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49 CFR Part 40

Procedures for Transportation Workplace Drug and Alcohol Testing Programs; Final Rule

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.

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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.