency, or a DOT-regulated employer that contracts with the laboratory for drug testing under the DOT drug testing program, or the designee of such an employer.

§ 40.109 What documentation must the laboratory keep, and for how long?

(a) As a laboratory, you must retain all records pertaining to each employee urine specimen for a minimum of two years.

(b) As a laboratory, you must also keep for two years employer-specific data required in § 40.111.

(c) Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain the records for an additional period of time (*e.g.,* for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the records at the end of the two-year period.

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in Appendix B to this part to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is likely that information about an employee's test result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) The summary must be sent by January 20 of each year for July 1 through December 31 of the prior year.

(4) The summary must also be sent by July 20 of each year for January 1 through June 30 of the current year.

(b) When the employer requests a summary in response to an inspection, audit, or review by a DOT agency, you must provide it unless the employer had fewer than five aggregate test results. In that case, you must send the employer a report indicating that not enough testing was conducted to warrant a summary. You may transmit the summary or report by hard copy, fax, or other electronic means.

(c) You must also release information to appropriate parties as provided in §§ 40.329 and 40.331.

§ 40.113 Where is other information concerning laboratories found in this regulation?

You can find more information concerning laboratories in several sections of this part:

§ 40.3—Definition.
§ 40.13—Prohibition on making specimens available for other purposes.
§ 40.31—Conflicts of interest concerning collectors.
§ 40.47—Laboratory rejections of test for improper form.
§ 40.125—Conflicts of interest concerning MROs.
§ 40.175—Role of first laboratory in split specimen tests.
§ 40.177—Role of second laboratory in split specimen tests (drugs).
§ 40.179—Role of second laboratory in split specimen tests (adulterants).
§ 40.181—Role of second laboratory in split specimen tests (substitution).
§§ 40.183–40.185—Transmission of split specimen test results to MRO.
§§ 40.201–40.205—Role in correcting errors.
§ 40.329—Release of information to employees.
§ 40.331—Limits on release of information.
§ 40.355—Role with respect to other service agents.

Subpart G—Medical Review Officers and the Verification Process

§ 40.121 Who is qualified to act as an MRO?

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, 400 7th Street, SW., Room 10403, 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) *Continuing Education.* During each three-year period from the date on which you satisfactorily complete the examination under paragraph (c)(2) of this section, you must complete continuing education consisting of at least 12 professional development hours (*e.g.,* Continuing Education Medical Units) relevant to performing MRO functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in MRO practice, pertaining to the DOT program, since the time you met the qualification training requirements of this section.

(2) Your continuing education activities must include assessment tools to assist you in determining whether you have adequately learned the material.

(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.

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

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.

§ 40.125 What relationship may an MRO have with a laboratory?

As an MRO, you may not enter into any relationship with an employer's laboratory that creates a conflict of interest or the appearance of a conflict of interest with your responsibilities to that employer. You may not derive any financial benefit by having an employer use a specific laboratory. For examples of relationships between laboratories and MROs that the Department views as creating a conflict of interest or the appearance of such a conflict, see § 40.101(b).

§ 40.127 What are the MRO's functions in reviewing negative test results?

As the MRO, you must do the following with respect to negative drug test results you receive from a laboratory, prior to verifying the result and releasing it to the DER:

(a) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to initiate corrective action or to cancel the test (see §§ 40.199 and 40.203).

(b) Review the negative laboratory test result and ensure that it is consistent with the information contained on the CCF.

(c) Before you report a negative test result, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF or the electronic laboratory results report that conveys the negative laboratory test result.

(d) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must request that the collector or laboratory send you a legible copy.

(e) On Copy 2 of the CCF, place a check mark in the ''Negative'' box (Step 6), provide your name, and sign, initial, or stamp and date the verification statement.

(f) Report the result in a confidential manner (see §§ 40.163–40.167).

(g) Staff under your direct, personal supervision may the administrative functions of this section for you, but only you can cancel a test.

(1) On specimen results that are reviewed by your staff, you are responsible for assuring the quality of their work.

(2) You are required to personally review at least 5 percent of all CCFs reviewed by your staff on a quarterly basis, including all results that required a corrective action. However, you need not review more than 500 negative results in any quarter.

(3) Your review must, as a minimum, include the CCF, negative laboratory test result, any accompanying corrective documents, and the report sent to the employer. You must correct any errors that you discover. You must take action as necessary to ensure compliance by your staff with this part and document your corrective action. You must attest to the quality assurance review by initialing the CCFs that you review.

(4) You must make these CCFs easily identifiable and retrievable by you for review by DOT agencies.

§ 40.129 What are the MRO's functions in reviewing laboratory confirmed positive, adulterated, substituted, or invalid drug test results?

(a) As the MRO, you must do the following with respect to confirmed positive, adulterated, substituted, or invalid drug tests you receive from a laboratory, before you verify the result and release it to the DER:

(1) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to cancel the test (see §§ 40.199 and 40.203). Staff under your direct, personal supervision may conduct this administrative review for you, but only you may verify or cancel a test.

(2) Review Copy 1 of the CCF and ensure that it is consistent with the information contained on Copy 2, that the test result is legible, and that the certifying scientist signed the form. You are not required to review any other documentation generated by the laboratory during their analysis or handling of the specimen (*e.g.,* the laboratory internal chain of custody).

(3) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must request that the collector or laboratory send you a legible copy.

(4) Except in the circumstances spelled out in § 40.133 , conduct a verification interview. This interview must include direct contact in person or by telephone between you and the employee. You may initiate the verification process based on the laboratory results report.

(5) Verify the test result as either negative, positive, test cancelled, or

refusal to test because of adulteration or substitution, consistent with the requirements of §§ 40.135–40.145 and 40.159 .

(b) Before you report a verified negative, positive, test cancelled, refusal to test because of adulteration or substitution, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF, containing the certifying scientist's signature.

(c) With respect to verified positive test results, place a check mark in the ''Positive'' box (Step 6) on Copy 2 of the CCF, indicate the drug(s)/ metabolite(s) detected on the ''Remarks'' line, sign and date the verification statement.

(d) Report the result in a confidential manner (see §§ 40.163–40.167).

(e) With respect to adulteration or substitution test results, check the ''refusal to test because:'' box (Step 6) on Copy 2 of the CCF, check the ''Adulterated'' or ''Substituted'' box, as appropriate, make appropriate annotation in the ''Remarks'' line, sign and date the verification statement.

(f) As the MRO, your actions concerning reporting confirmed positive, adulterated, or substituted results to the employer before you have completed the verification process are also governed by the stand-down provisions of § 40.21 .

(1) If an employer has a stand-down policy that meets the requirements of § 40.21 , you may report to the DER that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result, consistent with the terms of the waiver the employer received. You must not provide any further details about the test result (*e.g.,* the name of the drug involved).

(2) If the employer does not have a stand-down policy that meets the requirements of § 40.21 , you must not inform the employer that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result until you verify the test result. For example, as an MRO employed directly by a company, you must not tell anyone on the company's staff or management that you have received an employee's laboratory confirmed test result.

§ 40.131 How does the MRO or DER notify an employee of the verification process after a confirmed positive, adulterated, substituted, or invalid test result?

(a) When, as the MRO, you receive a confirmed positive, adulterated, substituted, or invalid test result from the laboratory, you must contact the employee directly (*i.e.,* actually talk to the employee), on a confidential basis, to determine whether the employee wants to discuss the test result. In making this contact, you must explain to the employee that, if he or she declines to discuss the result, you will verify the test as positive or as a refusal to test because of adulteration or substitution, as applicable.

(b) As the MRO, staff under your personal supervision may conduct this initial contact for you.

(1) This staff contact must be limited to scheduling the discussion between you and the employee and explaining the consequences of the employee's declining to speak with you (*i.e.,* that the MRO will verify the test without input from the employee). If the employee declines to speak with you, the staff person must document the employee's decision, including the date and time.

(2) A staff person must not gather any medical information or information concerning possible explanations for the test result.

(3) A staff person may advise an employee to have medical information (*e.g.,* prescriptions, information forming the basis of a legitimate medical explanation for a confirmed positive test result) ready to present at the interview with the MRO.

(4) Since you are required to speak personally with the employee, face-to-face or on the phone, your staff must not inquire if the employee wishes to speak with you.

(c) As the MRO, you or your staff must make reasonable efforts to reach the employee at the day and evening telephone numbers listed on the CCF. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF. If you or your staff cannot reach the employee directly after making these efforts, you or your staff must take the following steps:

(1) Document the efforts you made to contact the employee, including dates and times. If both phone numbers are incorrect (*e.g.,* disconnected, wrong number), you may take the actions listed in paragraph (c)(2) of this section without waiting the full 24-hour period.

(2) Contact the DER, instructing the DER to contact the employee.

(i) You must simply direct the DER to inform the employee to contact you.

(ii) You must not inform the DER that the employee has a confirmed positive, adulterated, substituted, or invalid test result.

(iii) You must document the dates and times of your attempts to contact the DER, and you must document the name of the DER you contacted and the date and time of the contact.

(d) As the DER, you must attempt to contact the employee immediately, using procedures that protect, as much as possible, the confidentiality of the MRO's request that the employee contact the MRO. If you successfully contact the employee (*i.e.,* actually talk to the employee), you must document the date and time of the contact, and inform the MRO. You must inform the employee that he or she must contact the MRO within the next 72 hours and tell the employee the consequences of failing to do so (see § 40.133(a)(2)).

(1) As the DER, you must not inform anyone else working for the employer that you are seeking to contact the employee on behalf of the MRO.

(2) If, as the DER, you have made all reasonable efforts to contact the employee but failed to do so, you may place the employee on temporary medically unqualified status or medical leave. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF.

(i) As the DER, you must document the dates and times of these efforts.

(ii) If, as the DER, you are unable to contact the employee within this 24-hour period, you must leave a message for the employee by any practicable means (*e.g.,* voice mail, e-mail, letter) to contact the MRO and inform the MRO of the date and time of this attempted contact.

§ 40.133 Under what circumstances may the MRO verify a test as positive, or as a refusal to test because of adulteration or substitution, without interviewing the employee?

(a) As the MRO, you normally may verify a confirmed positive test (for any drug or drug metabolite, including opiates), or as a refusal to test because of adulteration or substitution, only after interviewing the employee as provided in §§ 40.135–40.145 . However, there are three circumstances in which you may verify such a result without an interview:

(1) You may verify a test result as a positive or refusal to test, as applicable, if the employee expressly declines the opportunity to discuss the test with you. You must maintain complete documentation of this occurrence, including notation of informing, or

attempting to inform, the employee of the consequences of not exercising the option to speak with the you.

(2) You may verify a test result as a positive or refusal to test, as applicable, if the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee.

(3) You may verify a test result as a positive or refusal to test, as applicable, if neither you nor the DER, after making and documenting all reasonable efforts, has been able to contact the employee within ten days of the date on which the MRO receives the confirmed test result from the laboratory.

(b) As the MRO, when you verify a test result as a positive or refusal to test under this section, you must document the date, time and reason, following the instructions in § 40.163 .

(c) As the MRO, after you have verified a test result as a positive or refusal to test under this section and reported the result to the DER, you must allow the employee to present information to you within 60 days of the verification documenting that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/or DER in the times provided. On the basis of such information, you may reopen the verification, allowing the employee to present information concerning whether there is a legitimate medical explanation for the confirmed test result.

§ 40.135 What does the MRO tell the employee at the beginning of the verification interview?

(a) As the MRO, you must tell the employee that the laboratory has determined that the employee's test result was positive, adulterated, substituted, or invalid, as applicable. You must also tell the employee of the drugs for which his or her specimen tested positive, or the basis for the finding of adulteration or substitution.

(b) You must explain the verification interview process to the employee and inform the employee that your decision will be based on information the employee provides in the interview.

(c) You must explain that, if further medical evaluation is needed for the verification process, the employee must comply with your request for this evaluation and that failure to do so is equivalent of expressly declining to discuss the test result.

(d) As the MRO, you must warn an employee who has a confirmed positive, adulterated, substituted or invalid test that you are required to provide to third parties drug test result information and medical information affecting the performance of safety-sensitive duties that the employee gives you in the verification process without the employee's consent (see § 40.327).

(1) You must give this warning to the employee before obtaining any medical information as part of the verification process.

(2) For purposes of this paragraph (d), medical information includes information on medications or other substances affecting the performance of safety-sensitive duties that the employee reports using or medical conditions the employee reports having.

(3) For purposes of this paragraph (d), the persons to whom this information may be provided include the employer, a SAP evaluating the employee as part of the return to duty process (see § 40.293(g)), DOT, another Federal safety agency (*e.g.*, the NTSB), or any state safety agency as required by state law.

(e) You must also advise the employee that, before informing any third party about any medication the employee is using pursuant to a legally valid prescription under the Controlled Substances Act, you will, if the employee consents, contact the prescribing physician to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk.

§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, or PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system.

(b) You must offer the employee an opportunity to present a legitimate medical explanation in all cases.

(c) The employee has the burden of proof that a legitimate medical explanation exists. The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the test result, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence concerning a legitimate medical explanation within that time.

(d) If you determine that there is a legitimate medical explanation, you must verify the test result as negative. Otherwise, you must verify the test result as positive.

(e) In determining whether a legitimate medical explanation exists, you may consider the employee's use of a medication from a foreign country. You must exercise your professional judgment consistently with the following principles:

(1) There can be a legitimate medical explanation only with respect to a substance that is obtained legally in a foreign country.

(2) There can be a legitimate medical explanation only with respect to a substance that has a legitimate medical use. Use of a drug of abuse (*e.g.*, heroin, PCP, marijuana) or any other substance (see § 40.151(f) and (g)) that cannot be viewed as having a legitimate medical use can never be the basis for a legitimate medical explanation, even if the substance is obtained legally in a foreign country.

(3) Use of the substance can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose.

(4) Even if you find that there is a legitimate medical explanation under this paragraph (e) and verify a test negative, you may have a responsibility to raise fitness-for-duty considerations with the employer (see § 40.327).

§ 40.139 On what basis does the MRO verify test results involving opiates?

As the MRO, you must proceed as follows when you receive a laboratory confirmed positive opiate result:

(a) If the laboratory detects the presence of 6-acetylmorphine (6-AM) in the specimen, you must verify the test result positive.

(b) In the absence of 6-AM, if the laboratory detects the presence of either morphine or codeine at 15,000 ng/mL or above, you must verify the test result positive unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see § 40.137). Consumption of food products (*e.g.*, poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine at these concentrations.

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

(1) As an MRO, it is your responsibility to use your best

professional and ethical judgement and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that you may consider in making this judgement include, but are not limited to, the following:

(i) Recent needle tracks;

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

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

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

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

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

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

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

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

§ 40.141 How does the MRO obtain information for the verification decision?

As the MRO, you must do the following as you make the determinations needed for a verification decision:

(a) You must conduct a medical interview. You must review the employee's medical history and any other relevant biomedical factors presented to you by the employee. You may direct the employee to undergo further medical evaluation by you or another physician.

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication, you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information.

§ 40.143 [Reserved]

§ 40.145 On what basis does the MRO verify test results involving adulteration or substitution?

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive test for a drug or drug metabolite.

(b) You must follow the same procedures used for verification of a confirmed positive test for a drug or drug metabolite (see §§ 40.129–40.135, 40.141, 40.151), except as otherwise provided in this section.

(c) In the verification interview, you must explain the laboratory findings to the employee and address technical questions or issues the employee may raise.

(d) You must offer the employee the opportunity to present a legitimate medical explanation for the laboratory findings with respect to presence of the adulterant in, or the creatinine and specific gravity findings for, the specimen.

(e) The employee has the burden of proof that there is a legitimate medical explanation.

(1) To meet this burden in the case of an adulterated specimen, the employee must demonstrate that the adulterant found by the laboratory entered the specimen through physiological means.

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine, through physiological means, meeting the creatinine and specific gravity criteria of § 40.93(b).

(3) The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the specimen, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence supporting a legitimate medical explanation within that time.

(f) As the MRO or the employer, you are not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

(g) As the MRO, you must exercise your best professional judgment in deciding whether the employee has established a legitimate medical explanation.

(1) If you determine that the employee's explanation does not present a reasonable basis for concluding that there may be a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution, as applicable.

(2) If you believe that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, you must direct the employee to obtain, within the five-day period set forth in paragraph (e)(3) of this section, a further medical evaluation. This evaluation must be performed by a licensed physician (the ''referral physician''), acceptable to you, with expertise in the medical issues raised by the employee's explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(i) As the MRO or employer, you are not responsible for finding or paying a referral physician. However, on request of the employee, you must provide reasonable assistance to the employee's efforts to find such a physician. The final choice of the referral physician is the employee's, as long as the physician is acceptable to you.

(ii) As the MRO, you must consult with the referral physician, providing guidance to him or her concerning his or her responsibilities under this section. As part of this consultation, you must provide the following information to the referral physician:

(A) That the employee was required to take a DOT drug test, but the laboratory reported that the specimen was adulterated or substituted, which is treated as a refusal to test;

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

(C) That the referral physician must agree to follow the requirements of paragraphs (g)(3) through (g)(4) of this section; and

(D) That the referral physician must provide you with a signed statement of his or her recommendations.

(3) As the referral physician, you must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. You may conduct additional tests to determine whether

there is a legitimate medical explanation. Any additional urine tests must be performed in an HHS-certified laboratory.

(4) As the referral physician, you must then make a written recommendation to the MRO about whether the MRO should determine that there is a legitimate medical explanation. As the MRO, you must seriously consider and assess the referral physician's recommendation in deciding whether there is a legitimate medical explanation.

(5) As the MRO, if you determine that there is a legitimate medical explanation, you must cancel the test and inform ODAPC in writing of the determination and the basis for it (*e.g.*, referral physician's findings, evidence produced by the employee).

(6) As the MRO, if you determine that there is not a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution.

(h) The following are examples of types of evidence an employee could present to support an assertion of a legitimate medical explanation for a substituted result.

(1) Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of § 40.93(b) .

(i) To be regarded as medically valid, the evidence must have been gathered using appropriate methodology and controls to ensure its accuracy and reliability.

(ii) Assertion by the employee that his or her personal characteristics (*e.g.*, with respect to race, gender, weight, diet, working conditions) are responsible for the substituted result does not, in itself, constitute a legitimate medical explanation. To make a case that there is a legitimate medical explanation, the employee must present evidence showing that the cited personal characteristics actually result in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.93(b) .

(2) Information from a medical evaluation under paragraph (g) of this section that the individual has a medical condition that has been demonstrated to cause the employee to physiologically produce urine meeting the creatinine and specific gravity criteria of § 40.93(b) .

(i) A finding or diagnosis by the physician that an employee has a medical condition, in itself, does not constitute a legitimate medical explanation.

(ii) To establish there is a legitimate medical explanation, the employee must demonstrate that the cited medical condition actually results in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.93(b) .

§ 40.147 [Reserved]

§ 40.149 May the MRO change a verified positive drug test result or refusal to test?

(a) As the MRO, you may change a verified positive or refusal to test drug test result only in the following situations:

(1) When you have reopened a verification that was done without an interview with an employee (see § 40.133(c)).

(2) If you receive information, not available to you at the time of the original verification, demonstrating that the laboratory made an error in identifying (*e.g.,* a paperwork mistake) or testing (*e.g.,* a false positive or negative) the employee's primary or split specimen. For example, suppose the laboratory originally reported a positive test result for Employee X and a negative result for Employee Y. You verified the test results as reported to you. Then the laboratory notifies you that it mixed up the two test results, and X was really negative and Y was really positive. You would change X's test result from positive to negative and contact Y to conduct a verification interview.

(3) If, within 60 days of the original verification decision—

(i) You receive information that could not reasonably have been provided to you at the time of the decision demonstrating that there is a legitimate medical explanation for the presence of drug(s)/metabolite(s) in the employee's specimen; or

(ii) You receive credible new or additional evidence that a legitimate medical explanation for an adulterated or substituted result exists.

Example to Paragraph (a)(3): If the employee's physician provides you a valid prescription that he or she failed to find at the time of the original verification, you may change the test result from positive to negative if you conclude that the prescription provides a legitimate medical explanation for the drug(s)/ metabolite(s) in the employee's specimen.

(4) If you receive the information in paragraph (a)(3) of this section after the 60-day period, you must consult with ODAPC prior to changing the result.

(5) When you have made an administrative error and reported an incorrect result.

(b) If you change the result, you must immediately notify the DER in writing, as provided in §§ 40.163–40.165.

(c) You are the only person permitted to change a verified test result.

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

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) In reviewing the CCF, you must not consider evidence extrinsic to the CCF in determining whether the test is valid. For example, you must review only what is on the face of the CCF for this purpose, not assertions by the employee that the CCF does not accurately reflect what happened at the collection site.

(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 or 6-AM in a specimen. There are no legitimate medical explanations for the presence of these substances.

(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.

§ 40.153 How does the MRO notify employees of their right to a test of the split specimen?

(a) As the MRO, when you have verified a drug test as positive for a drug or drug metabolite, or as a refusal to test because of adulteration or substitution, you must notify the employee of his or her right to have the split specimen tested. You must also notify the employee of the procedures for requesting a test of the split specimen.

(b) You must inform the employee that he or she has 72 hours from the time you provide this notification to him or her to request a test of the split specimen.

(c) You must tell the employee how to contact you to make this request. You must provide telephone numbers or other information that will allow the employee to make this request. As the MRO, you must have the ability to receive the employee's calls at all times during the 72 hour period (*e.g.,* by use of an answering machine with a ''time stamp'' feature when there is no one in your office to answer the phone).

(d) You must tell the employee that if he or she makes this request within 72 hours, the employer must ensure that the test takes place, and that the employee is not required to pay for the test from his or her own funds before the test takes place. You must also tell the employee that the employer may seek reimbursement for the cost of the test (see § 40.173).

(e) You must tell the employee that additional tests of the specimen *e.g.,* DNA tests) are not authorized.

§ 40.155 What does the MRO do when a negative or positive test result is also dilute?

(a) When the laboratory reports that a specimen is dilute, you must, as the MRO, report to the DER that the specimen, in addition to being negative or positive, is dilute.

(b) You must check the ''dilute'' box (Step 6) on Copy 2 of the CCF.

(c) You may only report a dilute test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

(d) When you report a dilute specimen to the DER, you must explain to the DER the employer's obligations and choices under § 40.197.

§ 40.157 [Reserved]

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

(a) As the MRO, when the laboratory reports that the test result is an invalid result, you must do the following:

(1) Discuss the laboratory results with a certifying scientist to obtain more specific information.

(2) Contact the employee and inform the employee that the specimen was invalid or contained an unexplained interfering substance. In contacting the employee, use the procedures set forth in § 40.131.

(3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you should inquire as to medications the employee may have taken that may interfere with some immunoassay tests.

(4) If the employee gives an explanation that is acceptable, you must:

(i) Place a check mark in the ''Test Cancelled'' box (Step 6) on Copy 2 of the CCF and enter ''Invalid Result'' and ''direct observation collection not required'' on the ''Remarks'' line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that no further action is required unless a negative test result is required (*i.e.,* pre-employment, return-to-duty, or follow-up tests).

(5) If the employee is unable to provide an explanation and/or a valid prescription for a medication that interfered with the immunoassay test but denies having adulterated the specimen, you must:

(i) Place a check mark in the ''Test Cancelled'' box (Step 6) on Copy 2 of the CCF and enter ''Invalid Result'' and ''direct observation collection required'' on the ''Remarks'' line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take place immediately under direct observation.

(iii) Instruct the employer to ensure that the employee has the minimum possible advance notice that he or she must go to the collection site.

(b) You may only report an invalid test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

(c) If the employee admits to having adulterated or substituted the specimen, you must, on the same day, write and sign your own statement of what the employee told you. You must then report a refusal to test in accordance with § 40.163 .

§ 40.161 What does the MRO do when a drug test specimen is rejected for testing?

As the MRO, when the laboratory reports that the specimen is rejected for testing (*e.g.,* because of a fatal or uncorrected flaw), you must do the following:

(a) Place a check mark in the ''Test Cancelled'' box (Step 6) on Copy 2 of the CCF and enter the reason on the ''Remarks'' line.

(b) Report to the DER that the test is cancelled and the reason for cancellation, and that no further action is required unless a negative test is required (*e.g.,* in the case of a pre-employment, return-to-duty, or follow-up test).

(c) You may only report a test cancelled because of a rejected for testing test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

§ 40.163 How does the MRO report drug test results?

(a) As the MRO, it is your responsibility to report the drug test results to the employer in writing.

(1) You or a staff member may rubber stamp a report of negative results. If you use a rubber stamp, you or your staff must also initial the stamp to identify who affixed the stamp to the report.

(2) You, as the MRO, must sign reports of all other results.

(b) You may use a signed or stamped and dated legible photocopy of Copy 2 of the CCF to report test results.

(c) If you do not report test results using Copy 2 of the CCF for this purpose, you must provide a written report (*e.g.,* a letter) for each test result. This report must, as a minimum, include the following information:

(1) Full name, as indicated on the CCF, of the employee tested;

(2) Specimen ID number from the CCF and the donor SSN or employee ID number;

(3) Reason for the test as indicated on the CCF (*e.g.,* random, post-accident);

(4) Date of the collection;

(5) Result of the test (*i.e.,* positive, negative, dilute, refusal to test, test cancelled) and the date the result was verified by the MRO;

(6) For verified positive tests, the drug(s)/metabolite(s) for which the test was positive;

(7) For cancelled tests, the reason for cancellation; and

(8) For refusals to test, the reason for the refusal determination (e.g., in the case of an adulterated test result, the name of the adulterant).

(d) You must retain a signed or stamped and dated copy of Copy 2 of the CCF in your records. If you do not use Copy 2 for reporting results, you must maintain a copy of the signed or stamped and dated letter in addition to the signed or stamped and dated Copy 2.

(e) You must not use Copy 1 of the CCF to report drug test results.

(f) You must not provide quantitative values to the DER or C/TPA for drug or validity test results. However, you must provide the test information in your possession to a SAP who consults with you (see § 40.293(g)).

§ 40.165 To whom does the MRO transmit reports of drug test results?

(a) As the MRO, you must report all drug test results to the DER, except in the circumstances provided for in § 40.345 .

(b) If the employer elects to receive reports of results through a C/TPA, acting as an intermediary as provided in § 40.345 , you must report the results through the designated C/TPA.

§ 40.167 How are MRO reports of drug results transmitted to the employer?

As the MRO or C/TPA who transmits drug test results to the employer, you must comply with the following requirements:

(a) You must report the results in a confidential manner.

(b) You must transmit to the DER on the same day the MRO verifies the result or the next business day all verified positive test results, results requiring an immediate collection under direct observation, adulterated or substituted specimen results, and other refusals to test.

(1) Direct telephone contact with the DER is the preferred method of immediate reporting. Follow up your phone call with appropriate documentation (see § 40.163).

(2) You are responsible for identifying yourself to the DER, and the DER must have a means to confirm your identification.

(3) The MRO's report that you transmit to the employer must contain all of the information required by § 40.163 .

(c) You must transmit the MRO's written report of verified test to the DER so that the DER receives them within two days of verification by the MRO.

(d) In transmitting test results, you or the C/TPA and the employer must ensure the security of the transmission and limit access to any transmission, storage, or retrieval systems.

§ 40.169 Where is other information concerning the role of MROs and the verification process found in this regulation?

You can find more information concerning the role of MROs in several sections of this part:

§ 40.3—Definition.
§ § 40.47–40.49—Correction of form and kit errors.
§ 40.67—Role in direct observation and other atypical test situations.
§ 40.83—Laboratory handling of fatal and correctable flaws.
§ 40.97—Laboratory handling of test results and quantitative values.
§ 40.99—Authorization of longer laboratory retention of specimens.
§ 40.101—Relationship with laboratories; avoidance of conflicts of interest.
§ 40.105—Notification of discrepancies in blind specimen results.
§ 40.171—Request for test of split specimen.
§ 40.187—Action concerning split specimen test results.
§ 40.193—Role in ''shy bladder'' situations.
§ 40.195—Role in cancelling tests.
§§ 40.199–40.203—Documenting errors in tests.
§ 40.327—Confidentiality and release of information.
§ 40.347—Transfer of records.
§ 40.353—Relationships with service agents.

Subpart H—Split Specimen Tests

§ 40.171 How does an employee request a test of a split specimen?

(a) As an employee, when the MRO has notified you that you have a verified positive drug test or refusal to test because of adulteration or substitution, you have 72 hours from the time of notification to request a test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen.

(b)(1) If, as an employee, you have not requested a test of the split specimen within 72 hours, you may present to the MRO information documenting that serious injury, illness, lack of actual notice of the verified test result, inability to contact the MRO (*e.g.*, there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented you from making a timely request.

(2) As the MRO, if you conclude from the employee's information that there was a legitimate reason for the employee's failure to contact you within 72 hours, you must direct that the test of the split specimen take place, just as you would when there is a timely request.

(c) When the employee makes a timely request for a test of the split specimen under paragraphs (a) and (b) of this section, you must, as the MRO, immediately provide written notice to the laboratory that tested the primary specimen, directing the laboratory to forward the split specimen to a second HHS-certified laboratory. You must also document the date and time of the employee's request.

§ 40.173 Who is responsible for paying for the test of a split specimen?

(a) As the employer, you are responsible for making sure (*e.g.*, by establishing appropriate accounts with laboratories for testing split specimens) that the MRO, first laboratory, and second laboratory perform the functions noted in §§ 40.175–40.185 in a timely manner, once the employee has made a timely request for a test of the split specimen.

(b) As the employer, you must not condition your compliance with these requirements on the employee's direct payment to the MRO or laboratory or the employee's agreement to reimburse you for the costs of testing. For example, if you ask the employee to pay for some or all of the cost of testing the split specimen, and the employee is unwilling or unable to do so, you must ensure that the test takes place in a timely manner, even though this means that you pay for it.

(c) As the employer, you may seek payment or reimbursement of all or part of the cost of the split specimen from the employee (*e.g.*, through your written company policy or a collective bargaining agreement). This part takes

no position on who ultimately pays the cost of the test, so long as the employer ensures that the testing is conducted as required and the results released appropriately.

§ 40.175 What steps does the first laboratory take with a split specimen?

(a) As the laboratory at which the primary and split specimen first arrive, you must check to see whether the split specimen is available for testing.

(b) If the split specimen is unavailable or appears insufficient, you must then do the following:

(1) Continue the testing process for the primary specimen as you would normally. Report the results for the primary specimen without providing the MRO information regarding the unavailable split specimen.

(2) Upon receiving a letter from the MRO instructing you to forward the split specimen to another laboratory for testing, report to the MRO that the split specimen is unavailable for testing. Provide as much information as you can about the cause of the unavailability.

(c) As the laboratory that tested the primary specimen, you are not authorized to open the split specimen under any circumstances (except when the split specimen is redesignated as provided in § 40.83).

(d) When you receive written notice from the MRO instructing you to send the split specimen to another HHS-certified laboratory, you must forward the following items to the second laboratory:

(1) The split specimen in its original specimen bottle, with the seal intact;

(2) A copy of the MRO's written request; and

(3) A copy of Copy 1 of the CCF, which identifies the drug(s)/metabolite(s) or the validity criteria to be tested for.

(e) You must not send to the second laboratory any information about the identity of the employee. Inadvertent disclosure does not, however, cause a fatal flaw.

(f) This subpart does not prescribe who gets to decide which HHS-certified laboratory is used to test the split specimen. That decision is left to the parties involved.

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) detected in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.87 .

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported positive in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.91 .

(d) In addition, if the test fails to reconfirm the presence of the drugs/drugs metabolites or validity criteria that were reported in the primary specimen, you may transmit the specimen or an aliquot of it to another HHS-certified laboratory that will conduct another reconfirmation test.

§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the criteria of § 40.95 just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing the split specimen, you must test the split specimen using the criteria of § 40.93(b), just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.183 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the ''Reconfirmed'' box or the ''Failed to Reconfirm'' box (Step 5(b)) on Copy 1 of the CCF.

(b) If you check the ''Failed to Reconfirm'' box, one of the following statements must be included (as appropriate) on the ''Reason'' line (Step 5(b)):

(1) ''Drug(s)/Drug Metabolite(s) Not Detected.''

(2) ''Adulterant not found within criteria.''

(3) ''Specimen not consistent with substitution criteria [specify creatinine, specific gravity, or both]''

(4) ''Specimen not available for testing.''

(c) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

§ 40.185 Through what methods and to whom must a laboratory report split specimen results?

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

(b) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF, which has been signed by the certifying scientist.

(c) You must transmit the laboratory result to the MRO immediately, preferably on the same day or next business day as the result is signed and released.

§ 40.187 What does the MRO do with split specimen laboratory results?

As an MRO, you must take the following actions when a laboratory reports the following results of split specimen tests:

(a) *Reconfirmed.* (1) In the case of a reconfirmed positive test for a drug or drug metabolite, report the reconfirmation to the DER and the employee.

(2) In the case of a reconfirmed adulterated or substituted result, report to the DER and the employee that the specimen was adulterated or substituted, either of which constitutes a refusal to test. Therefore, ''refusal to test'' is the final result.

(b) *Failed to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(c) *Failed to Reconfirm: Adulteration or Substitution (as appropriate) Criteria Not Met.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(d) *Failed to Reconfirm: Specimen not Available for Testing.* (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) Using the format in Appendix D to this part, notify ODAPC of the failure to reconfirm.

(e) Enter your name, sign and date (Step 7) of Copy 2 of the CCF.

(f) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see § 40.163) to the employer and keep a copy for your records. Transmit the document as provided in § 40.167.

§ 40.189 Where is other information concerning split specimens found in this regulation?

You can find more information concerning split specimens in several sections of this part:

§ 40.3—Definition.
§ 40.65—Quantity of split specimen.
§ 40.67—Directly observed test when split specimen is unavailable.
§§ 40.71–40.73—Collection process for split specimens.
§ 40.83—Laboratory accessioning of split specimens.
§ 40.99—Laboratory retention of split specimens.
§ 40.103—Blind split specimens.
§ 40.153—MRO notice to employees on tests of split specimen.
§§ 40.193 and 40.201—MRO actions on insufficient or unavailable split specimens.
Appendix D to Part 40—Report format for split specimen failure to reconfirm.

Subpart I—Problems in Drug Tests

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

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

(1) Fail to appear for any test within a reasonable time, as determined by the employer, 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 C/TPA (see § 40.61(a));

(2) Fail to remain at the testing site until the testing process is complete;

(3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations;

(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 a second test the employer or collector has directed you to take;

(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 as part of the ''shy bladder'' procedures of this part (see § 40.193(d)); or

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

(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 (or in a separate document which you cause to be attached to the form), 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 ''refused to test because'' box (Step 6) on Copy 2 of the CCF, and add the reason on the ''Remarks'' line. 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.

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

(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.

(3) If the employee refuses to make the attempt to provide a new urine specimen, 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 working 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.

(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 ''Refusal to test because'' (Step 6) on the CCF and enter reason in the remarks line; and

(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.

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

(a) This section concerns a situation in which an employee has a medical condition that precludes him or her from providing a sufficient specimen for a pre-employment or return-to-duty test and the condition involves a permanent or long-term disability. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the employee's physician and/or the physician who conducted the evaluation under § 40.193(d).

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(3) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (*e.g.,* blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the employer as a negative test with written notations regarding results of both the evaluation conducted under § 40.193(d) and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist.

(1) Check ''Negative'' (Step 6) on the CCF.

(2) Sign and date the CCF.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding results of both the evaluation conducted under § 40.193(d) and any further medical examination. This report must state that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*i.e.,* the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test is needed for that purpose).

(d) For purposes of this section, permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever.

(1) Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genito-urinary matters.

(2) Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in paragraph (d)(1) of this section.

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

(a) As the employer, if the MRO informs you that a positive drug test was dilute, you simply treat the test as a verified positive test. You must not direct the employee to take another test based on the fact that the specimen was dilute.

(b) If the MRO informs you that a negative drug test was dilute, you may, but are not required to, direct the employee to take another test immediately. Such recollections must not be collected under direct observation, unless there is another basis for use of direct observation (see § 40.67(b) and (c)).

(c) You must treat all employees the same for this purpose. For example, you must not retest some employees and not others. You may, however, establish different policies for different types of tests (*e.g.,* conduct retests in pre-employment test situations, but not in random test situations). You must inform your employees in advance of your decisions on these matters.

(d) If you direct the employee to take another test, you must ensure that the employee is given the minimum possible advance notice that he or she must go to the collection site.

(e) If you direct the employee to take another test, the result of the second test—not that of the original test—becomes the test of record, on which you rely for purposes of this part.

(f) If you require employees to take another test, and the second test is also negative and dilute, you are not permitted to make the employee take a third test because the second test was dilute.

(g) If you direct the employee to take another test and the employee declines to do so, the employee has refused the test for purpose of this part and DOT agency regulations.

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

(a) As the MRO, when the laboratory discovers a ''fatal flaw'' during its processing of incoming specimens (see § 40.83), the laboratory will report to you that the specimen has been ''Rejected for Testing'' (with the reason stated). You must always cancel such a test.

(b) The following are ''fatal flaws'':

(1) There is no printed collector's name *and* no collector's signature;

(2) The specimen ID numbers on the specimen bottle and the CCF do not match;

(3) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be redesignated, see § 40.83(g)); and

(4) Because of leakage or other causes, there is an insufficient amount of urine in the primary specimen bottle for analysis and the specimens cannot be redesignated (see § 40.83(g)).

(c) You must report the result as provided in § 40.161 .

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

As the MRO, you must cancel a drug test when a laboratory reports that any of the following problems have occurred. You must inform the DER that the test was cancelled. You must also direct the DER to ensure that an additional collection occurs immediately, if required by the applicable procedures specified in paragraphs (a) through (e) of this section.

(a) The laboratory reports an ''Invalid Result.'' You must follow applicable procedures in § 40.159 (recollection under direct observation may be required).

(b) The laboratory reports the result as ''Rejected for Testing.'' You must follow applicable procedures in § 40.161 (a recollection may be required).

(c) The laboratory's test of the primary specimen is positive and the split specimen is reported by the laboratory as ''Failure to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected.'' You must follow applicable procedures in § 40.187(b) (no recollection is required in this case).

(d) The laboratory's test result for the primary specimen is adulterated or substituted and the split specimen is reported by the laboratory as ''Adulterant not found within criteria,'' or '' specimen not consistent with substitution criteria, as applicable. You must follow applicable procedures in § 40.187(c) (no recollection is required in this case).

(e) The laboratory's test of the primary specimen is positive, adulterated, or substituted and the split specimen is unavailable for testing. You must follow applicable procedures in § 40.187(d) (recollection under direct observation is required in this case).

(f) The examining physician has determined that there is an acceptable medical explanation of the employee's failure to provide a sufficient amount of urine. You must follow applicable procedures in § 40.193(d)(1) (no recollection is required in this case).

§ 40.203 What problems cause a drug test to be cancelled unless they are corrected?

(a) As the MRO, when a laboratory discovers a ''correctable flaw'' during its processing of incoming specimens (see § 40.83), the laboratory will attempt to correct it. If the laboratory is unsuccessful in this attempt, it will report to you that the specimen has been ''Rejected for Testing'' (with the reason stated).

(b) The following are ''correctable flaws'' that laboratories must attempt to correct:

(1) The collector's signature is omitted on the certification statement on the CCF.

(2) The specimen temperature was not checked and the ''Remarks'' line did not contain an entry regarding the temperature being out of range.

(c) As the MRO, when you discover a ''correctable flaw'' during your review of the CCF, you must cancel the test unless the flaw is corrected.

(d) The following are correctable flaws that you must attempt to correct:

(1) The employee's signature is omitted from the certification statement, unless the employee's failure or refusal to sign is noted on the ''Remarks'' line of the CCF.

(2) The certifying scientist's signature is omitted on the laboratory copy of the CCF for a positive, adulterated, substituted, or invalid test result.

(3) The collector uses a non-DOT form for the test, provided that the collection and testing process is conducted in accordance with DOT procedures in an HHS-certified laboratory following DOT initial and confirmation test criteria.

§ 40.205 How are drug test problems corrected?

(a) As a collector, you have the responsibility of trying to successfully complete a collection procedure for each employee.

(1) If, during or shortly after the collection process, you become aware of any event that prevents the completion of a valid test or collection (*e.g.,* a procedural or paperwork error), you must try to correct the problem promptly, if doing so is practicable. You may conduct another collection as part of this effort.

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

(b) If, as a collector, laboratory, MRO, employer, or other person implementing these drug testing regulations, you become aware of a problem that can be corrected (see § 40.203), but which has not already been corrected under paragraph (a) of this section, you must take all practicable action to correct the problem so that the test is not cancelled.

(1) If the problem resulted from the omission of required information, you 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 you are a collector, and you forgot to make a notation on the ''Remarks'' line of the CCF that the employee did not sign the certification. You would, when the problem is called to your attention, supply a signed statement that the employee failed or refused to sign the certification and that your statement is true and accurate. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

(2) If the problem is the use of a non-Federal form, you 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 your control. The statement must also list the steps you have 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. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

(3) You must maintain the written documentation of a correction with the CCF.

(4) You must mark the CCF in such a way (*e.g.,* stamp noting correction) as to make it obvious on the face of the CCF that you corrected the flaw.

(c) If the correction does not take place, as the MRO you must cancel the test.

§ 40.207 What is the effect of a cancelled drug test?

(a) A cancelled drug test is neither positive nor negative.

(1) As an employer, you must not attach to a cancelled test the consequences of a positive test or other violation of a DOT drug testing regulation (*e.g.,* removal from a safety-sensitive position).

(2) As an employer, you must not use a cancelled test for the purposes of a negative test to authorize the employee to perform safety-sensitive functions (*i.e.,* in the case of a pre-employment, return-to-duty, or follow-up test).

(3) However, as an employer, you must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph (a)(2) of this section or other provisions of this part that require another test to be conducted (*e.g.,* §§ 40.159(a)(5) and 40.187(b)).

(b) A cancelled test does not count toward compliance with DOT requirements (*e.g.,* being applied toward the number of tests needed to meet the employer's minimum random testing rate).

(c) A cancelled DOT test does not provide a valid basis for an employer to conduct a non-DOT test (*i.e.,* a test under company authority).

§ 40.209 What is the effect of procedural problems that are not sufficient to cancel a drug test?

(a) As a collector, laboratory, MRO, employer or other person administering the drug testing process, you must document any errors in the testing process of which you become aware, even if they are not considered problems that will cause a test to be cancelled as listed in this subpart. Decisions about the ultimate impact of these errors will be determined by other administrative or legal proceedings, subject to the limitations of paragraph (b) of this section.

(b) No person concerned with the testing process may declare a test cancelled based on an error that does not have a significant adverse effect on the right of the employee to have a fair and accurate test. Matters that do not result in the cancellation of a test include, but are not limited to, the following:

(1) A minor administrative mistake (*e.g.,* the omission of the employee's middle initial, a transposition of numbers in the employee's social security number);

(2) An error that does not affect employee protections under this part (*e.g.,* the collector's failure to add bluing agent to the toilet bowl, which adversely affects only the ability of the collector to detect tampering with the specimen by the employee);

(3) The collection of a specimen by a collector who is required to have been trained (see § 40.33), but who has not met this requirement;

(4) A delay in the collection process (see § 40.61(a));

(5) Verification of a test result by an MRO who has the basic credentials to be qualified as an MRO (see § 40.121(a) through (b)) but who has not met training and/or documentation requirements (see § 40.121(c) through (e));

(6) The failure to directly observe or monitor a collection that the rule requires or permits to be directly observed or monitored, or the unauthorized use of direct observation or monitoring for a collection;

(7) The fact that a test was conducted in a facility that does not meet the requirements of § 40.41;

(8) If the specific name of the courier on the CCF is omitted or erroneous;

(9) Personal identifying information is inadvertently contained on the CCF (*e.g.,* the employee signs his or her name on the laboratory copy); or

(10) Claims that the employee was improperly selected for testing.

(c) As an employer, these types of errors, even though not sufficient to cancel a drug test result, may subject you to enforcement action under DOT agency regulations.

Subpart J—Alcohol Testing Personnel

§ 40.211 Who conducts DOT alcohol tests?

(a) Screening test technicians (STTs) and breath alcohol technicians (BATs) meeting their respective requirements of this subpart are the only people authorized to conduct DOT alcohol tests.

(b) An STT can conduct only alcohol screening tests, but a BAT can conduct alcohol screening and confirmation tests.

(c) As a BAT- or STT-qualified immediate supervisor of a particular employee, you may not act as the STT or BAT when that employee is tested, unless no other STT or BAT is available and DOT agency regulations do not prohibit you from doing so.

§ 40.213 What training requirements must STTs and BATs meet?

To be permitted to act as a BAT or STT in the DOT alcohol testing program, you must meet each of the requirements of this section:

(a) *Basic information.* You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. These documents and information are available from ODAPC (Department of Transportation, 400 7th Street, SW., 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 meeting the requirements of this paragraph (b).

(1) Qualification training must be in accordance with the DOT Model BAT or STT Course, as applicable. The DOT Model Courses are available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590, 202–366–3784, or on the ODAPC web site, http://www.dot.gov/ost/dapc). The training can also be provided using a course of instruction equivalent to the DOT Model Courses. On request, ODAPC will review BAT and STT instruction courses for equivalency.

(2) Qualification training must include training to proficiency in using the alcohol testing procedures of this part and in the operation of the particular alcohol testing device(s) (*i.e.,* the ASD(s) or EBT(s)) you will be using.

(3) The training must emphasize that you are responsible for maintaining the integrity of the testing process, ensuring the privacy of employees being tested, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) The instructor must be an individual who has demonstrated necessary knowledge, skills, and abilities by regularly conducting DOT alcohol tests as an STT or BAT, as applicable, for a period of at least a year, who has conducted STT or BAT training, as applicable, under this part for a year, or who has successfully completed a ''train the trainer'' course.

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

(1) 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 an individual who meets the requirements of paragraph (b)(4) of this section.

(2) These tests must use the alcohol testing devices (*e.g.,* EBT(s) or ASD(s)) that you will use as a BAT or STT.

(3) If you are an STT who will be using an ASD that indicates readings by

changes, contrasts, or other readings in color, you must demonstrate as part of the mock test that you are able to discern changes, contrasts, or readings correctly.

(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 BAT or STT before August 1, 2001, you were required to have met the requirements set forth in paragraphs (b) and (c) of this section, and you do not have to meet them again.

(2) If you become a BAT or STT on or after August 1, 2001, you must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform BAT or STT 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 alcohol testing 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 (b)(4) 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 alcohol testing procedures of this part by completing three consecutive error-free mock tests. The mock tests 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 tests 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 negotiating to use your services.

(h) *Other persons who may serve as BATs or STTs.* (1) Anyone meeting the requirements of this section to be a BAT may act as an STT, provided that the individual has demonstrated initial proficiency in the operation of the ASD that he or she is using, as provided in paragraph (c) of this section.

(2) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. They are not required to also complete the training requirements of this section in order to act as BATs. In order for a test conducted by such an officer to be accepted under DOT alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT or ASD that was used for the test.

§ 40.215 What information about the DER do employers have to provide to BATs and STTs?

As an employer, you must provide to the STTs and BATs the name and telephone number of the appropriate DER (and C/TPA, where applicable) to contact about any problems or issues that may arise during the testing process.

§ 40.217 Where is other information on the role of STTs and BATs found in this regulation?

You can find other information on the role and functions of STTs and BATs in the following sections of this part:

§ 40.3—Definitions.
§ 40.223—Responsibility for supervising employees being tested.
§§ 40.225–40.227—Use of the alcohol testing form.
§§ 40.241–40.245—Screening test procedures with ASDs and EBTs.
§§ 40.251–40.255—Confirmation test procedures.
§ 40.261—Refusals to test.
§§ 40.263–40.265—Insufficient saliva or breath.
§ 40.267—Problems requiring cancellation of tests.
§§ 40.269–40.271—Correcting problems in tests.

Subpart K—Testing Sites, Forms, Equipment and Supplies Used in Alcohol Testing

§ 40.221 Where does an alcohol test take place?

(a) A DOT alcohol test must take place at an alcohol testing site meeting the requirements of this section.

(b) If you are operating an alcohol testing site, you must ensure that it meets the security requirements of § 40.223.

(c) If you are operating an alcohol testing site, you must ensure that it provides visual and aural privacy to the employee being tested, sufficient to prevent unauthorized persons from seeing or hearing test results.

(d) If you are operating an alcohol testing site, you must ensure that it has all needed personnel, materials, equipment, and facilities to provide for the collection and analysis of breath and/or saliva samples, and a suitable clean surface for writing.

(e) If an alcohol testing site fully meeting all the visual and aural privacy requirements of paragraph (c) is not readily available, this part allows a reasonable suspicion or post-accident test to be conducted at a site that partially meets these requirements. In this case, the site must afford visual and aural privacy to the employee to the greatest extent practicable.

(f) An alcohol testing site can be in a medical facility, a mobile facility (*e.g.,* a van), a dedicated collection facility, or any other location meeting the requirements of this section.

§ 40.223 What steps must be taken to protect the security of alcohol testing sites?

(a) If you are a BAT, STT, or other person operating an alcohol testing site, you must prevent unauthorized personnel from entering the testing site.

(1) The only people you are to treat as authorized persons are employees being tested, BATs, STTs, and other alcohol testing site workers, DERs, employee representatives authorized by the employer (*e.g.,* on the basis of employer policy or labor-management agreement), and DOT agency representatives.

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

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

(b) As the BAT or STT, you must not allow any person other than you, the employee, or a DOT agency representative to actually witness the testing process (see §§ 40.241–40.255).

(c) If you are operating an alcohol testing site, you must ensure that when an EBT or ASD is not being used for testing, you store it in a secure place.

(d) If you are operating an alcohol testing site, you must ensure that no one other than BATs or other employees of the site have access to the site when an EBT is unsecured.

(e) As a BAT or STT, to avoid distraction that could compromise security, you are limited to conducting an alcohol test for only one employee at a time.

(1) When an EBT screening test on an employee indicates an alcohol

concentration of 0.02 or higher, and the same EBT will be used for the confirmation test, you are not allowed to use the EBT for a test on another employee before completing the confirmation test on the first employee.

(2) As a BAT who will conduct both the screening and the confirmation test, you are to complete the entire screening and confirmation process on one employee before starting the screening process on another employee.

(3) You are not allowed to leave the alcohol testing site while the testing process for a given employee is in progress, except to notify a supervisor or contact a DER for assistance in the case an employee or other person who obstructs, interferes with, or unnecessarily delays the testing process.

§ 40.225 What form is used for an alcohol test?

(a) The DOT Alcohol Testing Form (ATF) must be used for every DOT alcohol test. The ATF must be a three-part carbonless manifold form. The ATF is found in Appendix G to this part. You may view this form on the ODAPC web site (http://www.dot.gov/ost/dapc).

(b) As an employer in the DOT alcohol testing program, you are not permitted to modify or revise the ATF except as follows:

(1) You may include other information needed for billing purposes, outside the boundaries of the form.

(2) You may use a ATF directly generated by an EBT which omits the space for affixing a separate printed result to the ATF, provided the EBT prints the result directly on the ATF.

(3) You may use an ATF that has the employer's name, address, and telephone number preprinted. In addition, a C/TPA's name, address, and telephone number may be included, to assist with negative results.

(4) You may use an ATF in which all pages are printed on white paper. The white pages must have either clearly discernible borders in the specified color for each page or designation statements for each copy in the specified color.

(5) As a BAT or STT, you may add, on the ''Remarks'' line of the ATF, the name of the DOT agency under whose authority the test occurred.

(6) As a BAT or STT, you may use a ATF that has your name, address, and telephone number preprinted, but under no circumstances can your signature be preprinted.

(c) As an employer, you may use an equivalent foreign-language version of the ATF approved by ODAPC. You may use such a non-English language form only in a situation where both the employee and BAT/STT understand and can use the form in that language.

§ 40.227 May employers use the ATF for non-DOT tests, or non-DOT forms for DOT tests?

(a) No, as an employer, BAT, or STT, you are prohibited from using the ATF for non-DOT alcohol tests. You are also prohibited from using non-DOT forms for DOT alcohol tests. Doing either subjects you to enforcement action under DOT agency regulations.

(b) If the STT or BAT, 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 ATF), uses a non-DOT form for a DOT test, the use of a non-DOT form does not, in and of itself, require the employer or service agent to cancel the test. However, in order for the test to be considered valid, a signed statement must be obtained from the STT or BAT in accordance with § 40.271(b) .

§ 40.229 What devices are used to conduct alcohol screening tests?

EBTs and ASDs on the NHTSA conforming products lists (CPL) for evidential and non-evidential devices are the only devices you are allowed to use to conduct alcohol screening tests under this part. An ASD can be used only for screening tests for alcohol, and may not be used for confirmation tests.

§ 40.231 What devices are used to conduct alcohol confirmation tests?

(a) EBTs on the NHTSA CPL for evidential devices that meet the requirements of paragraph (b) of this section are the only devices you may use to conduct alcohol confirmation tests under this part. Note that, among devices on the CPL for EBTs, only those devices listed without an asterisk (*) are authorized for use in confirmation testing in the DOT alcohol testing program.

(b) To conduct a confirmation test, you must use an EBT that has the following capabilities:

(1) Provides a printed triplicate result (or three consecutive identical copies of a result) of each breath test;

(2) Assigns a unique number to each completed test, which the BAT and employee can read before each test and which is printed on each copy of the result;

(3) Prints, on each copy of the result, the manufacturer's name for the device, its serial number, and the time of the test;

(4) Distinguishes alcohol from acetone at the 0.02 alcohol concentration level;

(5) Tests an air blank; and

(6) Performs an external calibration check.

§ 40.233 What are the requirements for proper use and care of EBTs?

(a) As an EBT manufacturer, you must submit, for NHTSA approval, a quality assurance plan (QAP) for your EBT before NHTSA places the EBT on the CPL.

(1) Your QAP must specify the methods used to perform external calibration checks on the EBT, the tolerances within which the EBT is regarded as being in proper calibration, and the intervals at which these checks must be performed. In designating these intervals, your QAP must take into account factors like frequency of use, environmental conditions (*e.g.,* temperature, humidity, altitude) and type of operation (*e.g.,* stationary or mobile).

(2) Your QAP must also specify the inspection, maintenance, and calibration requirements and intervals for the EBT.

(b) As the manufacturer, you must include, with each EBT, instructions for its use and care consistent with the QAP.

(c) As the user of the EBT (*e.g.,* employer, service agent), you must do the following:

(1) You must follow the manufacturer's instructions (see paragraph (b) of this section), including performance of external calibration checks at the intervals the instructions specify.

(2) In conducting external calibration checks, you must use only calibration devices appearing on NHTSA's CPL for ''Calibrating Units for Breath Alcohol Tests.''

(3) If an EBT fails an external check of calibration, you must take the EBT out of service. You may not use the EBT again for DOT alcohol testing until it is repaired and passes an external calibration check.

(4) You must maintain records of the inspection, maintenance, and calibration of EBTs as provided in § 40.333(a)(2) .

(5) You must ensure that inspection, maintenance, and calibration of the EBT are performed by its manufacturer or a maintenance representative certified either by the manufacturer or by a state health agency or other appropriate state agency.

§ 40.235 What are the requirements for proper use and care of ASDs?

(a) As an ASD manufacturer, you must submit, for NHTSA approval, a QAP for your ASD before NHTSA places the ASD on the CPL. Your QAP must

specify the methods used for quality control checks, temperatures at which the ASD must be stored and used, the shelf life of the device, and environmental conditions (*e.g.,* temperature, altitude, humidity) that may affect the ASD's performance.

(b) As a manufacturer, you must include with each ASD instructions for its use and care consistent with the QAP. The instructions must include directions on the proper use of the ASD, and, where applicable the time within which the device must be read, and the manner in which the reading is made.

(c) As the user of the ADS (*e.g.,* employer, STT), you must follow the QAP instructions.

(d) You are not permitted to use an ASD that does not pass the specified quality control checks or that has passed its expiration date.

(e) As an employer, with respect to breath ASDs, you must also follow the device use and care requirements of § 40.233 .

Subpart L—Alcohol Screening Tests

§ 40.241 What are the first steps in any alcohol screening test?

As the BAT or STT you will take the following steps to begin all alcohol screening tests, regardless of the type of testing device you are using:

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's worksite, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing and the employee does not appear, the C/TPA must notify the employee that he or she has refused to test.

(b) Ensure that, when the employee enters the alcohol testing site, you begin the alcohol testing process without undue delay. For example, you must not wait because the employee says he or she is not ready or because an authorized employer or employee representative is delayed in arriving.

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

(2) If the employee needs medical attention (*e.g.,* an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to conduct a test.

(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employer individual) or a Federal, state, or local government (*e.g.,* a driver's license). You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(d) If the employee asks, provide your identification to the employee. Your identification must include your name and your employer's name but is not required to include your picture, address, or telephone number.

(e) Explain the testing procedure to the employee, including showing the employee the instructions on the back of the ATF.

(f) Complete Step 1 of the ATF.

(g) Direct the employee to complete Step 2 on the ATF and sign the certification. If the employee refuses to sign this certification, you must document this refusal on the ''Remarks'' line of the ATF and immediately notify the DER. This is a refusal to test.

§ 40.243 What is the procedure for an alcohol screening test using an EBT or non-evidential breath ASD?

As the BAT or STT, you must take the following steps:

(a) Select, or allow the employee to select, an individually wrapped or sealed mouthpiece from the testing materials.

(b) Open the individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

(c) Instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

(d) Show the employee the displayed test result.

(e) If the device is one that prints the test number, testing device name and serial number, time, and result directly onto the ATF, you must check to ensure that the information has been printed correctly onto the ATF.

(f) If the device is one that prints the test number, testing device name and serial number, time and result, but on a separate printout rather than directly onto the ATF, you must affix the printout of the information to the designated space on the ATF with tamper-evident tape or use a self-adhesive label that is tamper-evident.

(g) If the device is one that does not print the test number, testing device name and serial number, time, and result, or it is a device not being used with a printer, you must record this information in Step 3 of the ATF.

§ 40.245 What is the procedure for an alcohol screening test using a saliva ASD?

As the STT, you must take the following steps:

(a) Check the expiration date on the device and show it to the employee. You may not use the device after its expiration date.

(b) Open an individually wrapped or sealed package containing the device in the presence of the employee.

(c) Offer the employee the opportunity to use the device. If the employee uses it, you must instruct the employee to insert it into his or her mouth and use it in a manner described by the device's manufacturer.

(d) If the employee chooses not to use the device, or in all cases in which a new test is necessary because the device did not activate (see paragraph (g) of this section), you must insert the device into the employee's mouth and gather saliva in the manner described by the device's manufacturer. You must wear single-use examination or similar gloves while doing so and change them following each test.

(e) When the device is removed from the employee's mouth, you must follow the manufacturer's instructions regarding necessary next steps in ensuring that the device has activated.

(f)(1) If you were unable to successfully follow the procedures of paragraphs (c) through (e) of this section (*e.g.,* the device breaks, you drop the device on the floor), you must discard the device and conduct a new test using a new device.

(2) The new device you use must be one that has been under your control or that of the employer before the test.

(3) You must note on the ''Remarks'' line of the ATF the reason for the new test. (Note: You may continue using the same ATF with which you began the test.)

(4) You must offer the employee the choice of using the device or having you use it unless the employee, in the opinion of the STT or BAT, was responsible (*e.g.,* the employee dropped the device) for the new test needing to be conducted.

(5) If you are unable to successfully follow the procedures of paragraphs (c)

through (e) of this section on the new test, you must end the collection and put an explanation on the ''Remarks'' line of the ATF.

(6) You must then direct the employee to take a new test immediately, using an EBT for the screening test.

(g) If you are able to successfully follow the procedures of paragraphs (c)–(e) of this section, but the device does not activate, you must discard the device and conduct a new test, in the same manner as provided in paragraph (f) of this section. In this case, you must place the device into the employee's mouth to collect saliva for the new test.

(h) You must read the result displayed on the device no sooner than the device's manufacturer instructs. In all cases the result displayed must be read within 15 minutes of the test. You must then show the device and its reading to the employee and enter the result on the ATF.

(i) You must never re-use devices, swabs, gloves or other materials used in saliva testing.

(j) You must note the fact that you used a saliva ASD in Step 3 of the ATF.

§ 40.247 What procedures does the BAT or STT follow after a screening test result?

(a) If the test result is an alcohol concentration of less than 0.02, as the BAT or STT, you must do the following:

(1) Sign and date Step 3 of the ATF; and

(2) Transmit the result to the DER in a confidential manner, as provided in § 40.255 .

(b) If the test result is an alcohol concentration of 0.02 or higher, as the BAT or STT, you must direct the employee to take a confirmation test.

(1) If you are the BAT who will conduct the confirmation test, you must then conduct the test using the procedures beginning at § 40.251 .

(2) If you are not the BAT who will conduct the confirmation test, direct the employee to take a confirmation test, sign and date Step 3 of the ATF, and give the employee Copy 2 of the ATF.

(3) If the confirmation test will be performed at a different site from the screening test, you must take the following additional steps:

(i) Advise the employee not to eat, drink, put anything (*e.g.,* cigarette, chewing gum) into his or her mouth, or belch;

(ii) Tell the employee the reason for the waiting period required by § 40.251(a) (*i.e.,* to prevent an accumulation of mouth alcohol from leading to an artificially high reading);

(iii) Explain that following your instructions concerning the waiting period is to the employee's benefit;

(iv) Explain that the confirmation test will be conducted at the end of the waiting period, even if the instructions have not been followed;

(v) Note on the ''Remarks'' line of the ATF that the waiting period instructions were provided;

(vi) Instruct the person accompanying the employee to carry a copy of the ATF to the BAT who will perform the confirmation test; and

(vii) Ensure that you or another BAT, STT, or employer representative observe the employee as he or she is transported to the confirmation testing site. You must direct the employee not to attempt to drive a motor vehicle to the confirmation testing site.

(c) If the screening test is invalid, you must, as the BAT or STT, tell the employee the test is cancelled and note the problem on the ''Remarks'' line of the ATF. If practicable, repeat the testing process (see § 40. 271).

Subpart M—Alcohol Confirmation Tests

§ 40.251 What are the first steps in an alcohol confirmation test?

As the BAT for an alcohol confirmation test, you must follow these steps to begin the confirmation test process:

(a) You must carry out a requirement for a waiting period before the confirmation test, by taking the following steps:

(1) You must ensure that the waiting period lasts at least 15 minutes, starting with the completion of the screening test. After the waiting period has elapsed, you should begin the confirmation test as soon as possible, but not more than 30 minutes after the completion of the screening test.

(i) If the confirmation test is taking place at a different location from the screening test (see § 40.247(b)(3)) the time of transit between sites counts toward the waiting period if the STT or BAT who conducted the screening test provided the waiting period instructions.

(ii) If you cannot verify, through review of the ATF, that waiting period instructions were provided, then you must carry out the waiting period requirement.

(iii) You or another BAT or STT, or an employer representative, must observe the employee during the waiting period.

(2) Concerning the waiting period, you must tell the employee:

(i) Not to eat, drink, put anything (*e.g.,* cigarette, chewing gum) into his or her mouth, or belch;

(ii) The reason for the waiting period (*i.e.,* to prevent an accumulation of mouth alcohol from leading to an artificially high reading);

(iii) That following your instructions concerning the waiting period is to the employee's benefit; and

(iv) That the confirmation test will be conducted at the end of the waiting period, even if the instructions have not been followed.

(3) If you become aware that the employee has not followed the instructions, you must note this on the ''Remarks'' line of the ATF.

(b) If you did not conduct the screening test for the employee, you must require positive identification of the employee, explain the confirmation procedures, and use a new ATF. You must note on the ''Remarks'' line of the ATF that a different BAT or STT conducted the screening test.

(c) Complete Step 1 of the ATF.

(d) Direct the employee to complete Step 2 on the ATF and sign the certification. If the employee refuses to sign this certification, you must document this refusal on the ''Remarks'' line of the ATF and immediately notify the DER. This is a refusal to test.

(e) Even if more than 30 minutes have passed since the screening test result was obtained, you must begin the confirmation test procedures in § 40.253, not another screening test.

(f) You must note on the ''Remarks'' line of the ATF the time that elapsed between the two events, and if the confirmation test could not begin within 30 minutes of the screening test, the reason why.

(g) Beginning the confirmation test procedures after the 30 minutes have elapsed does not invalidate the screening or confirmation tests, but it may constitute a regulatory violation subject to DOT agency sanction.

§ 40.253 What are the procedures for conducting an alcohol confirmation test?

As the BAT conducting an alcohol confirmation test, you must follow these steps in order to complete the confirmation test process:

(a) In the presence of the employee, you must conduct an air blank on the EBT you are using before beginning the confirmation test and show the reading to the employee.

(1) If the reading is 0.00, the test may proceed. If the reading is greater than 0.00, you must conduct another air blank.

(2) If the reading on the second air blank is 0.00, the test may proceed. If the reading is greater than 0.00, you must take the EBT out of service.

(3) If you take an EBT out of service for this reason, no one may use it for testing until the EBT is found to be

within tolerance limits on an external check of calibration.

(4) You must proceed with the test of the employee using another EBT, if one is available.

(b) You must open a new individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

(c) You must ensure that you and the employee read the sequential test number displayed on the EBT.

(d) You must instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

(e) You must show the employee the result displayed on the EBT.

(f) You must show the employee the result and unique test number that the EBT prints out either directly onto the ATF or onto a separate printout.

(g) If the EBT provides a separate printout of the result, you must attach the printout to the designated space on the ATF with tamper-evident tape, or use a self-adhesive label that is tamper-evident.

§ 40.255 What happens next after the alcohol confirmation test result?

(a) After the EBT has printed the result of an alcohol confirmation test, you must, as the BAT, take the following additional steps:

(1) Sign and date Step 3 of the ATF.

(2) If the alcohol confirmation test result is lower than 0.02, nothing further is required of the employee. As the BAT, you must sign and date Step 3 of the ATF.

(3) If the alcohol confirmation test result is 0.02 or higher, direct the employee to sign and date Step 4 of the ATF. If the employee does not do so, you must note this on the ''Remarks'' line of the ATF. However, this is not considered a refusal to test.

(4) If the test is invalid, tell the employee the test is cancelled and note the problem on the ''Remarks'' line of the ATF. If practicable, conduct a re-test. (see § 40.271).

(5) Immediately transmit the result directly to the DER in a confidential manner.

(i) You may transmit the results using Copy 1 of the ATF, in person, by telephone, or by electronic means. In any case, you must immediately notify the DER of any result of 0.02 or greater by any means (*e.g.,* telephone or secure fax machine) that ensures the result is immediately received by the DER. You must not transmit these results through C/TPAs or other service agents.

(ii) If you do not make the initial transmission in writing, you must follow up the initial transmission with Copy 1 of the ATF.

(b) As an employer, you must take the following steps with respect to the receipt and storage of alcohol test result information:

(1) If you receive any test results that are not in writing (*e.g.,* by telephone or electronic means), you must establish a mechanism to establish the identity of the BAT sending you the results.

(2) You must store all test result information in a way that protects confidentiality.

Subpart N—Problems in Alcohol Testing

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

(a) As an employee, you are considered to have refused to take an alcohol test if you:

(1) Fail to appear for any test within a reasonable time, as determined by the employer, 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 C/TPA (see § 40.241(b)(1));

(2) Fail to remain at the testing site until the testing process is complete;

(3) Fail to attempt to provide a saliva or breath specimen, as applicable, for any test required by this part or DOT agency regulations;

(4) Fail to provide a sufficient breath specimen, and the physician has determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see § 40.265(c));

(5) Fail to undergo a medical examination or evaluation, as directed by the employer as part of the insufficient breath procedures outlined at § 40.265(c);

(6) Fail to sign the certification at Step 2 of the ATF (see § 40.241(b)(7)); or

(7) Fail to cooperate with any part of the testing process.

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

(c) As a BAT or an STT, or as the physician evaluating a ''shy lung'' situation, when an employee refuses to test as provided in paragraph (a) of this section, you must terminate the portion of the testing process in which you are involved, document the refusal on the ATF (or in a separate document which you cause to be attached to the form), immediately notify the DER by any means (*e.g.,* telephone or secure fax machine) that ensures the refusal notification is immediately received. You must make this notification directly to the DER (not using a C/TPA as an intermediary).

(d) 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 such a refusal.

§ 40.263 What happens when an employee is unable to provide a sufficient amount of saliva for an alcohol screening test?

(a) As the STT, you must take the following steps if an employee is unable to provide sufficient saliva to complete a test on a saliva screening device (*e.g.*, the employee does not provide sufficient saliva to activate the device).

(1) You must conduct a new screening test using a new screening device.

(2) If the employee refuses to make the attempt to complete the new test, you must discontinue testing, note the fact on the ''Remarks'' line of the ATF, and immediately notify the DER. This is a refusal to test.

(3) If the employee has not provided a sufficient amount of saliva to complete the new test, you must note the fact on the ''Remarks'' line of the ATF and immediately notify the DER.

(b) As the DER, when the STT informs you that the employee has not provided a sufficient amount of saliva (see paragraph (a)(3) of this section), you must immediately arrange to administer an alcohol test to the employee using an EBT or other breath testing device.

§ 40.265 What happens when an employee is unable to provide a sufficient amount of breath for an alcohol test?

(a) If an employee does not provide a sufficient amount of breath to permit a valid breath test, you must take the steps listed in this section.

(b) As the BAT or STT, you must instruct the employee to attempt again to provide a sufficient amount of breath and about the proper way to do so.

(1) If the employee refuses to make the attempt, you must discontinue the test, note the fact on the ''Remarks'' line of the ATF, and immediately notify the DER. This is a refusal to test.

(2) If the employee again attempts and fails to provide a sufficient amount of breath, you may provide another opportunity to the employee to do so if you believe that there is a strong likelihood that it could result in providing a sufficient amount of breath.

(3) When the employee's attempts under paragraph (b)(2) of this section

have failed to produce a sufficient amount of breath, you must note the fact on the ''Remarks'' line of the ATF and immediately notify the DER.

(4) If you are using an EBT that has the capability of operating manually, you may attempt to conduct the test in manual mode.

(5) If you are qualified to use a saliva ASD and you are in the screening test stage, you may change to a saliva ASD only to complete the screening test.

(c) As the employer, when the BAT or STT informs you that the employee has not provided a sufficient amount of breath, you must direct the employee to obtain, within five days, an evaluation from a licensed physician who is acceptable to you and who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen.

(1) You are required to provide the physician who will conduct the evaluation with the following information and instructions:

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

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

(iii) That the physician must provide you with a signed statement of his or her conclusions; and

(iv) That the physician, in his or her reasonable medical judgment, must base those conclusions on one of the following determinations:

(A) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of breath. The physician must not include in the signed statement detailed information on the employee's medical condition. In this case, the test is cancelled.

(B) 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 breath. This constitutes a refusal to test.

(C) For purposes of paragraphs (c)(1)(iv)(A) and (B) of this section, a medical condition includes an ascertainable physiological condition (*e.g.*, a respiratory system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or hyperventilation.

(2) As the physician making the evaluation, after making your determination, you must provide a written statement of your conclusions and the basis for them to the DER directly (and not through a C/TPA acting as an itermediary). You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(3) Upon receipt of the report from the examining physician, as the DER you must immediately inform the employee and take appropriate action based upon your DOT agency regulations.

§ 40.267 What problems always cause an alcohol test to be cancelled?

As an employer, a BAT, or an STT, you must cancel an alcohol test if any of the following problems occur. These are ''fatal flaws.'' You must inform the DER that the test was cancelled and must be treated as if the test never occurred. These problems are:

(a) In the case of a screening test conducted on a saliva ASD:

(1) The STT reads the result either sooner than or later than the time allotted by the manufacturer (see § 40.245(h));

(2) The device does not activate (see § 40.245(g)); or

(3) The device is used for a test after the expiration date printed on its package (see § 40.245(a)).

(b) In the case of a screening or confirmation test conducted on an EBT, the sequential test number or alcohol concentration displayed on the EBT is not the same as the sequential test number or alcohol concentration on the printed result (see § 40.253(c), (e) and (f)).

(c) In the case of a confirmation test:

(1) The BAT conducts the confirmation test before the end of the minimum 15-minute waiting period (see § 40.251(a)(1));

(2) The BAT does not conduct an air blank before the confirmation test (see § 40.253(a));

(3) There is not a 0.00 result on the air blank conducted before the confirmation test (see § 40.253(a)(1) and (2));

(4) The EBT does not print the result (see § 40.253(f)); or

(5) The next external calibration check of the EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this case, every result of 0.02 or above obtained on the EBT since the last valid external calibration check is cancelled (see § 40.233(a)(1) and (d)).

§ 40.269 What problems cause an alcohol test to be cancelled unless they are corrected?

As a BAT or STT, or employer, you must cancel an alcohol test if any of the following problems occur, unless they are corrected. These are ''correctable flaws.'' These problems are:

(a) The BAT or STT does not sign the ATF (see § § 40.247(a)(1) and 40.255(a)(1)).

(b) The BAT or STT fails to note on the ''Remarks'' line of the ATF that the employee has not signed the ATF after the result is obtained (see § 40.255(a)(2)).

(c) The BAT or STT uses a non-DOT form for the test (see § 40.225(a)).

§ 40.271 How are alcohol testing problems corrected?

(a) As a BAT or STT, you have the responsibility of trying to complete successfully an alcohol test for each employee.

(1) If, during or shortly after the testing process, you become aware of any event that will cause the test to be cancelled (see § 40.267), you must try to correct the problem promptly, if practicable. You may repeat the testing process as part of this effort.

(2) If repeating the testing process is necessary, you must begin a new test as soon as possible. You must use a new ATF, a new sequential test number, and, if needed, a new ASD and/or a new EBT. It is permissible to use additional technical capabilities of the EBT (*e.g.*, manual operation) if you have been trained to do so in accordance with § 40.213(c) .

(3) If repeating the testing process is necessary, you are not limited in the number of attempts to complete the test, provided that the employee is making a good faith effort to comply with the testing process.

(4) If another testing device is not available for the new test at the testing site, you must immediately notify the DER and advise the DER that the test could not be completed. As the DER who receives this information, you must make all reasonable efforts to ensure that the test is conducted at another testing site as soon as possible.

(b) If, as an STT, BAT, employer or other service agent administering the testing process, you become aware of a ''correctable flaw'' (see § 40.269) that has not already been corrected, you must take all practicable action to correct the problem so that the test is not cancelled.

(1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply in writing the missing information and a signed statement that it is true and accurate. For example, suppose you are a BAT and you forgot to make a notation on the ''Remarks'' line of the ATF that

the employee did not sign the certification. You would, when the problem is called to your attention, supply a signed statement that the employee failed or refused to sign the certification after the result was obtained, and that your signed statement is true and accurate.

(2) If the problem is the use of a non-DOT form, you must, as the person responsible for the use of the incorrect form, certify in writing that the incorrect form contains all the information needed for a valid DOT alcohol test. You must also provide a signed statement that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond your control, and the steps you have taken to prevent future use of non-DOT forms for DOT tests. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

(c) If you cannot correct the problem, you must cancel the test.

§ 40.273 What is the effect of a cancelled alcohol test?

(a) A cancelled alcohol test is neither positive nor negative.

(1) As an employer, you must not attach to a cancelled test the consequences of a test result that is 0.02 or greater (*e.g.*, removal from a safety-sensitive position).

(2) As an employer, you must not use a cancelled test in a situation where an employee needs a test result that is below 0.02 (*e.g.*, in the case of a return-to-duty or follow-up test to authorize the employee to perform safety-sensitive functions).

(3) As an employer, you must not direct a recollection for an employee because a test has been cancelled, except in the situations cited in paragraph (a)(2) of this section or other provisions of this part.

(b) A cancelled test does not count toward compliance with DOT requirements, such as a minimum random testing rate.

(c) When a test must be cancelled, if you are the BAT, STT, or other person who determines that the cancellation is necessary, you must inform the affected DER within 48 hours of the cancellation.

(d) A cancelled DOT test does not provide a valid basis for an employer to conduct a non-DOT test (*i.e.*, a test under company authority).

§ 40.275 What is the effect of procedural problems that are not sufficient to cancel an alcohol test?

(a) As an STT, BAT, employer, or a service agent administering the testing process, you must document any errors in the testing process of which you become aware, even if they are not ''fatal flaws'' or ''correctable flaws'' listed in this subpart. Decisions about the ultimate impact of these errors will be determined by administrative or legal proceedings, subject to the limitation of paragraph (b) of this section.

(b) No person concerned with the testing process may declare a test cancelled based on a mistake in the process that does not have a significant adverse effect on the right of the employee to a fair and accurate test. For example, it is inconsistent with this part to cancel a test based on a minor administrative mistake (*e.g.*, the omission of the employee's middle initial) or an error that does not affect employee protections under this part. Nor does the failure of an employee to sign in Step 4 of the ATF result in the cancellation of the test. Nor is a test to be cancelled on the basis of a claim by an employee that he or she was improperly selected for testing.

(c) As an employer, these errors, even though not sufficient to cancel an alcohol test result, may subject you to enforcement action under DOT agency regulations.

§ 40.277 Are alcohol tests other than saliva or breath permitted under these regulations?

No, other types of alcohol tests (*e,g.,* blood and urine) are not authorized for testing done under this part. Only saliva or breath for screening tests and breath for confirmation tests using approved devices are permitted.

Subpart O—Substance Abuse Professionals and the Return-to-Duty Process

§ 40.281 Who is qualified to act as a SAP?

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

(a) *Credentials.* You must have one of the following credentials:

(1) You are a licensed physician (Doctor of Medicine or Osteopathy);

(2) You are a licensed or certified social worker;

(3) You are a licensed or certified psychologist;

(4) You are a licensed or certified employee assistance professional; or

(5) You are a drug and alcohol counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC) or by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse (ICRC).

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

(1) You must be knowledgeable about and have clinical experience in the diagnosis and treatment of alcohol and controlled substances-related disorders.

(2) You must be knowledgeable about the SAP function as it relates to employer interests in safety-sensitive duties.

(3) You must be knowledgeable about this part, the DOT agency regulations applicable to the employers for whom you evaluate employees, and the DOT SAP Guidelines, and you keep current on any changes to these materials. These documents are available from ODAPC (Department of Transportation, 400 7th Street, SW., Room 10403, 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) Background, rationale, and coverage of the Department's drug and alcohol testing program;

(ii) 49 CFR Part 40 and DOT agency drug and alcohol testing rules;

(iii) Key DOT drug testing requirements, including collections, laboratory testing, MRO review, and problems in drug testing;

(iv) Key DOT alcohol testing requirements, including the testing process, the role of BATs and STTs, and problems in alcohol tests;

(v) SAP qualifications and prohibitions;

(vi) The role of the SAP in the return-to-duty process, including the initial employee evaluation, referrals for education and/or treatment, the follow-up evaluation, continuing treatment recommendations, and the follow-up testing plan;

(vii) SAP consultation and communication with employers, MROs, and treatment providers;

(viii) Reporting and recordkeeping requirements;

(ix) Issues that SAPs confront in carrying out their duties under the program.

(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 professional or training organization. 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 a SAP before August 1, 2001, you must meet the qualification training requirement no later than December 31, 2003.

(ii) If you become a SAP between August 1, 2001, and December 31, 2003, you must meet the qualification training requirement no later than December 31, 2003.

(iii) If you become a SAP on or after January 1, 2004, you must meet the qualification training requirement before you begin to perform SAP functions.

(d) *Continuing education.* During each three-year period from the date on which you satisfactorily complete the examination under paragraph (c)(2) of this section, you must complete continuing education consisting of at least 12 professional development hours (*e.g.*, CEUs) relevant to performing SAP functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in SAP practice, pertaining to the DOT program, since the time you met the qualification training requirements of this section.

(2) Your continuing education activities must include documentable assessment tools to assist you in determining whether you have adequately learned the material.

(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 contemplating using your services.

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

(a) If you represent a certification organization that wants DOT to authorize its certified drug and alcohol counselors to be added to § 40.281(a)(5), you may submit a written petition to DOT requesting a review of your petition for inclusion.

(b) You must obtain the National Commission for Certifying Agencies (NCCA) accreditation before DOT will act on your petition.

(c) You must also meet the minimum requirements of Appendix E to this part before DOT will act on your petition.

§ 40.285 When is a SAP evaluation required?

(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.

§ 40.287 What information is an employer required to provide concerning SAP services to an employee who has a DOT drug and alcohol regulation violation?

As an employer, you must provide to each employee (including an applicant or new employee) who violates a DOT drug and alcohol regulation a listing of SAPs readily available to the employee and acceptable to you, with names, addresses, and telephone numbers. You cannot charge the employee any fee for compiling or providing this list. You may provide this list yourself or through a C/TPA or other service agent.

§ 40.289 Are employers required to provide SAP and treatment services to employees?

(a) As an employer, you are not required to provide a SAP evaluation or any subsequent recommended education or treatment for an employee who has violated a DOT drug and alcohol regulation.

(b) However, if you offer that employee an opportunity to return to a DOT safety-sensitive duty following a violation, you must, before the employee again performs that duty, ensure that the employee receives an evaluation by a SAP meeting the requirements of § 40.281 and that the employee successfully complies with the SAP's evaluation recommendations.

(c) Payment for SAP evaluations and services is left for employers and employees to decide and may be governed by existing management-labor agreements and health care benefits.

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

(a) As a SAP, you are charged with:

(1) Making a face-to-face clinical assessment and evaluation to determine what assistance is needed by the employee to resolve problems associated with alcohol and/or drug use;

(2) Referring the employee to an appropriate education and/or treatment program;

(3) Conducting a face-to-face follow-up evaluation to determine if the employee has actively participated in the education and/or treatment program and has demonstrated successful compliance with the initial assessment and evaluation recommendations;

(4) Providing the DER with a follow-up drug and/or alcohol testing plan for the employee; and

(5) Providing the employee and employer with recommendations for continuing education and/or treatment.

(b) As a SAP, you are not an advocate for the employer or employee. Your function is to protect the public interest in safety by professionally evaluating the employee and recommending appropriate education/treatment, follow-up tests, and aftercare.

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

As a SAP, for every employee who comes to you following a DOT drug and alcohol regulation violation, you must accomplish the following:

(a) Provide a comprehensive face-to-face assessment and clinical evaluation.

(b) Recommend a course of education and/or treatment with which the employee must demonstrate successful compliance prior to returning to DOT safety-sensitive duty.

(1) You must make such a recommendation for every individual who has violated a DOT drug and alcohol regulation.

(2) You must make a recommendation for education and/or treatment that will, to the greatest extent possible, protect public safety in the event that the employee returns to the performance of safety-sensitive functions.

(c) Appropriate education may include, but is not limited to, self-help groups (*e.g.,* Alcoholics Anonymous) and community lectures, where attendance can be independently verified, and bona fide drug and alcohol education courses.

(d) Appropriate treatment may include, but is not limited to, in-patient hospitalization, partial in-patient treatment, out-patient counseling programs, and aftercare.

(e) You must provide a written report directly to the DER highlighting your specific recommendations for assistance (see § 40.311(c)).

(f) For purposes of your role in the evaluation process, you must assume that a verified positive test result has conclusively established that the employee committed a DOT drug and

alcohol regulation violation. You must not take into consideration in any way, as a factor in determining what your recommendation will be, any of the following:

(1) A claim by the employee that the test was unjustified or inaccurate;

(2) Statements by the employee that attempt to mitigate the seriousness of a violation of a DOT drug or alcohol regulation (*e.g.,* related to assertions of use of hemp oil, ''medical marijuana'' use, ''contact positives,'' poppy seed ingestion, job stress); or

(3) Personal opinions you may have about the justification or rationale for drug and alcohol testing.

(g) In the course of gathering information for purposes of your evaluation in the case of a drug-related violation, you may consult with the MRO. As the MRO, you are required to cooperate with the SAP and provide available information the SAP requests. It is not necessary to obtain the consent of the employee to provide this information.

§ 40.295 May employees or employers seek a second SAP evaluation if they disagree with the first SAP's recommendations?

(a) As an employee with a DOT drug and alcohol regulation violation, when you have been evaluated by a SAP, you must not seek a second SAP's evaluation in order to obtain another recommendation.

(b) As an employer, you must not seek a second SAP's evaluation if the employee has already been evaluated by a qualified SAP. If the employee, contrary to paragraph (a) of this section, has obtained a second SAP evaluation, as an employer you may not rely on it for any purpose under this part.

§ 40.297 Does anyone have the authority to change a SAP's initial evaluation?

(a) Except as provided in paragraph (b) of this section, no one (*e.g.,* an employer, employee, a managed-care provider, any service agent) may change in any way the SAP's evaluation or recommendations for assistance. For example, a third party is not permitted to make more or less stringent a SAP's recommendation by changing the SAP's evaluation or seeking another SAP's evaluation.

(b) The SAP who made the initial evaluation may modify his or her initial evaluation and recommendations based on new or additional information (*e.g.,* from an education or treatment program).

§ 40.299 What is the SAP's role and what are the limits on a SAP's discretion in referring employees for education and treatment?

(a) As a SAP, upon your determination of the best recommendation for assistance, you will serve as a referral source to assist the employee's entry into a education and/or treatment program.

(b) To prevent the appearance of a conflict of interest, you must not refer an employee requiring assistance to your private practice or to a person or organization from which you receive payment or to a person or organization in which you have a financial interest. You are precluded from making referrals to entities with which you are financially associated.

(c) There are four exceptions to the prohibitions contained in paragraph (b) of this section. You may refer an employee to any of the following providers of assistance, regardless of your relationship with them:

(1) A public agency (*e.g.,* treatment facility) operated by a state, county, or municipality;

(2) The employer or a person or organization under contract to the employer to provide alcohol or drug treatment and/or education services (*e.g.,* the employer's contracted treatment provider);

(3) The sole source of therapeutically appropriate treatment under the employee's health insurance program (*e.g.,* the single substance abuse in-patient treatment program made available by the employee's insurance coverage plan); or

(4) The sole source of therapeutically appropriate treatment reasonably available to the employee (*e.g.,* the only treatment facility or education program reasonably located within the general commuting area).

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

(a) As a SAP, after you have prescribed assistance under § 40.293, you must re-evaluate the employee to determine if the employee has successfully carried out your education and/or treatment recommendations.

(1) This is your way to gauge for the employer the employee's ability to demonstrate successful compliance with the education and/or treatment plan.

(2) Your evaluation may serve as one of the reasons the employer decides to return the employee to safety-sensitive duty.

(b) As the SAP making the follow-up evaluation determination, you must:

(1) Confer with or obtain appropriate documentation from the appropriate education and/or treatment program professionals where the employee was referred; and

(2) Conduct a face-to-face clinical interview with the employee to determine if the employee demonstrates successful compliance with your initial evaluation recommendations.

(c) (1) If the employee has demonstrated successful compliance, you must provide a written report directly to the DER highlighting your clinical determination that the employee has done so with your initial evaluation recommendation (see § 40.311(d)).

(2) You may determine that an employee has successfully demonstrated compliance even though the employee has not yet completed the full regimen of education and/or treatment you recommended or needs additional asssitance. For example, if the employee has successfully completed the 30-day in-patient program you prescribed, you may make a ''successful compliance'' determination even though you conclude that the employee has not yet completed the out-patient counseling you recommended or should continue in an aftercare program.

(d)(1) As the SAP, if you believe, as a result of the follow-up evaluation, that the employee has not demonstrated successful compliance with your recommendations, you must provide written notice directly to the DER (see § 40.311(e)).

(2) As an employer who receives the SAP's written notice that the employee has not successfully complied with the SAP's recommendations, you must not return the employee to the performance of safety-sensitive duties.

(3) As the SAP, you may conduct additional follow-up evaluation(s) if the employer determines that doing so is consistent with the employee's progress as you have reported it and with the employer's policy and/or labor-management agreements.

(4) As the employer, following a SAP report that the employee has not demonstrated successful compliance, you may take personnel action consistent with your policy and/or labor-management agreements.

§ 40.303 What happens if the SAP believes the employee needs additional treatment, aftercare, or support group services even after the employee returns to safety-sensitive duties?

(a) As a SAP, if you believe that ongoing services (in addition to follow-up tests) are needed to assist an employee to maintain sobriety or abstinence from drug use after the

employee resumes the performance of safety-sensitive duties, you must provide recommendations for these services in your follow-up evaluation report (see § 40.311(d)(10)).

(b) As an employer receiving a recommendation for these services from a SAP, you may, as part of a return-to-duty agreement with the employee, require the employee to participate in the recommended services. You may monitor and document the employee's participation in the recommended services. You may also make use of SAP and employee assistance program (EAP) services in assisting and monitoring employees' compliance with SAP recommendations. Nothing in this section permits an employer to fail to carry out its obligations with respect to follow-up testing (see § 40.309).

(c) As an employee, you are obligated to comply with the SAP's recommendations for these services. If you fail or refuse to do so, you may be subject to disciplinary action by your employer.

§ 40.305 How does the return-to-duty process conclude?

(a) As the employer, if you decide that you want to permit the employee to return to the performance of safety-sensitive functions, you must ensure that the employee takes a return-to-duty test. This test cannot occur until after the SAP has determined that the employee has successfully complied with prescribed education and/or treatment. The employee must have a negative drug test result and/or an alcohol test with an alcohol concentration of less than 0.02 before resuming performance of safety-sensitive duties.

(b) As an employer, you must not return an employee to safety-sensitive duties until the employee meets the conditions of paragraph (a) of this section. However, you are not required to return an employee to safety-sensitive duties because the employee has met these conditions. That is a personnel decision that you have the discretion to make, subject to collective bargaining agreements or other legal requirements.

(c) As a SAP or MRO, you must not make a ''fitness for duty'' determination as part of this re-evaluation unless required to do so under an applicable DOT agency regulation. It is the employer, rather than you, who must decide whether to put the employee back to work in a safety-sensitive position.

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

(a) As a SAP, for each employee who has committed a DOT drug or alcohol regulation violation, and who seeks to resume the performance of safety-sensitive functions, you must establish a written follow-up testing plan. You do not establish this plan until after you determine that the employee has successfully complied with your recommendations for education and/or treatment.

(b) You must present a copy of this plan directly to the DER (see § 40.311(d)(9)).

(c) You are the sole determiner of the number and frequency of follow-up tests and whether these tests will be for drugs, alcohol, or both, unless otherwise directed by the appropriate DOT agency regulation. For example, if the employee had a positive drug test, but your evaluation or the treatment program professionals determined that the employee had an alcohol problem as well, you should require that the employee have follow-up tests for both drugs and alcohol.

(d) However, you must, at a minimum, direct that the employee be subject to six unannounced follow-up tests in the first 12 months of safety-sensitive duty following the employee's return to safety-sensitive functions.

(1) You may require a greater number of follow-up tests during the first 12-month period of safety-sensitive duty (*e.g.*, you may require one test a month during the 12-month period; you may require two tests per month during the first 6-month period and one test per month during the final 6-month period).

(2) You may also require follow-up tests during the 48 months of safety-sensitive duty following this first 12-month period.

(3) You are not to establish the actual dates for the follow-up tests you prescribe. The decision on specific dates to test is the employer's.

(4) As the employer, you must not impose additional testing requirements (*e.g.*, under company authority) on the employee that go beyond the SAP's follow-up testing plan.

(e) The requirements of the SAP's follow-up testing plan ''follow the employee'' to subsequent employers or through breaks in service.

Example 1 to Paragraph (e): The employee returns to duty with Employer A. Two months afterward, after completing the first two of six follow-up tests required by the SAP's plan, the employee quits his job with Employer A and begins to work in a similar position for Employer B. The employee remains obligated to complete the four additional tests during the next 10 months of safety-sensitive duty, and Employer B is responsible for ensuring that the employee does so. Employer B learns of this obligation through the inquiry it makes under § 40.25.

Example 2 to Paragraph (e): The employee returns to duty with Employer A. Three months later, after the employee completes the first two of six follow-up tests required by the SAP's plan, Employer A lays the employee off for economic or seasonal employment reasons. Four months later, Employer A recalls the employee. Employer A must ensure that the employee completes the remaining four follow-up tests during the next nine months.

(f) As the SAP, you may modify the determinations you have made concerning follow-up tests. For example, even if you recommended follow-up testing beyond the first 12-months, you can terminate the testing requirement at any time after the first year of testing. You must not, however, modify the requirement that the employee take at least six follow-up tests within the first 12 months after returning to the performance of safety-sensitive functions.

§ 40.309 What are the employer's responsibilities with respect to the SAP's directions for follow-up tests?

(a) As the employer, you must carry out the SAP's follow-up testing requirements. You may not allow the employee to continue to perform safety-sensitive functions unless follow-up testing is conducted as directed by the SAP.

(b) You should schedule follow-up tests on dates of your own choosing, but you must ensure that the tests are unannounced with no discernable pattern as to their timing, and that the employee is given no advance notice.

(c) You cannot substitute any other tests (*e.g.*, those carried out under the random testing program) conducted on the employee for this follow-up testing requirement.

(d) You cannot count a follow-up test that has been cancelled as a completed test. A cancelled follow-up test must be recollected.

§ 40.311 What are the requirements concerning SAP reports?

(a) As the SAP conducting the required evaluations, you must send the written reports required by this section in writing directly to the DER and not to a third party or entity for forwarding to the DER (except as provided in § 40.355(e)). You may, however, forward the document simultaneously to the DER and to a C/TPA.

(b) As an employer, you must ensure that you receive SAP written reports directly from the SAP performing the evaluation and that no third party or

entity changed the SAP's report in any way.

(c) The SAP's written report, following an initial evaluation that determines what level of assistance is needed to address the employee's drug and/or alcohol problems, must be on the SAP's own letterhead (and not the letterhead of another service agent) signed and dated by the SAP, and must contain the following delineated items:

(1) Employee's name and SSN;

(2) Employer's name and address;

(3) Reason for the assessment (specific violation of DOT regulations and violation date);

(4) Date(s) of the assessment;

(5) SAP's education and/or treatment recommendation; and

(6) SAP's telephone number.

(d) The SAP's written report concerning a follow-up evaluation that determines the employee has demonstrated successful compliance must be on the SAP's own letterhead (and not the letterhead of another service agent), signed by the SAP and dated, and must contain the following items:

(1) Employee's name and SSN;

(2) Employer's name and address;

(3) Reason for the initial assessment (specific violation of DOT regulations and violation date);

(4) Date(s) of the initial assessment and synopsis of the treatment plan;

(5) Name of practice(s) or service(s) providing the recommended education and/or treatment;

(6) Inclusive dates of employee's program participation;

(7) Clinical characterization of employee's program participation;

(8) SAP's clinical determination as to whether the employee has demonstrated successful compliance;

(9) Follow-up testing plan;

(10) Employee's continuing care needs with specific treatment, aftercare, and/or support group services recommendations; and

(11) SAP's telephone number.

(e) The SAP's written report concerning a follow-up evaluation that determines the employee has not demonstrated successful compliance must be on the SAP's own letterhead (and not the letterhead of another service agent), signed by the SAP and dated, and must contain the following items:

(1) Employee's name and SSN;

(2) Employer's name and address;

(3) Reason for the initial assessment (specific DOT violation and date);

(4) Date(s) of initial assessment and synopsis of treatment plan;

(5) Name of practice(s) or service(s) providing the recommended education and/or treatment;

(6) Inclusive dates of employee's program participation;

(7) Clinical characterization of employee's program participation;

(8) Date(s) of the first follow-up evaluation;

(9) Date(s) of any further follow-up evaluation the SAP has scheduled;

(10) SAP's clinical reasons for determining that the employee has not demonstrated successful compliance; and

(11) SAP's telephone number.

(f) As a SAP, you must also provide these written reports directly to the employee if the employee has no current employer and to the gaining DOT regulated employer in the event the employee obtains another transportation industry safety-sensitive position.

(g) As a SAP, you are to maintain copies of your reports to employers for 5 years, and your employee clinical records in accordance with Federal, state, and local laws regarding record maintenance, confidentiality, and release of information. You must make these records available, on request, to DOT agency representatives (*e.g.*, inspectors conducting an audit or safety investigation) and representatives of the NTSB in an accident investigation.

(h) As an employer, you must maintain your reports from SAPs for 5 years from the date you received them.

§ 40.313 Where is other information on SAP functions and the return-to-duty process found in this regulation?

You can find other information on the role and functions of SAPs in the following sections of this part:

§ 40.3—Definition.

§ 40.347—Service agent assistance with SAP-required follow-up testing.

§ 40.355—Transmission of SAP reports.

§ 40.329(c)—Making SAP reports available to employees on request.

Appendix E to Part 40—SAP Equivalency Requirements for Certification Organizations.

Subpart P—Confidentiality and Release of Information

§ 40.321 What is the general confidentiality rule for drug and alcohol test information?

Except as otherwise provided in this subpart, as a service agent or employer participating in the DOT drug or alcohol testing process, you are prohibited from releasing individual test results or medical information about an employee to third parties without the employee's specific written consent.

(a) A ''third party'' is any person or organization to whom other subparts of this regulation do not explicitly authorize or require the transmission of information in the course of the drug or alcohol testing process.

(b) ''Specific written consent'' means a statement signed by the employee that he or she agrees to the release of a particular piece of information to a particular, explicitly identified, person or organization at a particular time. ''Blanket releases,'' in which an employee agrees to a release of a category of information (*e.g.,* all test results) or to release information to a category of parties (*e.g.,* other employers who are members of a C/TPA, companies to which the employee may apply for employment), are prohibited under this part.

§ 40.323 May program participants release drug or alcohol test information in connection with legal proceedings?

(a) As an employer, you may release information pertaining to an employee's drug or alcohol test without the employee's consent in certain legal proceedings.

(1) These proceedings include a lawsuit (*e.g.,* a wrongful discharge action), grievance (*e.g.,* an arbitration concerning disciplinary action taken by the employer), or administrative proceeding (*e.g.,* an unemployment compensation hearing) brought by, or on behalf of, an employee and resulting from a positive DOT drug or alcohol test or a refusal to test (including, but not limited to, adulterated or substituted test results).

(2) These proceedings also include a criminal or civil action resulting from an employee's performance of safety-sensitive duties, in which a court of competent jurisdiction determines that the drug or alcohol test information sought is relevant to the case and issues an order directing the employer to produce the information. For example, in personal injury litigation following a truck or bus collision, the court could determine that a post-accident drug test result of an employee is relevant to determining whether the driver or the driver's employer was negligent. The employer is authorized to respond to the court's order to produce the records.

(b) In such a proceeding, you may release the information to the decisionmaker in the proceeding (*e.g.,* the court in a lawsuit). You may release the information only with a binding stipulation that the decisionmaker to whom it is released will make it available only to parties to the proceeding.

(c) If you are a service agent, and the employer requests its employee's drug or alcohol testing information from you to use in a legal proceeding as authorized in paragraph (a) of this

section (*e.g.,* the laboratory's data package), you must provide the requested information to the employer.

(d) As an employer or service agent, you must immediately notify the employee in writing of any information you release under this section.

§ 40.325 [Reserved]

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

(a) As the MRO, you must, except as provided in paragraph (c) of this section, report drug test results and medical information you learned as part of the verification process to third parties without the employee's consent if you determine, in your reasonable medical judgment, that:

(1) The information is likely to result in the employee being determined to be medically unqualified under an applicable DOT agency regulation; or

(2) The information indicates that continued performance by the employee of his or her safety-sensitive function is likely to pose a significant safety risk.

(b) The third parties to whom you are authorized to provide information by this section include the employer, a physician or other health care provider responsible for determining the medical qualifications of the employee under an applicable DOT agency safety regulation, a SAP evaluating the employee as part of the return to duty process (see § 40.293(g)), a DOT agency, or the National Transportation Safety Board in the course of an accident investigation.

(c) If the law of a foreign country (*e.g.,* Canada) prohibits you from providing medical information to the employer, you may comply with that prohibition.

§ 40.329 What information must laboratories, MROs, and other service agents release to employees?

(a) As an MRO or service agent you must provide, within 10 business days of receiving a written request from an employee, copies of any records pertaining to the employee's use of alcohol and/or drugs, including records of the employee's DOT-mandated drug and/or alcohol tests. You may charge no more than the cost of preparation and reproduction for copies of these records.

(b) As a laboratory, you must provide, within 10 business days of receiving a written request from an employee, and made through the MRO, the records relating to the results of the employee's drug test (*i.e.,* laboratory report and data package). You may charge no more than the cost of preparation and reproduction for copies of these records.

(c) As a SAP, you must make available to an employee, on request, a copy of all SAP reports (see § 40.311).

§ 40.331 To what additional parties must employers and service agents release information?

As an employer or service agent you must release information under the following circumstances:

(a) If you receive a specific, written consent from an employee authorizing the release of information about that employee's drug or alcohol tests to an identified person, you must provide the information to the identified person. For example, as an employer, when you receive a written request from a former employee to provide information to a subsequent employer, you must do so. In providing the information, you must comply with the terms of the employee's consent.

(b) If you are an employer, you must, upon request of DOT agency representatives, provide the following:

(1) Access to your facilities used for this part and DOT agency drug and alcohol program functions.

(2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations.

(c) If you are a service agent, you must, upon request of DOT agency representatives, provide the following:

(1) Access to your facilities used for this part and DOT agency drug and alcohol program functions.

(2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations.

(d) If requested by the National Transportation Safety Board as part of an accident investigation, you must provide information concerning post-accident tests administered after the accident.

(e) If requested by a Federal, state or local safety agency with regulatory authority over you or the employee, you must provide drug and alcohol test records concerning the employee.

(f) Except as otherwise provided in this part, as a laboratory you must not release or provide a specimen or a part of a specimen to a requesting party, without first obtaining written consent from ODAPC. If a party seeks a court order directing you to release a specimen or part of a specimen contrary to any provision of this part, you must take necessary legal steps to contest the issuance of the order (*e.g.,* seek to quash a subpoena, citing the requirements of § 40.13). This part does not require you to disobey a court order, however.

§ 40.333 What records must employers keep?

(a) As an employer, you must keep the following records for the following periods of time:

(1) You must keep the following records for five years:

(i) Records of employee alcohol test results indicating an alcohol concentration of 0.02 or greater;

(ii) Records of employee verified positive drug test results;

(iii) Documentation of refusals to take required alcohol and/or drug tests (including substituted or adulterated drug test results);

(iv) SAP reports; and

(v) All follow-up tests and schedules for follow-up tests.

(2) You must keep records for three years of information obtained from previous employers under § 40.25 concerning drug and alcohol test results of employees.

(3) You must keep records of the inspection, maintenance, and calibration of EBTs, for two years.

(4) You must keep records of negative and cancelled drug test results and alcohol test results with a concentration of less than 0.02 for one year.

(b) You do not have to keep records related to a program requirement that does not apply to you (*e.g.,* a maritime employer who does not have a DOT-mandated random alcohol testing program need not maintain random alcohol testing records).

(c) You must maintain the records in a location with controlled access.

(d) A service agent may maintain these records for you. However, you must ensure that you can produce these records at your principal place of business in the time required by the DOT agency. For example, as a motor carrier, when an FMCSA inspector requests your records, you must ensure that you can provide them within two working days.

Subpart Q—Roles and Responsibilities of Service Agents

§ 40.341 Must service agents comply with DOT drug and alcohol testing requirements?

(a) As a service agent, the services you provide to transportation employers must meet the requirements of this part

and the DOT agency drug and alcohol testing regulations.

(b) If you do not comply, DOT may take action under the Public Interest Exclusions procedures of this part (see Subpart R of this part) or applicable provisions of other DOT agency regulations.

§ 40.343 What tasks may a service agent perform for an employer?

As a service agent, you may perform for employers the tasks needed to comply with DOT agency drug and alcohol testing regulations, subject to the requirements and limitations of this part.

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

(a) As a C/TPA or other service agent, you may act as an intermediary in the transmission of drug and alcohol testing information in the circumstances specified in this section only if the employer chooses to have you do so. Each employer makes the decision about whether to receive some or all of this information from you, acting as an intermediary, rather than directly from the service agent who originates the information (*e.g.*, an MRO or BAT).

(b) The specific provisions of this part concerning which you may act as an intermediary are listed in Appendix F to this part. These are the only situations in which you may act as an intermediary. You are prohibited from doing so in all other situations.

(c) In every case, you must ensure that, in transmitting information to employers, you meet all requirements (*e.g.*, concerning confidentiality and timing) that would apply if the service agent originating the information (*e.g.*, an MRO or collector) sent the information directly to the employer. For example, if you transmit drug testing results from MROs to DERs, you must transmit each drug test result to the DER in compliance with the MRO requirements set forth in § 40.167 .

§ 40.347 What functions may C/TPAs perform with respect to administering testing?

As a C/TPA, except as otherwise specified in this part, you may perform the following functions for employers concerning random selection and other selections for testing.

(a) You may operate random testing programs for employers and may assist (*i.e.*, through contracting with laboratories or collection sites, conducting collections) employers with other types of testing (*e.g.*, pre-employment, post-accident, reasonable suspicion, return-to-duty, and follow-up).

(b) You may combine employees from more than one employer or one transportation industry in a random pool if permitted by all the DOT agency drug and alcohol testing regulations involved.

(1) If you combine employees from more than one transportation industry, you must ensure that the random testing rate is at least equal to the highest rate required by each DOT agency.

(2) Employees not covered by DOT agency regulations may not be part of the same random pool with DOT covered employees.

(c) You may assist employers in ensuring that follow-up testing is conducted in accordance with the plan established by the SAP. However, neither you nor the employer are permitted to randomly select employees from a ''follow-up pool'' for follow-up testing.

§ 40.349 What records may a service agent receive and maintain?

(a) Except where otherwise specified in this part, as a service agent you may receive and maintain all records concerning DOT drug and alcohol testing programs, including positive, negative, and refusal to test individual test results. You do not need the employee's consent to receive and maintain these records.

(b) You may maintain all information needed for operating a drug/alcohol program (*e.g.*, CCFs, ATFs, names of employees in random pools, random selection lists, copies of notices to employers of selected employees) on behalf of an employer.

(c) If a service agent originating drug or alcohol testing information, such as an MRO or BAT, sends the information directly to the DER, he or she may also provide the information simultaneously to you, as a C/TPA or other service agent who maintains this information for the employer.

(d) If you are serving as an intermediary in transmitting information that is required to be provided to the employer, you must ensure that it reaches the employer in the same time periods required elsewhere in this part.

(e) You must ensure that you can make available to the employer within two days any information the employer is asked to produce by a DOT agency representative.

(f) On request of an employer, you must, at any time on the request of an employer, transfer immediately all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it. You are not required to obtain employee consent for this transfer. You must not charge more than your reasonable administrative costs for conducting this transfer. You may not charge a fee for the release of these records.

(g) If you are planning to go out of business or your organization will be bought by or merged with another organization, you must immediately notify all employers and offer to transfer all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it. You are not required to obtain employee consent for this transfer. You must not charge more than your reasonable administrative costs for conducting this transfer. You may not charge a fee for the release of these records.

§ 40.351 What confidentiality requirements apply to service agents?

Except where otherwise specified in this part, as a service agent the following confidentiality requirements apply to you:

(a) When you receive or maintain confidential information about employees (*e.g.*, individual test results), you must follow the same confidentiality regulations as the employer with respect to the use and release of this information.

(b) You must follow all confidentiality and records retention requirements applicable to employers.

(c) You may not provide individual test results or other confidential information to another employer without a specific, written consent from the employee. For example, suppose you are a C/TPA that has employers X and Y as clients. Employee Jones works for X, and you maintain Jones' drug and alcohol test for X. Jones wants to change jobs and work for Y. You may not inform Y of the result of a test conducted for X without having a specific, written consent from Jones. Likewise, you may not provide this information to employer Z, who is not a C/TPA member, without this consent.

(d) You must not use blanket consent forms authorizing the release of employee testing information.

(e) You must establish adequate confidentiality and security measures to ensure that confidential employee records are not available to unauthorized persons. This includes protecting the physical security of

records, access controls, and computer security measures to safeguard confidential data in electronic data bases.

§ 40.353 What principles govern the interaction between MROs and other service agents?

As a service agent other than an MRO (*e.g.,* a C/TPA), the following principles govern your interaction with MROs:

(a) You may provide MRO services to employers, directly or through contract, if you meet all applicable provisions of this part.

(b) If you employ or contract for an MRO, the MRO must perform duties independently and confidentially. When you have a relationship with an MRO, you must structure the relationship to ensure that this independence and confidentiality are not compromised. Specific means (including both physical and operational measures, as appropriate) to separate MRO functions and other service agent functions are essential.

(c) Only your staff who are actually under the day-to-day supervision and control of an MRO with respect to MRO functions may perform these functions. This does not mean that those staff may not perform other functions at other times. However, the designation of your staff to perform MRO functions under MRO supervision must be limited and not used as a subterfuge to circumvent confidentiality and other requirements of this part and DOT agency regulations. You must ensure that MRO staff operate under controls sufficient to ensure that the independence and confidentiality of the MRO process are not compromised.

(d) Like other MROs, an MRO you employ or contract with must personally conduct verification interviews with employees and must personally make all verification decisions. Consequently, your staff cannot perform these functions.

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

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).

(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 are authorized by a DOT agency regulation to do so, 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 the laboratory copy 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 RSPA 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.

Subpart R—Public Interest Exclusions

§ 40.361 What is the purpose of a public interest exclusion (PIE)?

(a) To protect the public interest, including protecting transportation employers and employees from serious noncompliance with DOT drug and alcohol testing rules, the Department's policy is to ensure that employers conduct business only with responsible service agents.

(b) The Department therefore uses PIEs to exclude from participation in DOT's drug and alcohol testing program any service agent who, by serious noncompliance with this part or other DOT agency drug and alcohol testing regulations, has shown that it is not currently acting in a responsible manner.

(c) A PIE is a serious action that the Department takes only to protect the public interest. We intend to use PIEs only to remedy situations of serious noncompliance. PIEs are not used for the purpose of punishment.

(d) Nothing in this subpart precludes a DOT agency or the Inspector General from taking other action authorized by its regulations with respect to service agents or employers that violate its regulations.

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

(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.

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

(a) It is the Department's policy to start a PIE proceeding only in cases of serious, uncorrected noncompliance with the provisions of this part, affecting such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives.

(b) The following are examples of the kinds of serious noncompliance that, as a matter of policy, the Department views as appropriate grounds for starting a PIE proceeding. These examples are not intended to be an exhaustive or exclusive list of the grounds for starting a PIE proceeding. We intend them to illustrate the level of seriousness that the Department believes supports starting a PIE proceeding. The examples follow:

(1) For an MRO, verifying tests positive without interviewing the employees as required by this part or providing MRO services without meeting the qualifications for an MRO required by this part;

(2) For a laboratory, refusing to provide information to the Department, an employer, or an employee as required by this part; failing or refusing to conduct a validity testing program when required by this part; or a pattern or practice of testing errors that result in the cancellation of tests. (As a general matter of policy, the Department does not intend to initiate a PIE proceeding concerning a laboratory with respect to matters on which HHS initiates certification actions under its laboratory guidelines.);

(3) For a collector, a pattern or practice of directly observing collections when doing so is unauthorized, or failing or refusing to directly observe collections when doing so is mandatory;

(4) For collectors, BATs, or STTs, a pattern or practice of using forms, testing equipment, or collection kits that do not meet the standards in this part;

(5) For a collector, BAT, or STT, a pattern or practice of ''fatal flaws'' or other significant uncorrected errors in the collection process;

(6) For a laboratory, MRO or C/TPA, failing or refusing to report tests results as required by this part or DOT agency regulations;

(7) For a laboratory, falsifying, concealing, or destroying documentation concerning any part of the drug testing process, including, but not limited to, documents in a ''litigation package'';

(8) For SAPs, providing SAP services while not meeting SAP qualifications required by this part or performing evaluations without face-to-face interviews;

(9) For any service agent, maintaining a relationship with another party that constitutes a conflict of interest under this part (*e.g.,* a laboratory that derives a financial benefit from having an employer use a specific MRO);

(10) For any service agent, representing falsely that the service agent or its activities is approved or certified by the Department or a DOT agency;

(11) For any service agent, disclosing an employee's test result information to any party this part or a DOT agency regulation does not authorize, including by obtaining a ''blanket'' consent from employees or by creating a data base from which employers or others can retrieve an employee's DOT test results without the specific consent of the employee;

(12) For any service agent, interfering or attempting to interfere with the ability of an MRO to communicate with the Department, or retaliating against an MRO for communicating with the Department;

(13) For any service agent, directing or recommending that an employer fail or refuse to implement any provision of this part; or

(14) With respect to noncompliance with a DOT agency regulation, conduct that affects important provisions of Department-wide concern (*e.g.,* failure to properly conduct the selection process for random testing).

§ 40.367 Who initiates a PIE proceeding?

The following DOT officials may initiate a PIE proceeding:

(a) The drug and alcohol program manager of a DOT agency;

(b) An official of ODAPC, other than the Director; or

(c) The designee of any of these officials.

§ 40.369 What is the discretion of an initiating official in starting a PIE proceeding?

(a) Initiating officials have broad discretion in deciding whether to start a PIE proceeding.

(b) In exercising this discretion, the initiating official must consider the Department's policy regarding the seriousness of the service agent's conduct (see § 40.365) and all information he or she has obtained to this point concerning the facts of the case. The initiating official may also consider the availability of the resources needed to pursue a PIE proceeding.

(c) A decision not to initiate a PIE proceeding does not necessarily mean that the Department regards a service agent as being in compliance or that the Department may not use other applicable remedies in a situation of noncompliance.

§ 40.371 On what information does an initiating official rely in deciding whether to start a PIE proceeding?

(a) An initiating official may rely on credible information from any source as the basis for starting a PIE proceeding.

(b) Before sending a correction notice (see § 40.373), the initiating official informally contacts the service agent to determine if there is any information that may affect the initiating official's

determination about whether it is necessary to send a correction notice. The initiating official may take any information resulting from this contact into account in determining whether to proceed under this subpart.

§ 40.373 Before starting a PIE proceeding, does the initiating official give the service agent an opportunity to correct problems?

(a) If you are a service agent, the initiating official must send you a correction notice before starting a PIE proceeding.

(b) The correction notice identifies the specific areas in which you must come into compliance in order to avoid being subject to a PIE proceeding.

(c) If you make and document changes needed to come into compliance in the areas listed in the correction notice to the satisfaction of the initiating official within 60 days of the date you receive the notice, the initiating official does not start a PIE proceeding. The initiating official may conduct appropriate fact finding to verify that you have made and maintained satisfactory corrections. When he or she is satisfied that you are in compliance, the initiating official sends you a notice that the matter is concluded.

§ 40.375 How does the initiating official start a PIE proceeding?

(a) As a service agent, if your compliance matter is not correctable (see § 40.373(a)), or if have not resolved compliance matters as provided in § 40.373(c), the initiating official starts a PIE proceeding by sending you a notice of proposed exclusion (NOPE). The NOPE contains the initiating official's recommendations concerning the issuance of a PIE, but it is not a decision by the Department to issue a PIE.

(b) The NOPE includes the following information:

(1) A statement that the initiating official is recommending that the Department issue a PIE concerning you;

(2) The factual basis for the initiating official's belief that you are not providing drug and/or alcohol testing services to DOT-regulated employers consistent with the requirements of this part or are in serious noncompliance with a DOT agency drug and alcohol regulation;

(3) The factual basis for the initiating official's belief that your noncompliance has not been or cannot be corrected;

(4) The initiating official's recommendation for the scope of the PIE;

(5) The initiating official's recommendation for the duration of the PIE; and

(6) A statement that you may contest the issuance of the proposed PIE, as provided in § 40.379.

(c) The initiating official sends a copy of the NOPE to the ODAPC Director at the same time he or she sends the NOPE to you.

§ 40.377 Who decides whether to issue a PIE?

(a) The ODAPC Director, or his or her designee, decides whether to issue a PIE. If a designee is acting as the decisionmaker, all references in this subpart to the Director refer to the designee.

(b) To ensure his or her impartiality, the Director plays no role in the initiating official's determination about whether to start a PIE proceeding.

(c) There is a ''firewall'' between the initiating official and the Director. This means that the initiating official and the Director are prohibited from having any discussion, contact, or exchange of information with one another about the matter, except for documents and discussions that are part of the record of the proceeding.

§ 40.379 How do you contest the issuance of a PIE?

(a) If you receive a NOPE, you may contest the issuance of the PIE.

(b) If you want to contest the proposed PIE, you must provide the Director information and argument in opposition to the proposed PIE in writing, in person, and/or through a representative. To contest the proposed PIE, you must take one or more of the steps listed in this paragraph (b) within 30 days after you receive the NOPE.

(1) You may request that the Director dismiss the proposed PIE without further proceedings, on the basis that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in § 40.365.

(2) You may present written information and arguments, consistent with the provisions of § 40.381, contesting the proposed PIE.

(3) You may arrange with the Director for an informal meeting to present your information and arguments.

(c) If you do not take any of the actions listed in paragraph (b) of this section within 30 days after you receive the NOPE, the matter proceeds as an uncontested case. In this event, the Director makes his or her decision based on the record provided by the initiating official (*i.e.,* the NOPE and any supporting information or testimony) and any additional information the Director obtains.

§ 40.381 What information do you present to contest the proposed issuance of a PIE?

(a) As a service agent who wants to contest a proposed PIE, you must present at least the following information to the Director:

(1) Specific facts that contradict the statements contained in the NOPE (see § 40.375(b)(2) and (3)). A general denial is insufficient to raise a genuine dispute over facts material to the issuance of a PIE;

(2) Identification of any existing, proposed or prior PIE; and

(3) Identification of your affiliates, if any.

(b) You may provide any information and arguments you wish concerning the proposed issuance, scope and duration of the PIE (see § 40.375(b)(4) and (5)).

(c) You may provide any additional relevant information or arguments concerning any of the issues in the matter.

§ 40.383 What procedures apply if you contest the issuance of a PIE?

(a) DOT conducts PIE proceedings in a fair and informal manner. The Director may use flexible procedures to allow you to present matters in opposition. The Director is not required to follow formal rules of evidence or procedure in creating the record of the proceeding.

(b) The Director will consider any information or argument he or she determines to be relevant to the decision on the matter.

(c) You may submit any documentary evidence you want the Director to consider. In addition, if you have arranged an informal meeting with the Director, you may present witnesses and confront any person the initiating official presents as a witness against you.

(d) In cases where there are material factual issues in dispute, the Director or his or her designee may conduct additional fact-finding.

(e) If you have arranged a meeting with the Director, the Director will make a transcribed record of the meeting available to you on your request. You must pay the cost of transcribing and copying the meeting record.

§ 40.385 Who bears the burden of proof in a PIE proceeding?

(a) As the proponent of issuing a PIE, the initiating official bears the burden of proof.

(b) This burden is to demonstrate, by a preponderance of the evidence, that the service agent was in serious noncompliance with the requirements of this part for drug and/or alcohol testing-related services or with the requirements of another DOT agency drug and alcohol testing regulation.

§ 40.387 What matters does the Director decide concerning a proposed PIE?

(a) Following the service agent's response (see § 40.379(b)) or, if no response is received, after 30 days have passed from the date on which the service agent received the NOPE, the Director may take one of the following steps:

(1) In response to a request from the service agent (see § 40.379(b)(1)) or on his or her own motion, the Director may dismiss a PIE proceeding if he or she determines that it does not concern serious noncompliance with this part or DOT agency regulations, consistent with the Department's policy as stated in § 40.365.

(i) If the Director dismisses a proposed PIE under this paragraph (a), the action is closed with respect to the noncompliance alleged in the NOPE.

(ii) The Department may initiate a new PIE proceeding against you on the basis of different or subsequent conduct that is in noncompliance with this part or other DOT drug and alcohol testing rules.

(2) If the Director determines that the initiating official's submission does not have complete information needed for a decision, the Director may remand the matter to the initiating official. The initiating official may resubmit the matter to the Director when the needed information is complete. If the basis for the proposed PIE has changed, the initiating official must send an amended NOPE to the service agent.

(b) The Director makes determinations concerning the following matters in any PIE proceeding that he or she decides on the merits:

(1) Any material facts that are in dispute;

(2) Whether the facts support issuing a PIE;

(3) The scope of any PIE that is issued; and

(4) The duration of any PIE that is issued.

§ 40.389 What factors may the Director consider?

This section lists examples of the kind of mitigating and aggravating factors that the Director may consider in determining whether to issue a PIE concerning you, as well as the scope and duration of a PIE. This list is not exhaustive or exclusive. The Director may consider other factors if appropriate in the circumstances of a particular case. The list of examples follows:

(a) The actual or potential harm that results or may result from your noncompliance;

(b) The frequency of incidents and/or duration of the noncompliance;

(c) Whether there is a pattern or prior history of noncompliance;

(d) Whether the noncompliance was pervasive within your organization, including such factors as the following:

(1) Whether and to what extent your organization planned, initiated, or carried out the noncompliance;

(2) The positions held by individuals involved in the noncompliance, and whether your principals tolerated their noncompliance; and

(3) Whether you had effective standards of conduct and control systems (both with respect to your own organization and any contractors or affiliates) at the time the noncompliance occurred;

(e) Whether you have demonstrated an appropriate compliance disposition, including such factors as the following:

(1) Whether you have accepted responsibility for the noncompliance and recognize the seriousness of the conduct that led to the cause for issuance of the PIE;

(2) Whether you have cooperated fully with the Department during the investigation. The Director may consider when the cooperation began and whether you disclosed all pertinent information known to you;

(3) Whether you have fully investigated the circumstances of the noncompliance forming the basis for the PIE and, if so, have made the result of the investigation available to the Director;

(4) Whether you have taken appropriate disciplinary action against the individuals responsible for the activity that constitutes the grounds for issuance of the PIE; and

(5) Whether your organization has taken appropriate corrective actions or remedial measures, including implementing actions to prevent recurrence;

(f) With respect to noncompliance with a DOT agency regulation, the degree to which the noncompliance affects matters common to the DOT drug and alcohol testing program;

(g) Other factors appropriate to the circumstances of the case.

§ 40.391 What is the scope of a PIE?

(a) The scope of a PIE is the Department's determination about the divisions, organizational elements, types of services, affiliates, and/or individuals (including direct employees of a service agent and its contractors) to which a PIE applies.

(b) If, as a service agent, the Department issues a PIE concerning you, the PIE applies to all your divisions, organizational elements, and types of services that are involved with or affected by the noncompliance that forms the factual basis for issuing the PIE.

(c) In the NOPE (see § 40.375(b)(4)), the initiating official sets forth his or her recommendation for the scope of the PIE. The proposed scope of the PIE is one of the elements of the proceeding that the service agent may contest (see § 40.381(b)) and about which the Director makes a decision (see § 40.387(b)(3)).

(d) In recommending and deciding the scope of the PIE, the initiating official and Director, respectively, must take into account the provisions of paragraphs (e) through (j) of this section.

(e) The pervasiveness of the noncompliance within a service agent's organization (see § 40.389(d)) is an important consideration in determining the scope of a PIE. The appropriate scope of a PIE grows broader as the pervasiveness of the noncompliance increases.

(f) The application of a PIE is not limited to the specific location or employer at which the conduct that forms the factual basis for issuing the PIE was discovered.

(g) A PIE applies to your affiliates, if the affiliate is involved with or affected by the conduct that forms the factual basis for issuing the PIE.

(h) A PIE applies to individuals who are officers, employees, directors, shareholders, partners, or other individuals associated with your organization in the following circumstances:

(1) Conduct forming any part of the factual basis of the PIE occurred in connection with the individual's performance of duties by or on behalf of your organization; or

(2) The individual knew of, had reason to know of, approved, or acquiesced in such conduct. The individual's acceptance of benefits derived from such conduct is evidence of such knowledge, acquiescence, or approval.

(i) If a contractor to your organization is solely responsible for the conduct that forms the factual basis for a PIE, the PIE does not apply to the service agent itself unless the service agent knew or should have known about the conduct and did not take action to correct it.

(j) PIEs do not apply to drug and alcohol testing that DOT does not regulate.

(k) The following examples illustrate how the Department intends the provisions of this section to work:

Example 1 to § 40.391. Service Agent P provides a variety of drug testing services. P's SAP services are involved in a serious violation of this Part 40. However, P's other

services fully comply with this part, and P's overall management did not plan or concur in the noncompliance, which in fact was contrary to P's articulated standards. Because the noncompliance was isolated in one area of the organization's activities, and did not pervade the entire organization, the scope of the PIE could be limited to SAP services.

Example 2 to § 40.391. Service Agent Q provides a similar variety of services. The conduct forming the factual basis for a PIE concerns collections for a transit authority. As in Example 1, the noncompliance is not pervasive throughout Q's organization. The PIE would apply to collections at all locations served by Q, not just the particular transit authority or not just in the state in which the transit authority is located.

Example 3 to § 40.391. Service Agent R provides a similar array of services. One or more of the following problems exists: R's activities in several areas—collections, MROs, SAPs, protecting the confidentiality of information—are involved in serious noncompliance; DOT determines that R's management knew or should have known about serious noncompliance in one or more areas, but management did not take timely corrective action; or, in response to an inquiry from DOT personnel, R's management refuses to provide information about its operations. In each of these three cases, the scope of the PIE would include all aspects of R's services.

Example 4 to § 40.391. Service Agent W provides only one kind of service (*e.g.,* laboratory or MRO services). The Department issues a PIE concerning these services. Because W only provides this one kind of service, the PIE necessarily applies to all its operations.

Example 5 to § 40.391. Service Agent X, by exercising reasonably prudent oversight of its collection contractor, should have known that the contractor was making numerous ''fatal flaws'' in tests. Alternatively, X received a correction notice pointing out these problems in its contractor's collections. In neither case did X take action to correct the problem. X, as well as the contractor, would be subject to a PIE with respect to collections.

Example 6 to § 40.391. Service Agent Y could not reasonably have known that one of its MROs was regularly failing to interview employees before verifying tests positive. When it received a correction notice, Y immediately dismissed the erring MRO. In this case, the MRO would be subject to a PIE but Y would not.

Example 7 to § 40.391. The Department issues a PIE with respect to Service Agent Z. Z provides services for DOT-regulated transportation employers, a Federal agency under the HHS-regulated Federal employee testing program, and various private businesses and public agencies that DOT does not regulate. The PIE applies only to the DOT-regulated transportation employers with respect to their DOT-mandated testing, not to the Federal agency or the other public agencies and private businesses. The PIE does not prevent the non-DOT regulated entities from continuing to use Z's services.

§ 40.393 How long does a PIE stay in effect?

(a) In the NOPE (see § 40.375(b)(5)), the initiating official proposes the duration of the PIE. The duration of the PIE is one of the elements of the proceeding that the service agent may contest (see § 40.381(b)) and about which the Director makes a decision (see § 40.387(b)(4)).

(b) In deciding upon the duration of the PIE, the Director considers the seriousness of the conduct on which the PIE is based and the continued need to protect employers and employees from the service agent's noncompliance. The Director considers factors such as those listed in § 40.389 in making this decision.

(c) The duration of a PIE will be between one and five years, unless the Director reduces its duration under § 40.407.

§ 40.395 Can you settle a PIE proceeding?

At any time before the Director's decision, you and the initiating official can, with the Director's concurrence, settle a PIE proceeding.

§ 40.397 When does the Director make a PIE decision?

The Director makes his or her decision within 60 days of the date when the record of a PIE proceeding is complete (including any meeting with the Director and any additional fact-finding that is necessary). The Director may extend this period for good cause for additional periods of up to 30 days.

§ 40.399 How does the Department notify service agents of its decision?

If you are a service agent involved in a PIE proceeding, the Director provides you written notice as soon as he or she makes a PIE decision. The notice includes the following elements:

(a) If the decision is not to issue a PIE, a statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute.

(b) If the decision is to issue a PIE—

(1) A reference to the NOPE;

(2) A statement of the reasons for the decision, including findings of fact with respect to any material factual issues that were in dispute;

(3) A statement of the scope of the PIE; and

(4) A statement of the duration of the PIE.

§ 40.401 How does the Department notify employers and the public about a PIE?

(a) The Department maintains a document called the ''List of Excluded Drug and Alcohol Service Agents.'' This document may be found on the Department's web site (http://www.dot.gov/ost/dapc). You may also request a copy of the document from ODAPC.

(b) When the Director issues a PIE, he or she adds to the List the name and address of the service agent, and any other persons or organizations, to whom the PIE applies and information about the scope and duration of the PIE.

(c) When a service agent ceases to be subject to a PIE, the Director removes this information from the List.

(d) The Department also publishes a **Federal Register** notice to inform the public on any occasion on which a service agent is added to or taken off the List.

§ 40.403 Must a service agent notify its clients when the Department issues a PIE?

(a) As a service agent, if the Department issues a PIE concerning you, you must notify each of your DOT-regulated employer clients, in writing, about the issuance, scope, duration, and effect of the PIE. You may meet this requirement by sending a copy of the Director's PIE decision or by a separate notice. You must send this notice to each client within three working days of receiving from the Department the notice provided for in § 40.399(b).

(b) As part of the notice you send under paragraph (a) of this section, you must offer to transfer immediately all records pertaining to the employer and its employees to the employer or to any other service agent the employer designates. You must carry out this transfer as soon as the employer requests it.

§ 40.405 May the Federal courts review PIE decisions?

The Director's decision is a final administrative action of the Department. Like all final administrative actions of Federal agencies, the Director's decision is subject to judicial review under the Administrative Procedure Act (5 U.S.C. 551 *et. seq*).

§ 40.407 May a service agent ask to have a PIE reduced or terminated?

(a) Yes, as a service agent concerning whom the Department has issued a PIE, you may request that the Director terminate a PIE or reduce its duration and/or scope. This process is limited to the issues of duration and scope. It is not an appeal or reconsideration of the decision to issue the PIE.

(b) Your request must be in writing and supported with documentation.

(c) You must wait at least nine months from the date on which the Director issued the PIE to make this request.

(d) The initiating official who was the proponent of the PIE may provide information and arguments concerning your request to the Director.

(e) If the Director verifies that the sources of your noncompliance have been eliminated and that all drug or alcohol testing-related services you would provide to DOT-regulated employers will be consistent with the requirements of this part, the Director may issue a notice terminating or reducing the PIE.

§ 40.409 What does the issuance of a PIE mean to transportation employers?

(a) As an employer, you are deemed to have notice of the issuance of a PIE when it appears on the List mentioned in § 40.401(a) or the notice of the PIE appears in the **Federal Register** as provided in § 40.401(d). You should check this List to ensure that any service agents you are using or planning to use are not subject to a PIE.

(b) As an employer who is using a service agent concerning whom a PIE is issued, you must stop using the services of the service agent no later than 90 days after the Department has published the decision in the **Federal Register** or posted it on its web site. You may apply to the ODAPC Director for an extension of 30 days if you demonstrate that you cannot find a substitute service agent within 90 days.

(c) Except during the period provided in paragraph (b) of this section, you must not, as an employer, use the services of a service agent that are covered by a PIE that the Director has issued under this subpart. If you do so, you are in violation of the Department's regulations and subject to applicable DOT agency sanctions (*e.g.,* civil penalties, withholding of Federal financial assistance).

(d) You also must not obtain drug or alcohol testing services through a contractor or affiliate of the service agent to whom the PIE applies.

Example to Paragraph (d): Service Agent R was subject to a PIE with respect to SAP services. As an employer, not only must you not use R's own SAP services, but you also must not use SAP services you arrange through R, such as services provided by a subcontractor or affiliate of R or a person or organization that receives financial gain from its relationship with R.

(e) This section's prohibition on using the services of a service agent concerning which the Director has issued a PIE applies to employers in all industries subject to DOT drug and alcohol testing regulations.

Example to Paragraph (e): The initiating official for a PIE was the FAA drug and alcohol program manager, and the conduct forming the basis of the PIE pertained to the aviation industry. As a motor carrier, transit authority, pipeline, railroad, or maritime employer, you are also prohibited from using the services of the service agent involved in connection with the DOT drug and alcohol testing program.

(f) The issuance of a PIE does not result in the cancellation of drug or alcohol tests conducted using the service agent involved before the issuance of the Director's decision or up to 90 days following its publication in the **Federal Register** or posting on the Department's web site, unless otherwise specified in the Director's PIE decision or the Director grants an extension as provided in paragraph (b) of this section.

Example to Paragraph (f): The Department issues a PIE concerning Service Agent N on September 1. All tests conducted using N's services before September 1, and through November 30, are valid for all purposes under DOT drug and alcohol testing regulations, assuming they meet all other regulatory requirements.

§ 40.411 What is the role of the DOT Inspector General's office?

(a) Any person may bring concerns about waste, fraud, or abuse on the part of a service agent to the attention of the DOT Office of Inspector General.

(b) In appropriate cases, the Office of Inspector General may pursue criminal or civil remedies against a service agent.

(c) The Office of Inspector General may provide factual information to other DOT officials for use in a PIE proceeding.

§ 40.413 How are notices sent to service agents?

(a) If you are a service agent, DOT sends notices to you, including correction notices, notices of proposed exclusion, decision notices, and other notices, in any of the ways mentioned in paragraph (b) or (c) of this section.

(b) DOT may send a notice to you, your identified counsel, your agent for service of process, or any of your partners, officers, directors, owners, or joint venturers to the last known street address, fax number, or e-mail address. DOT deems the notice to have been received by you if sent to any of these persons.

(c) DOT considers notices to be received by you—

(1) When delivered, if DOT mails the notice to the last known street address, or five days after we send it if the letter is undeliverable;

(2) When sent, if DOT sends the notice by fax or five days after we send it if the fax is undeliverable; or

(3) When delivered, if DOT sends the notice by e-mail or five days after DOT sends it if the e-mail is undeliverable.

Appendix A to Part 40—DOT Standards for Urine Collection Kits

The Collection Kit Contents

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 °C/90–100 °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 to Part 40—DOT Drug Testing Semi-Annual Laboratory Report

The following items are required on each report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
Employer Identification: (name; may include billing code or ID code)
C/C/TPA Identification: (where applicable; name and address)
1. Number of specimen results reported: (total number)
   By test type:
   (a) Pre-employment testing: (number)
   (b) Post-accident testing: (number)
   (c) Random testing: (number)
   (d) Reasonable suspicion/cause testing: (number)
   (e) Return-to-duty testing: (number)
   (f) Follow-up testing: (number)
   (g) Type not noted on CCF: (number)
2. Number of specimens reported as
   (a) Negative: (total number)
   (b) Negative-dilute: (number)
3. Number of specimens reported as Rejected for Testing: (total number)
By reason:
   (a) Fatal flaw: (number)
   (b) Uncorrected flaw: (number)
4. Number of specimens reported as Positive: (total number)
   By drug:
   (a) Marijuana Metabolite: (number)
   (b) Cocaine Metabolite: (number)
   (c) Opiates:
   (1) Codeine: (number)
   (2) Morphine: (number)
   (3) 6–AM: (number)
   (d) Phencyclidine: (number)
   (e) Amphetamines: (number)
   (1) Amphetamine: (number)
   (2) Methamphetamine: (number):
5. Adulterated: (number)
6. Substituted: (number)
7. Invalid results: (number)

Appendix C to Part 40—[Reserved]

Appendix D to Part 40—Report Format: Split Specimen Failure to Reconfirm

Fax or mail to: Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 400 7th Street, SW., Room 10403, Washington, DC 20590 (fax) 202–366–3897.

1. MRO name, address, phone number, and fax number.

2. Collection site name, address, and phone number.

3. Date of collection.

4. Specimen I.D. number.

5. Laboratory accession number.

6. Primary specimen laboratory name, address, and phone number.

7. Date result reported or certified by primary laboratory.

8. Split specimen laboratory name, address, and phone number.

9. Date split specimen result reported or certified by split specimen laboratory.

10. Primary specimen results (*e.g.,* name of drug, adulterant) in the primary specimen.

11. Reason for split specimen failure-to-reconfirm result (*e.g.,* drug or adulterant not present, specimen invalid, split not collected, insufficient volume).

12. Actions taken by the MRO (*e.g.,* notified employer of failure to reconfirm and requirement for recollection).

13. Additional information explaining the reason for cancellation.

14. Name of individual submitting the report (if not the MRO).

Appendix E to Part 40—SAP Equivalency Requirements for Certification Organizations

1. *Experience:* Minimum requirements are for three years of full-time supervised experience or 6,000 hours of supervised experience as an alcoholism and/or drug abuse counselor. The supervision must be provided by a licensed or certified practitioner. Supervised experience is important if the individual is to be considered a professional in the field of alcohol and drug abuse evaluation and counseling.

2. *Education:* There exists a requirement of 270 contact hours of education and training in alcoholism and/or drug abuse or related training. These hours can take the form of formal education, in-service training, and professional development courses. Part of any professional counselor's development is participation in formal and non-formal education opportunities within the field.

3. *Continuing Education:* The certified counselor must receive at least 40–60 hours of continuing education units (CEU) during each two year period. These CEUs are important to the counselor's keeping abreast of changes and improvements in the field.

4. *Testing:* A passing score on a national test is a requirement. The test must accurately measure the application of the knowledge, skills, and abilities possessed by the counselor. The test establishes a national standard that must be met to practice.

5. *Testing Validity:* The certification examination must be reviewed by an independent authority for validity (examination reliability and relationship to the knowledge, skills, and abilities required by the counseling field). The reliability of the exam is paramount if counselor attributes are to be accurately measured. The examination passing score point must be placed at an appropriate minimal level score as gauged by statistically reliable methodology.

6. *Measurable Knowledge Base:* The certification process must be based upon measurable knowledge possessed by the applicant and verified through collateral data and testing. That level of knowledge must be of sufficient quantity to ensure a high quality of SAP evaluation and referral services.

7. *Measurable Skills Base:* The certification process must be based upon measurable skills possessed by the applicant and verified through collateral data and testing. That level of skills must be of sufficient quality to ensure a high quality of SAP evaluation and referral services.

8. *Quality Assurance Plan:* The certification agency must ensure that a means exists to determine that applicant records are verified as being true by the certification staff. This is an important check to ensure that true information is being accepted by the certifying agency.

9. *Code of Ethics:* Certified counselors must pledge to adhere to an ethical standard for practice. It must be understood that code violations could result in de-certification. These standards are vital in maintaining the integrity of practitioners. High ethical standards are required to ensure quality of client care and confidentiality of client information as well as to guard against inappropriate referral practices.

10. *Re-certification Program:* Certification is not just a one-time event. It is a continuing privilege with continuing requirements. Among these are continuing education, continuing state certification, and concomitant adherence to the code of ethics. Re-certification serves as a protector of client interests by removing poor performers from the certified practice.

11. *Fifty State Coverage:* Certification must be available to qualified counselors in all 50 states and, therefore, the test must be available to qualified applicants in all 50 states. Because many companies are multi-state operators, consistency in SAP evaluation quality and opportunities is paramount. The test need not be given in all 50 states but should be accessible to candidates from all states.

12. *National Commission for Certifying Agencies (NCCA) Accreditation:* Having NCCA accreditation is a means of demonstrating to the Department of Transportation that your certification has been reviewed by a panel of impartial experts that have determined that your examination(s) has met stringent and appropriate testing standards.

Appendix F to Part 40—Drug and Alcohol Testing Information that C/TPAs May Transmit to Employers

1. If you are a C/TPA, you may, acting as an intermediary, transmit the information in the following sections of this part to the DER for an employer, if the employer chooses to have you do so. These are the only items that you are permitted to transmit to the employer as an intermediary. The use of C/TPA intermediaries is prohibited in all other cases, such as transmission of laboratory drug test results to MROs, the transmission of medical information from MROs to employers, the transmission of SAP reports to employers, the transmission of positive alcohol test results, and the transmission of medical information from MROs to employers.

2. In every case, you must ensure that, in transmitting the information, you meet all

requirements (*e.g.,* concerning confidentiality and timing) that would apply if the party originating the information (*e.g.,* an MRO or collector) sent the information directly to the employer. For example, if you transmit MROs' drug testing results to DERs, you must transmit each drug test result to the DER in compliance with the requirements for MROs set forth in § 40.167.

Drug Testing Information

§ 40.25: Previous two years' test results
§ 40.35: Notice to collectors of contact information for DER
§ 40.61(a): Notification to DER that an employee is a ''no show'' for a drug test
§ 40.63(e): Notification to DER of a collection under direct observation
§ 40.65(b)(6) and (7) and (c)(2) and (3): Notification to DER of a refusal to provide a specimen or an insufficient specimen
§ 40.73(a)(9): Transmission of CCF copies to DER (However, MRO copy of CCF must be sent by collector directly to the MRO, not through the C/TPA.)
§ 40.111(a): Transmission of laboratory statistical report to employer
§ 40.129 (d): Report of test results to DER
§ 40.129(f)(1): Report to DER of confirmed positive test in stand-down situation
§ 40.149(b): Report to DER of changed test result
§ 40.155(a): Report to DER of dilute specimen
§§ 40.159(a)(4)(ii); 40.161(b): Reports to DER that test is cancelled
§ 40.167(b) and (c): Reports of test results to DER
§ 40.187(a), (b)(1), (c)(1), (d)(1) and (2): Reports to DER concerning the reconfirmation of tests
§ 40.191(d): Notice to DER concerning refusals to test
§ 40.193(b)(3): Notification to DER of refusal in shy bladder situation
§ 40.193(b)(4): Notification to DER of insufficient specimen
§ 40.193(b)(5): Transmission of CCF copies to DER (not to MRO)
§ 40.199: Report to DER of cancelled test and direction to DER for additional collection
§ 40.201: Report to DER of cancelled test

Alcohol Testing Information

§ 40.215: Notice to BATs and STTs of contact information for DER
§ 40.241(b)(1): Notification to DER that an employee is a ''no show'' for an alcohol test
§ 40.247(a)(2): Transmission of alcohol screening test results only when the test result is less than 0.02
§ 40.255(a)(4): Transmission of alcohol confirmation test results only when the test result is less than 0.02
§ 40.263(a)(3) and 263(b)(3): Notification of insufficient saliva and failure to provide sufficient amount of breath

Appendix G to Part 40—Alcohol Testing Form

The following form is the alcohol testing form required for use in the DOT alcohol testing program beginning August 1, 2001. Use of the form is authorized beginning January 18, 2001.

BILLING CODE 4910–62–P

U.S. Department of Transportation (DOT)
Alcohol Testing Form

(The instructions for completing this form are on the back of Copy 3)

Step 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____
(Print) (First, M.I., Last)

B: SSN or Employee ID No. _____

C: Employer Name _____
Street
City, ST ZIP _____

_____

DER Name and Telephone No. _____(____)_____
DER Name **DER Phone Number**

D: Reason for Test: ☐Random ☐Reasonable Susp ☐Post-Accident ☐Return to Duty ☐Follow-up ☐Pre-employment

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by US Department of Transportation regulations and that the identifying information provided on the form is true and correct.

_____ _____/____/____
Signature of Employee **Date Month Day Year**

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

(If the technician conducting the screening test is not the same technician who will be conducting the confirmation test, each technician must complete their own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the US Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: ☐BAT ☐STT **DEVICE:** ☐SALIVA ☐BREATH* **15-Minute Wait:** ☐Yes ☐No

SCREENING TEST: *(For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)*

Test #	Testing Device Name	Device Serial # *OR* Lot # & Exp Date	Activation Time	Reading Time	Result

CONFIRMATION TEST: *Results MUST be affixed to each copy of this form or printed directly onto the form.*

REMARKS:

_____
_____
_____

_____ _____
Alcohol Technician's Company **Company Street Address**

_____ _____(____)_____
(PRINT) Alcohol Technician's Name (First, M.I., Last) **Company City, State, Zip** **Phone Number**

_____ _____/____/____
Signature of Alcohol Technician **Date Month Day Year**

STEP 4: TO BE COMPLETED BY EMPLOYEE IF TEST RESULT IS 0.02 OR HIGHER

I certify that I have submitted to the alcohol test, the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment because the results are 0.02 or greater.

_____ _____/____/____
Signature of Employee **Date Month Day Year**

COPY 1 – ORIGINAL – FORWARD TO THE EMPLOYER

Affix Or Print Screening Results *Here*

Affix With Tamper Evident Tap

Affix Or Print Confirmation Result *Here*

Affix With Tamper Evident Tape

Affix Or Print Additional Results Here

Affix With Tamper Evident Tape

U.S. Department of Transportation (DOT)
Alcohol Testing Form

(The instructions for completing this form are on the back of Copy 3)

Step 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____
(Print) (First, M.I., Last)

B: SSN or Employee ID No. _____

C: Employer Name _____
Street
City, ST ZIP _____

_____

DER Name and Telephone No. _____ (____) _____
DER Name DER Phone Number

D: Reason for Test: ☐Random ☐Reasonable Susp ☐Post-Accident ☐Return to Duty ☐Follow-up ☐Pre-employment

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by US Department of Transportation regulations and that the identifying information provided on the form is true and correct.

_____ ____/____/____
Signature of Employee Date Month Day Year

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

(If the technician conducting the screening test is not the same technician who will be conducting the confirmation test, each technician must complete their own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the US Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: ☐BAT ☐STT DEVICE: ☐SALIVA ☐BREATH* 15-Minute Wait: ☐Yes ☐No

SCREENING TEST: *(For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)*

Test #	Testing Device Name	Device Serial # OR Lot # & Exp Date	Activation Time	Reading Time	Result

CONFIRMATION TEST: *Results MUST be affixed to each copy of this form or printed directly onto the form.*

REMARKS:

_____

_____

_____

_____ _____
Alcohol Technician's Company Company Street Address

_____ _____ (____) _____
(PRINT) Alcohol Technician's Name (First, M.I., Last) Company City, State, Zip Phone Number

_____ ____/____/____
Signature of Alcohol Technician Date Month Day Year

STEP 4: TO BE COMPLETED BY EMPLOYEE IF TEST RESULT IS 0.02 OR HIGHER

I certify that I have submitted to the alcohol test, the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment because the results are 0.02 or greater.

_____ ____/____/____
Signature of Employee Date Month Day Year

COPY 2 – EMPLOYEE RETAINS

Affix Or Print Screening Results *Here*

Affix With Tamper Evident Tap

Affix Or Print Confirmation Result *Here*

Affix With Tamper Evident Tape

Affix Or Print Additional Results Here

Affix With Tamper Evident Tape

U.S. Department of Transportation (DOT)
Alcohol Testing Form

(The instructions for completing this form are on the back of Copy 3)

Step 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____
(Print) (First, M.I., Last)

B: SSN or Employee ID No. _____

C: Employer Name _____
Street
City, ST ZIP _____

_____

DER Name and Telephone No. _____ (____) _____
DER Name **DER Phone Number**

D: Reason for Test: ☐**Random** ☐**Reasonable Susp** ☐**Post-Accident** ☐**Return to Duty** ☐**Follow-up** ☐**Pre-employment**

Affix Or Print Screening Results *Here*

Affix With Tamper Evident Tap

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by US Department of Transportation regulations and that the identifying information provided on the form is true and correct.

_____ ____/____/____
Signature of Employee **Date Month Day Year**

Affix Or Print Confirmation Results *Here*

Affix With Tamper Evident Tape

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

(If the technician conducting the screening test is not the same technician who will be conducting the confirmation test, each technician must complete their own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the US Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: ☐**BAT** ☐ **STT** **DEVICE:** ☐ **SALIVA** ☐**BREATH*** **15-Minute Wait:** ☐ **Yes** ☐ **No**

SCREENING TEST: *(For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)*

Test #	Testing Device Name	Device Serial # *OR* Lot # & Exp Date	Activation Time	Reading Time	Result

CONFIRMATION TEST: *Results MUST be affixed to each copy of this form or printed directly onto the form.*

REMARKS:

_____

_____

_____

_____ _____
Alcohol Technician's Company **Company Street Address**

_____ _____ (____) _____
(PRINT) Alcohol Technician's Name (First, M.I., Last) **Company City, State, Zip** **Phone Number**

_____ ____/____/____
Signature of Alcohol Technician **Date Month Day Year**

Affix Or Print Additional Results Here

Affix With Tamper Evident Tape

STEP 4: TO BE COMPLETED BY EMPLOYEE IF TEST RESULT IS 0.02 OR HIGHER

I certify that I have submitted to the alcohol test, the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment because the results are 0.02 or greater.

_____ ____/____/____
Signature of Employee **Date Month Day Year**

COPY 3 – ALCOHOL TECHNICIAN RETAINS

PAPERWORK REDUCTION ACT NOTICE (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information is estimated for each respondent to average: 1 minute/employee, 4 minutes/Breath Alcohol Technician. Individuals may send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to U.S. Department of Transportation, Drug and alcohol Policy and Compliance, Room 10403, 400 Seventh St., SW, Washington, D.C. 20590 or Office of Management and Budget, Paperwork Reduction Project, Room 3001, 725 Seventeenth St., NW, Washington, D.C. 20503.

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INSTRUCTIONS FOR COMPLETING THE U.S. DEPARTMENT OF TRANSPORTATION ALCOHOL TESTING FORM

NOTE: Use a ballpoint pen, press hard, and check all copies for legibility.

STEP 1 The Breath Alcohol Technician (BAT) or Screening Test Technician (STT) completes the information required in this step. Be sure to print the employee's name and check the box identifying the reason for the test.

NOTE: If the employee refuses to provide SSN or I.D. number, be sure to indicate this in the remarks section in STEP 3. Proceed with STEP 2.

STEP 2 Instruct the employee to read, sign, and date the employee certification statement in STEP 2.

NOTE: If the employee refuses to sign the certification statement, do not proceed with the alcohol test. Contact the designated employer representative.

STEP 3 The BAT or STT completes the information required in this step and checks the type of device (saliva or breath) being used. After conducting the alcohol screening test, do the following (as appropriate):

Enter the information for the screening test (test number, testing device name, testing device serial number or lot number and expiration date, time of test with any device-dependent activation times, and the results), on the front of the AFT. For a breath testing device capable of printing, the information may be part of the printed record.

NOTE: Be sure to enter the result of the test exactly as it is indicated on the breath testing device, e.g., 0.00, 0.02, 0.04, etc.

Affix the printed information in the space provided, in a tamper-evident manner (e.g., tape), or the device may print the results directly on the ATF. If the results of the screening test are less than 0.02, print, sign your name, and enter today's date in the space provided. The test process is complete.

If the results of the screening test are 0.02 or greater, a confirmation test must be administered in accordance with DOT regulations. An EVIDENTIAL BREATH TESTING device that is capable of printing confirmation test information must be used in conducting this test.

After conducting the alcohol confirmation test, affix the printed information in the space provided, in a tamper-evident manner (e.g., tape), or the device may print the results directly on the ATF. Print, sign your name, and enter the date in the space provided. Go to STEP 4.

STEP 4 If the employee has a breath alcohol confirmation test result of 0.02 or higher, instruct the employee to read, sign, and date the employee certification statement in STEP 4.

NOTE: If the employee refuses to sign the certification statement in STEP 4, be sure to indicate this in the remarks line in STEP 3.

Immediately notify the DER if the employee has a breath alcohol confirmation test result of 0.02 or higher.

Forward **Copy 1** to the employer. Give **Copy 2** to the employee. Retain **Copy 3** for BAT/STT records.

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