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49 CFR Part 40

Procedures for Transportation Workplace Drug and Alcohol Testing Programs; Proposed Rules

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: Notice of proposed rulemaking.

SUMMARY: The Department of Transportation proposes to revise 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.

DATES: Comments should be received by April 7, 2000. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Comments should be sent to Docket Clerk, Attn: Docket No. OST–99–6578, Department of Transportation, 400 7th Street, SW., Room PL401, Washington DC, 20590. For the convenience of persons wishing to review the docket, it is requested that comments be sent in triplicate. Persons wishing their comments to be acknowledged should enclose a stamped, self-addressed postcard with their comments. The docket clerk will date stamp the postcard and return it to the sender. Comments may be reviewed at the above address from 9:00 a.m. through 5:30 p.m. Monday through Friday. Commenters may also submit their comments electronically. Instructions for electronic submission may be found at the following web address: http://dms.dot.gov/submit/.. The public may also review docketed comments electronically. The following web address provides instructions and access to the DOT electronic docket: http://dms.dot.gov/search/.

FOR FURTHER INFORMATION CONTACT: Mary Bernstein, Director, Office of Drug and Alcohol Policy and Compliance (ODAPC), 400 7th Street, SW., Room 10403, Washington DC, 20590, 202–366–3784 (voice), 202–366–3897 (fax), or *mary.bernstein@ost.dot.gov* (e-mail); Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, Washington DC, 20590, 202–366–9306 (voice), 202–366–9313 (fax), or *bob.ashby@ost.dot.gov* (e-mail); or Jim L. Swart, Drug and Alcohol Policy Advisor, Office of Drug and Alcohol Policy and Compliance (ODAPC), 400 7th Street, SW., Room 10403, Washington DC, 20590, 202–366–3784 (voice), 202–366–3897 (fax), or *jim.swart@ost.dot.gov* (e-mail).

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. The rule was based on the Department of Health and Human Services (HHS) guidelines for Federal agency employee drug testing, with some adaptations for the transportation workplace drug testing program. 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 15, 1994, final rule (59 FR 7340). This rule also modified drug testing procedures pertaining to split samples. 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, ''shy bladder'' procedures).

In the 10 years since Part 40 was first published, the Department has 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 been incorporated into the regulatory 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, making it desirable to update some regulatory provisions. Because the rule was originally based on that of another agency, 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.

Organization of Draft

Perhaps the first thing readers will notice about this proposal is that Part 40 has been thoroughly restructured, with subparts organized by subject matter area. Compared to the present rule, the text is divided into many more sections, with fewer paragraphs each on average, to make it easier to find regulatory provisions. The proposal uses a question-answer format, with language specifically directing particular parties to take particular actions (*e.g.,* ''As an MRO, you must . . .''). We have also tried to express the (admittedly sometimes technical) requirements of the rule in plain language. The Department seeks comment on the clarity, format, and style of the NPRM and solicits suggestions for improving it.

Noteworthy Substantive Changes Proposed

The following section of the preamble lists the NPRM's most noteworthy proposed substantive changes from the existing rule and briefly states the reasons for them.

Interpretations/Exemptions

To avoid confusion and the possibility of overlapping or contradictory guidance, § 40.5 spells out specifically the sources and dates of authoritative guidance of the proposed rule. Guidance would come from the Office of the Secretary (OST), either ODAPC or General Counsel's office. It could later be incorporated in written guidance issued by the DOT agencies, though it would be identified as ODAPC/General Counsel's office guidance. Since this proposal is intended to lead to a revised regulation, the language states that only post-issuance guidance or interpretations are valid, since earlier material pertains to the old version of the rule. ODAPC intends to follow a practice of putting new Part 40 interpretations and guidance on the DOT Web site for users' convenience.

This is an OST rule. Therefore, anyone wanting an exemption from it would use the procedures and standards of 49 CFR Part 5, OST's rulemaking procedures. These procedures, rather than those of any of the DOT agencies, would apply to such a request. The proposed section spells out the long-standing procedures of Part 5 for granting an exemption. These standards are intended to preclude ''rulemaking by exemption,'' which is contrary to good rulemaking practice and the Administrative Procedure Act.

Service Agent Assurance

Proposed § 40.11 includes new provisions that call for both regulated employers and their service agents to sign a contract provision committing them to compliance with Part 40 provisions. ''Service agent'' is a new term, intended to encompass participants in the testing process other than employers themselves (*e.g.,* medical review officers (MROs), substance abuse professionals (SAPs), collectors, laboratories, third-party administrators). The Department is using ''service agent'' as a working term for this collection of participants who provide testing-regulated services to employers. The Department invites suggestions for other terms for this group of service providers.

NRC Procedures

In response to a comment from the Nuclear Regulatory Commission (NRC), the proposed rule would permit an entity which has employees covered by both DOT and NRC testing requirements to use either agency's procedural requirements.

Prohibition of Additional Testing

This section places a number of long-standing DOT interpretations into the regulatory text. It proposes to say that there must be a firewall between DOT and non-DOT tests, which extends to the use of Federal forms for non-DOT tests. Tests not expressly authorized by DOT rules on ''DOT specimens'' are forbidden (*e.g.,* tests for additional drugs, DNA tests). Nor can anyone take into account an unauthorized test (*e.g.,* in a situation in which an employee with a positive test obtains a test result from his own doctor that he attempts to use in a grievance proceeding).

The rule text omits current language permitting testing of additional drugs with DOT and HHS regulatory consent. HHS has never authorized any additional drugs. If additional drugs are authorized, the Department can amend the rule at that time.

Collector Training

While current Part 40 has specific training requirements for screening test technicians (STTs) and breath alcohol technicians (BATs) in the alcohol testing program, it does not have analogous requirements for drug testing collectors. The Department is also aware that mistakes in the collection process are generally regarded as being a common cause of problems in the drug testing process. Consequently, the Department proposes in § 40.33 that collectors read and understand DOT rules and guidance concerning collections, demonstrate proficiency by completing three consecutive error-free trial collections, and receive retraining as needed. The Department seeks comment on whether self-instruction is adequate for this purpose or whether more formal training should be required (*e.g.,* a specified course with a certification requirement, as is the case for STTs and BATs).

In this and several other contexts, we propose to require individuals who are training or evaluating participants in the testing process to be ''sufficiently knowledgeable'' about testing requirements and procedures. We recognize that this term does not precisely define the experience and information the individual must possess. Our aim in using this language is to ensure that people involved in the training process know what they need to know to judge fairly whether a collector, BAT, etc. has grasped the essentials of the function. It is not our intent, however, to require formal instruction or a standard curriculum for trainers. Doing so could increase costs and make the program unnecessarily rigid. We seek comment on whether a different term or other requirements would be appropriate in this area.

Drug Testing Forms and Materials

The NPRM proposes (§§ 40.47 and 40.49) that no one can use a DOT drug testing form for a non-DOT test or vice-versa. However, because obtaining a test result is the more important factor, use of a non-DOT form for a DOT test is, in cases where a look-alike form is used, a correctable error in the testing process. Collectors also must use a testing kit conforming to DOT requirements (see Appendix A for additional information on the kit). This proposal is based on our experience and a thorough review of testing kits by DOT staff. The Department also seeks comment on what, if any, additional security measures would be appropriate for testing materials and supplies. The proposal (§ 40.45(e)) also would continue existing policy that foreign employers can use foreign-language versions of the forms (*e.g.,* Spanish in Mexico, French in Canada). Should U.S. employers also be permitted to use these or other foreign-language versions of the forms? If this is allowed, additional questions may arise (*e.g.,* should a foreign-language form be used only when both collector and employee understand the language?).

HHS is presently revising that form and has published it for public comment in a Notice of Proposed Revision in the **Federal Register** [November 15, 1999 (Volume 64, Number 219)]. We will not publish, in this NPRM, copies of the HHS-proposed Federal Drug Testing Custody and Control Form (CCF) or the CCF currently in use. (Nor will we publish the Breath Alcohol Testing Form (BATF) currently in use.)

Electronic Records and Signatures

From time to time, interested parties have raised, and the Department has sought comment about, the potential use of electronic records and signatures in the DOT drug and alcohol testing program. The regulatory text of this NPRM does not make any new proposals in this area. However, the Department is willing to consider ideas that would, to a greater degree than is currently the case, permit the use of electronic records and signatures in the program.

We are also aware that other Federal agencies have taken steps to encourage greater use of electronic records and signatures. For example, the Food and Drug Administration (FDA) issued rules to this effect (62 FR 13430; March 20, 1997). The FDA rules authorize electronic signatures in many documents submitted to the agency, with a number of safeguards designed to ensure the reliability and trustworthiness of the signatures.

The Department again seeks comment on the potential applications, advantages, risks, and safeguards for the use of electronic signatures and the greater use of electronic records in the DOT drug and alcohol testing program. For example, are there electronic ''stamping'' mechanisms we should permit for use with the CCF?

Collection Process

Section 40.61 incorporates a number of provisions that are new or based on existing interpretations (*e.g.,* collections are to begin without delay, it is improper to attempt to collect urine from unconscious employees, collectors can inspect boots for adulterants). Sections 40.63–65 provide a step-by-step process for collectors for the initial stages of the collection process. Collection steps concerning completion of the CCF are written in this NPRM based upon the collector's use of the current Federal form. When HHS approves use of a new form, the Department will modify Part 40 collection steps (as well as laboratory and MRO responsibilities for completion of the CCF) accordingly.

The proposed rule would stipulate that in the event an employee, after presenting an insufficient amount of urine, refuses to drink fluids as directed by the collector, the collector is to stop

the collection proceedings. A failure to drink as directed would constitute a refusal to test (§§ 40.191(a)(5) and 40.193(b)(2)). The Department seeks comment on this proposal. Should the collection be curtailed at this point and the refusal to test be the final result? Or, should the employee have up to three hours to present a complete specimen, with the ''shy bladder'' procedures taking place if the employee subsequently fails to provide the required amount of urine?

Directly Observed and Monitored Collections

In §§ 40.67 and 40.69, the NPRM consolidates in one place the requirements concerning directly observed and monitored collections, respectively. The language states that an immediate collection under direct observation would be called for in some situations involving unsuitable specimens or when a previous test has been canceled because of the unavailability of a split specimen. The Department seeks comment on whether we should also require an immediate recollection under direct observation if an employee's specimen is dilute. We also seek comment on whether employers should be permitted the ability to reject a negative test result when a specimen is reported negative but dilute by the MRO. Currently, the rules permit an employer to have the employee's next test to be collected under direct observation, but this opportunity may not occur for months.

The proposal notes that a refusal to permit a directly observed or monitored collection has the same effect as any other refusal to test. The NPRM clearly distinguishes between the activities of an observer (*e.g.,* who actually watches the urination) and a monitor (who stands by and listens but does not watch).

Laboratories

Some laboratory-related material (*e.g.,* present § 40.27, concerning personnel) would be deleted, as unnecessarily duplicative of the HHS guidelines. The NPRM would make laboratories subject to public interest exclusions if they failed to comply with DOT rules, even if their HHS certification remained intact (§ 40.81(c), (d)). The Department asks for comment on whether, in the case of an amphetamine positive, the laboratory should perform a d-and l-separation in all cases.

For the first time, laboratories would be required to test for nitrites, pH, creatinine and, in certain circumstances, specific gravity (§ 40.91). This so-called ''adulteration panel'' would increase the ability of the testing process to catch attempts to cheat. We note that, under HHS guidance for the Federal agency personnel testing program, these tests are discretionary. We seek comment on the advantages, disadvantages, costs, and benefits of mandatory adulterant testing. In addition, the NPRM contains largely new procedures for dealing with unsuitable specimens and situations in which a split specimen does not reconfirm the result of the primary specimen (§§ 40.151 and 40.177).

The rule text, like that of the present rule, is silent on the issue of who selects a laboratory for testing. From the Department's point of view, any HHS-certified laboratory will do. The selection of the laboratory can be made by the employer, or it could be made as a matter of collective bargaining where applicable. In any case, the laboratory must be suitable to the employer.

To reduce paperwork and save time in the process, laboratories would no longer have to routinely send original copies of certain copies of the drug testing form to the MRO. The MRO would request original copies if, for example, faxed copies were unclear.

The proposed rules (§§ 40.83 and 40.155) would also clarify under what circumstances a laboratory may reject a specimen for testing and one circumstance that they must reject a specimen for testing. The Department seeks comment on the length of time laboratories should maintain rejected specimens. In addition, the rules delineate the laboratory reporting requirements as well as the role of the MRO in ruling out collector error as being the causative factor. MRO reporting requirements are highlighted. DOT seeks comments on the viability of having the employee return for a second collection if collector error results in a laboratory's rejecting a specimen for testing.

In its implementation of the existing rule, the Department has identified a number of situations that potentially present conflicts of interest or their appearance. In a number of cases, the Department has provided guidance to employers and service agents that these practices are inappropriate. Examples of such practices are: the laboratory employs the MRO; the laboratory has a contract or retainer with the MRO; the laboratory designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or refers the employer to or recommends certain MROs; the laboratory gives the employer a discount or other incentive to use a particular MRO; the laboratory has its place of business co-located with that of the MRO; the laboratory derives a financial or other benefit from having an employer use a particular MRO; and the laboratory permits an MRO, or an MRO's organization, to have a significant financial interest in the laboratory. It should be noted that problems of this kind arise when a laboratory has a relationship with an MRO who reviews the laboratory's DOT test results.

The Department seeks comment on whether the text of the final rule should, in order to provide clear notice to affected parties, provide a specific list of prohibited practices. If so, should the items above be part of such a list? Should items be added or deleted? We are also interested in your comments on what limitations, if any, should be placed on laboratories and MROs serving as third-party administrators or collection sites, and what conflict of interest issues these relationships may raise.

The NPRM would require each laboratory to sign a certification that there exists no conflict of interest or the appearance of conflict of interest between the laboratory and any MRO to whom they transmit DOT test results. In the absence of regulatory specification of the nature of such conflicts, is this proposed requirement meaningful or enforceable? For enforcement purposes, would it be useful for a laboratory to maintain a list of the MROs to whom this certification applies?

Laboratory Reports

49 CFR Part 40, published December 1, 1989, contained the same requirements for the laboratory summary report (monthly at that time) as the requirements contained in the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (*i.e.,* the number of specimens received, screened positive, and the number that subsequently confirmed positive, by type of drug).

An amendment to Part 40, published August 19, 1994, changed the original requirement for monthly reports to quarterly, clarified authority for laboratories to provide these reports to consortia, and changed the type of information that should be included by deleting the requirement for screening results. One of the Department's concerns underlying this change was to avoid the potential for identifying individuals who may have been positive, but whose results were subsequently ''downgraded'' based on medical use. This issue is important in that if laboratories report confirmed laboratory positive results by type of test (*e.g.,* pre-employment, reasonable suspicion), the potential exists to

identify individuals, even if there are more than five tests results listed on the report.

The following chart compares current DOT and HHS laboratory report requirements:

DOT	HHS
Initial Testing: 1. Number of samples received for testing.	Initial Testing: 1. Number of samples received. 2. Number of samples reported out. 3. Number screened positive for: A. marijuana metabolites. B. cocaine metabolite. C. opiate metabolites. D. phencyclidine. E. amphetamines.
Confirmatory Testing: 2. Number confirmed positive for: A. marijuana metabolites B. cocaine metabolite C. opiate metabolites D. phencyclidine. E. amphetamines 3. Number for which test was not performed.	Confirmatory Testing: 1. Number received for confirmation. 2. Number confirmed positive for: A. marijuana metabolites. B. cocaine metabolite. C. opiate metabolites. D. phencyclidine. E. amphetamines. F. methamphetamines.

DOT and HHS agree that the laboratory summary reports required by each agency should be the same. This would minimize additional paperwork that laboratories would be subjected to in providing two different reports. Additionally, deleting the HHS requirement to report screened results would lower the laboratory workload and shorten the report.

Currently, there is no requirement for laboratories to report to employers the number of tests received by the laboratory by type of test (pre-employment, random, etc.). However, it appears that many employers want this information, thinking that it could be used as a check on their own statistical data. Large employers and service agents generally maintain appropriate statistical data for their programs and the Department is interested in hearing from the industry if this type of additional information from the laboratories is truly helpful.

The Department would also like to know if information identifying the number of specimens that must be canceled and/or are adulterated would be useful to employers, service agents, or in the overall enforcement process. Please note that the requirements would be for submission of the report on a monthly basis under HHS regulations and semi-annually under the proposed DOT rules, with more frequent reporting as required by the Federal agency with regulatory authority over the employer.

The Department also seeks comment on record retention requirements for laboratories (see § 40.109). Are the proposed record retention periods appropriate? Should any of the periods be lengthened or shortened?

Blind Specimens

Current rules require employers to send ''blind'' urine specimens to laboratories for drug testing. These samples are unannounced and are made to look like normal samples. Whether they are negative or positive (and for which drugs) is known in advance only by the senders. These specimens are used to test the accuracy of the laboratory testing system. Together with other quality control procedures, blind specimens are an important means of keeping the testing program legitimate in the eyes of the courts, congress, and employee groups.

Currently, all employers must send these samples to the respective laboratories they use. The NPRM, in the interest of reducing burdens on regulated parties, would reduce blind specimen requirements from current levels (§ 40.103). Parties with fewer than 2000 DOT covered employees would no longer have to provide blind specimens (§ 40.103(a)). For other parties, blind specimens would only have to be provided at a one percent rate, up to a cap of fifty blind specimens per calendar quarter. This change is intended to be helpful to small businesses. In addition, since consortiums that send in large numbers of specimens collected from a variety of employers will continue to have to submit blind specimens, we do not expect that this change will adversely affect the accuracy of the laboratory testing process.

The Department seeks comment on whether the blind specimen requirement should be eliminated entirely or modified in a different way from the NPRM proposal. The proposed language provides examples of how the blind specimen requirements would work. Section 40.105 would specify what happens if there is a laboratory error on any specimen, to include a blind specimen. In addition, we ask whether testing blind specimens for adulterants is warranted.

MRO Training and Responsibilities

MROs would have to take a training course every two years or certify that they have reviewed and understand Part 40 and applicable DOT agency regulations and guidance. The NPRM also sets out a list of MRO responsibilities, including acting as an independent ''gatekeeper'' for the accuracy and integrity of the testing process and correcting and reporting problems when they are found (§ 40.123). It is particularly important that MROs not be involved in relationships with laboratories that could create a conflict of interest or the appearance of such a conflict. There are proposed conflict of interest requirements for MROs parallel to those for laboratories (§ 40.125).

The Department wishes to emphasize its view that the MRO is a very important player in the testing process, who more than any other person is responsible for maintaining the integrity of that process. It is the MRO's responsibility to advocate for and defend the accuracy of the process. This part of the MRO's role makes a conflict

of interest especially sensitive. These issues are not necessarily limited to MRO/laboratory relationships. Given the MRO's role as an evaluator of the testing process, does the MRO's ownership or administration of a collection site create the appearance or reality of a conflict of interest?

The rule, at various points, sets time frames for certain actions by MROs (*e.g.,* 14 days for verifying a ''non-contact positive'' in § 40.133(a)(2)). Should such time frames be expressed in ''business days'' (*i.e.,* excluding weekends and holidays) rather than calendar days?

It is common for MROs to conduct their functions across state lines. An MRO located in one state may perform functions concerning drug tests and employees located in many other states. Recently, we have learned of some concerns that some state medical licensing agencies may believe that out-of-state MROs who are not licensed to practice in the state may not be authorized to perform MRO functions with respect to employees located in the state. The Department is interested in learning whether this is a significant issue, and if so whether the issue poses a serious obstacle to the performance of MRO functions in a national safety program. If there is such a problem, should the Department take regulatory action to address it? If so, what action would be appropriate?

MRO Reviews of Test Results

The Department believes that it is important to draw a clear distinction between the roles of the MRO, on one hand, and the MRO's staff, on the other. MROs are responsible for supervising their staffs (see for instance § 40.127(a)). When MRO staff review test result documents, MROs would personally have to oversee their work, including direct re-review of a portion of the documents they have reviewed. Staff members can handle administrative contacts with employees and remind them to have medical information ready for their MRO interviews, but actually gathering medical information and drawing conclusions from the information would be the personal responsibility of the MRO (see for instance § 40.131(b)).

The ways a MRO makes use of a designated employer representative (DER) to contact a difficult-to-find employee are also spelled out in greater detail than in the present rule. In response to a number of requests, the proposal would define a reasonable time for a DER to contact an employee as two attempts over a 24-hour period. The rule (§ 40.133(a)(2)) would also authorize MROs to verify a test positive if neither the MRO nor the DER had been able to contact the employee within 14 days of the MRO's receipt of the confirmed positive test result. The Department seeks comment on whether this time period is appropriate, or a longer or shorter period should be used.

The MRO provisions of the NPRM contain proposed language consistent with the Department's discussion of the ''stand-down'' issue (see ''Employer Actions'' below). The MRO provisions in the proposed regulatory text would prohibit MROs from telling or, in the alternative, permit MROs to tell, the employer for whom the MRO is working that the MRO has received a laboratory confirmed positive test result, pending the completion of the MRO verification process (§ 40.129(d)). The rule text will contain both options.

MRO Verification Process

Section 40.135 lists explicitly what MROs would have to tell employees at the beginning of the verification interview, including warnings about the effect of the refusal to provide information for a medical evaluation (see § 40.135(c)) and that the MRO may provide medical information to employers or others under some circumstances.

Sections 40.137 and 40.139 distinguish between the burdens of proof applicable to opiates and to all other drug types. The MRO bears the burden of showing unauthorized use of opiates, while the employee bears the burden of showing that there was a legitimate medical explanation for the presence of other drugs. The MRO would have to offer the employee the chance to provide a legitimate medical explanation. The Department seeks comment on whether an exception to this rule should be made in the case of PCP, for which there are no known legitimate medical applications.

In making a verification of the unauthorized use of opiates, the MRO may consider such factors as needle tracks, behavioral or psychological signs of acute addiction, clinical history of unauthorized use (including admissions by employees), or use of foreign medication without substantiation that the medication was obtained and used legally. It should be emphasized that the MRO is intended to exercise good professional judgment on a case-by-case basis; the rule does not mandate a finding of positive or negative on the basis of any particular piece of evidence (aside from a laboratory finding of the presence of 6–AM).

In the case of opiate verifications, the Department seeks comment on whether it would be appropriate to shift the burden of proof in cases of very high opiate levels. That is, if the quantity of opiates in a specimen is very high (i.e., at or above 15,000 ng/mL), making an innocent-ingestion explanation (e.g., poppy seed bagels) very unlikely, then the employee would have the burden of proving that there was a legitimate medical explanation (e.g., a prescription medication) for the laboratory positive. In such a situation, the verification process for high levels of opiates would work like the verification process for other drugs. The proposed rule text incorporates this approach. In reaching this decision, the Department reviewed a number of scientific studies of food products containing poppy seeds. While most studies found concentrations of 5,000 ng/mL or below, in only one study (C. M. Selavka. ''Poppy seed ingestion as a contributing factor to opiate-positive urinalysis results: the Pacific perspective.'' Journal of Forensic Sciences, 1991;36(3):685–696.), did a product show concentration above 5000, this one at 11,571 ng/mL. Is our level of 15,000 ng/mL (which is approximately thirty percent above any known concentration attributable to poppy seed ingestion) too high or too low?

MROs are cautioned against considering evidence from unauthorized sources (e.g., non-DOT urine tests, blood tests, hair tests, DNA tests) and evidence outside the test documentation (e.g., an employee's assertion that the documents do not accurately reflect what happened at the collection site). MROs are also cautioned against considering ''innocent ingestion'' defenses (e.g., ''Someone slipped the drug into my drink at the party;'' ''I ate a hemp product;'' ''I was hanging out with people who were smoking funny-looking cigarettes'') that, even if true, do not constitute a legitimate medical explanation for the presence of a drug in an employee's specimen (§ 40.143). This is also true of statements by an employee that he or she has used marijuana for medical purposes in a state that has a so-called ''medical marijuana'' law. Use of marijuana on the basis of a doctor's prescription or recommendation does not constitute a legitimate medical explanation that is sufficient to permit an MRO to verify a test as negative. Use of a hemp product is not a legitimate medical explanation, either.

In the context of pre-employment testing, the NPRM states that a person with a permanent or long-term disability preventing him or her from providing a sufficient specimen may be regarded as testing negative. In such a case, the individual must undergo a medical examination to determine if the individual is free of signs or symptoms

of illegal drug use. The Department seeks comment on whether a similar provision should be created to apply to other types of testing. For example, if an individual has this type of permanent or long-term disability, should the individual undergo a medical examination to determine if he or she is free of signs or symptoms of drug abuse in lieu of a futile attempt to complete a random drug test in the usual way? This would avoid the necessity of going through the ''shy bladder'' procedure repeatedly, while providing a surrogate for the drug test that could accomplish the safety goal of testing.

One of the most common misunderstandings of the current rule is that an employee who makes a timely request for the test of a split specimen (where such testing is mandated by statute) may be denied such a test if he or she does not pay for it up front from his or her own funds. To avoid this problem in the future, § 40.145 specifies that an MRO must explicitly inform the employee that, if he or she has a verified positive test and asks for a test of the split specimen in a timely manner, the test will be performed, regardless of whether the employee complies with a request from a laboratory, employer, or other party to pay for it in advance. While the rule is intentionally silent on who ultimately pays for a test, the employer is responsible for ensuring the test occurs. (See also §§ 40.171 and 40.173.)

The text also proposes that MROs can conduct the verification process and report results if the MRO has received legible copies of the MRO and laboratory copies of the CCF. The text also delineates an MRO's responsibility in pre-employment testing situations when the employee has a disability preventing the submission of a urine specimen.

Adulterated, Substituted, and Dilute Tests

This NPRM proposes to mandate testing for adulterated and substituted specimens (''validity testing''), which will likely increase the number of situations in which laboratories determine that a specimen has been adulterated or substituted. This proposal is based on the concern that adulteration and substitution are real and possibly increasing threats to the integrity of the Department's drug testing program, with the potential for increased safety risks if drug users succeed in frustrating the testing process.

The proposed rule (§ 40.93) sets forth standards and a process for determining when a specimen is adulterated, substituted, or dilute. For substituted and adulterated specimens, the proposed rule, consistent with HHS guidance, requires laboratories to test two different aliquots of the primary specimen. In many cases, the laboratory must use different procedures, at least one of which is quantitative, for each of the aliquots. Only then does the laboratory determine that the specimen is substituted or adulterated. The requirement to test two different aliquots is designed to ensure that the laboratory makes such a determination only on the basis of a reproducible result. This is an important safeguard for the accuracy of the process.

DOT policy provides that an individual who has been found to have adulterated or substituted a specimen is viewed as having refused to test. Such a refusal is a violation of DOT agency regulations, with consequences similar to those of a positive test. That is, an employee who refuses to test is prohibited from performing safety-sensitive functions unless and until he or she completes the return-to-duty process. Under some DOT agency regulations (*e.g.,* the FRA), the consequences of a refusal to test can be more stringent than those of a positive test. There are also some employer policies that treat refusals more strictly than positive tests.

The increased prominence of testing for adulteration and substitution of specimens, combined with the seriousness of consequences for refusing to test, has resulted in increased interest in safeguards for employees. In particular, some unions and other parties have suggested that the Department should apply split specimen testing procedures to specimens that have been found to be adulterated or substituted.

This suggestion grows out of a requirement in the Federal Motor Carrier Safety Administration (FMCSA) [prior to January 1, 2000, the Federal Highway Administration], the Federal Transit Administration (FTA), the Federal Railroad Administration (FRA), and the Federal Aviation Administration (FAA) testing rules that employees who test positive for drugs are entitled to ask for a test of a second, or ''split,'' specimen at a second laboratory to confirm the presence of the drug. This requirement is mandated by provisions of the Omnibus Transportation Employee Testing Act of 1991. In the Research and Special Programs Administration (RSPA) and United States Coast Guard (USCG) programs, which are not covered by the Omnibus Act, split specimens are optional with employers.

The Department is seeking comment on three options concerning this issue. The first option is to do nothing beyond the procedure set forth in the regulatory text, in which there would be two separate tests of the primary specimen before a finding of substitution or adulteration is made. The Department is confident that this option is legally defensible. It also is less costly and less prone to the possibility of administrative error than a system involving testing of the split specimen.

Split specimen testing, even in the context of positive drug test results, is not constitutionally mandated. The Department's drug testing rules, prior to the 1994 amendments implementing the Omnibus Act, left split specimen testing to the discretion of employers. The Department's drug testing requirements and procedures were upheld as constitutional by the courts before those amendments were made. It is not reasonable to assert that the Department is constitutionally required to expand the application of a procedure which is not constitutionally required to be used in the first place.

Nor is split specimen testing required by the statutes and regulations governing the Department drug testing programs. The split specimen provision of the FMCSA, FTA, FRA, and FAA rules results from a requirement of the Omnibus Transportation Employee Testing Act of 1991 (49 U.S.C. § 5331(d)(5)). This section provides that:

> . . . each specimen be subdivided, secured, and labeled in the presence of the tested individual and that a part of the specimen be retained in a secure manner to prevent the possibility of tampering, so that *if the individual's confirmation test results are positive* the individual has an opportunity to have the retained part tested by a 2d confirmation test done independently at another certified laboratory if the individual requests the 2d confirmation test not later than 3 days after being advised of the results of the first confirmation test. [emphasis added]

This provision is implemented in the Department's current drug testing procedural regulations:

> . . . the MRO shall notify each employee *who has a confirmed positive test* that the employee has 72 hours in which to request a test of the split specimen, *if the test is verified as positive*. . . . If the [second laboratory's] analysis fails to reconfirm the presence of *the drug(s) or drug metabolite(s)* found in the primary specimen, . . . the MRO shall cancel the test. . . . [49 CFR § 40.33(f); emphasis added]

In the first instance, both the statutory and regulatory language create a right to a test of the split specimen only in situations where there is a confirmed

positive test. A confirmed positive test occurs only when the laboratory confirmation test detects sufficient quantities of the specified drug(s) or drug metabolite(s). In a case where the laboratory has found an adulterant in the specimen or has determined it to be substituted, the laboratory does not report a confirmed positive test to the MRO. The condition precedent to the right to a second confirmation test has not occurred, since there has never been a confirmed positive test for a drug reported to the MRO in the first place.

The current regulation, in spelling out the procedure for requesting a test of a split specimen, provides that a request must be made within 72 hours of a *verified* positive test. (The MRO verifies a confirmed laboratory test as positive if the MRO cannot determine that there is a legitimate medical explanation for a laboratory confirmed positive test result.) In the absence of a confirmed positive test, there can never be a verified positive test, which is the trigger for the employee's opportunity to request a test of the split specimen.

The current regulation further provides that if the test of the split specimen fails ''to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen,'' the test must be canceled. In a case involving a finding of adulteration or substitution, there has never been a reported finding that drug(s) or drug metabolite(s) are present in the employee's specimen. One cannot ''reconfirm'' a finding that has never been made. The regulation requires cancellation of a test only if the presence of drug(s) or drug metabolite(s) is not reconfirmed in the split specimen.

In addition to the use of split specimen testing in adulteration or substitution cases not being legally required, the first option is supported by three policy considerations. First, the Department is very concerned that present adulterants and other interfering substances may degrade over time. That is, when an adulterant is present in the primary specimen but degrades chemically to the point where it cannot be detected or changes to another chemical state in the split specimen (e.g., HHS has recently identified one adulterant that appears to degrade in a matter of hours), our making split specimen testing available for adulterants could help drug users ''beat the test.'' In addition, manufacturers of commercial products intended to defeat drug testing—who engage in a well-publicized ''arms race'' to find new means of defeating drug tests—may well be able to develop, in the future, adulterants that degrade even faster.

Second, the Department's experience is that the overwhelming majority of test cancellations related to split specimens result from collection or logistical problems (*e.g.,* collector fails to collect the split specimen, a split specimen is lost or leaks in transit). The Department has been reluctant to expand the application of split specimen testing to areas where it is not required by statute, which could have the result of canceling otherwise valid tests and allowing drug users to continue to perform safety-sensitive functions.

Third, the Department has viewed an adulterated or substituted specimen as more closely analogous to a refusal to test than to a positive test. Employee A flatly tells the collector that he will not provide a specimen, or simply does not show up for the test. Employee B shows up, provides a specimen, signs the statement on the custody and control form certifying that he or she has not tampered with the specimen, but nevertheless puts a substance into the specimen that prevents the laboratory from testing it. The actions of Employee A and Employee B are equivalent. Having a second opportunity to defeat the testing process is no more appropriate for Employee B than for Employee A.

The second and third options would both add a further element to the language in the proposed regulatory text. The Department seeks comment on all three options, as well as any other suggestions commenters may have on this subject.

The second option would be to treat an adulterated or substituted test result the same as a verified positive and allow the employee to request a split specimen test by a second laboratory. For example, suppose a laboratory makes an adulteration or substitution finding. Within 72 hours of being informed of the finding, the employee would have the opportunity to request a test of the split specimen by the second laboratory to see if the adulteration or substitution finding could be reconfirmed. If it were not reconfirmed, the test would be canceled, just as in the case where a split specimen fails to reconfirm the presence of a drug or metabolite found in a positive primary specimen. This option would ensure that employees who face similar or more severe employment consequences compared to employees with positive tests for drugs have an equal ability to challenge a laboratory's primary specimen determination. The argument in favor of this approach is basically one of fairness.

This additional safeguard for the fairness of the process could provide reassurance to the vast majority of employees who fully and honestly cooperate in drug testing programs. It could also discourage frivolous challenges to drug test results by employees who know they have submitted adulterated samples.

In addition, more research needs to be done in the area of adulterants degrading over time. There are technical questions that need to be resolved about the protocols and standards to be applied in split specimen reconfirmation in adulteration and substitution situations. The Department is working with HHS to ensure that this information is available in time for the final rule. Meanwhile, we invite comment on the technical and scientific issues concerning adulteration and substitution testing and reconfirmation.

The Department seeks comment on whether, if a provision for split specimen testing for adulterated and substituted specimens is included in the final rule, it should be required or optional. That is, should we require employers to make split specimen testing available in these circumstances, or should employers (or employers and unions, where collective bargaining agreements apply to drug testing issues) have the choice of whether to make split specimen testing available?

In addition, we seek comment on whether Part 40 should also be amended to require employer submissions of adulterated and substituted specimens as part of the external quality control (''blind specimen'') program. If so, how should selection of adulterants be made? How many adulterated specimens should be included within the minimum number of blind specimens submitted? To what extent have such specimens been included in existing blind testing programs? What practical issues could arise with regard to administration of such a program?

A third option occupies a middle ground between the first two options. When a laboratory finds that a primary specimen has been adulterated or substituted, it would immediately test a third aliquot of the same specimen to see if the same result was obtained (two aliquots would already have been tested before the original finding of adulteration or substitution had been made). If the retest did not confirm the original finding, the test would be canceled. The Department seeks comment on what the standards should be for this additional test. For example, should we set a standard that to be regarded as confirming the presence of an adulterant, the additional test result should be within +/− 20 percent of the

original result (while still satisfying the initial reporting criteria)?

This approach would add a safeguard for employees, by adding another level of assurance that the laboratory was relying on a reproducible result. Reproducibility is a key component of the validity of any scientific process, and this approach would ensure that no one would suffer adverse consequences on the basis of a result that could not be reproduced.

Since the retest would occur immediately, degradation of most adulterants would not be a major problem. In addition, because it would take place in the same laboratory and would not involve the split specimen, collection or transmission errors affecting the split specimen would not result in the cancellation of an otherwise valid adulteration or substitution result.

Finally, the proposed rule text includes material adapted from the DOT and HHS guidance concerning other types of ''problem tests'' (§§ 40.147 through 40.153). As current DOT guidance states, a retest under direct observation is required in situations of some ''unsuitable'' specimens. The Department seeks comment on whether a retest under direct observation should also be required in cases of dilute specimens. The Department also seeks comment on a frequently-asked question about dilute specimens: should an employer have the discretion to disregard a dilute result? For example, if an employer in a pre-employment test situation receives a test result that is negative and dilute, should the employer be able to require that the applicant take another test and get a negative result from an undiluted specimen before beginning to work in a safety-sensitive position?

Employer Actions

Section 40.159 addresses the so-called ''stand-down'' issue. Some employers have expressed a preference for standing-down employees—taking them temporarily out of service based on a report from the MRO that the employee has a confirmed positive test, pending completion of the verification process. Some employers who have an in-house MRO appear particularly attracted to this approach. The proponents of this approach assert that it enhances safety and that it can include safeguards for employee privacy.

In the program for regulated industries, the Department's current rules and interpretations have prohibited stand-down. The reason for this approach is that such policies may result in the stigmatization of employees as drug users in cases when positive laboratory results are downgraded as a result of the MRO verification process. The Department's rules have always striven to provide a balance between safety objectives and the protection of legitimate employee privacy interests. In addition, the Department is not aware of any evidence that, in the millions of tests conducted in compliance with the Department's rules since the program began in 1988, the existing prohibition on stand-downs has ever had adverse safety consequences.

However, the Department's internal drug testing program for DOT employees, which applies to air traffic controllers and other safety-sensitive employees, has used a stand-down procedure for many years. Consequently, the Department's overall approach to this issue has been inconsistent.

Given this situation, the Department has decided to seek comment on both approaches. The proposed regulatory text includes language, in the alternative, relating to both. Alternative 1 is the present approach, which prohibits stand-down. Alternative 2 would permit stand-down, with requirements for maintaining confidentiality of information concerning the confirmed positive test result of the employee. We seek comment on which alternative is preferable for the final rule. If the final rule permits employers to implement stand-down policies, the Department seeks comment on several associated issues.

For example, should the rule specify that an employee who is stood down may continue to perform non-safety sensitive duties? What should be the pay status of an individual being stood-down? What additional privacy provisions, if any, are needed to limit dissemination of information about the employee's stand-down status based upon the existence of a laboratory positive test? Difficulties in maintaining confidentiality may be particularly acute in smaller companies (*e.g.,* a trucking company with 10 or fewer drivers). Are there any special provisions we should include for small employers? Finally, how would a stand-down policy apply to owner-operators? It seems implausible that owner-operators would stand themselves down after being informed of laboratory positive tests by MROs.

We also point out that, in addition to the proposed alternative language in §§ 40.129 and 40.159, there may be a need for conforming changes to other sections of the regulation in the event we choose Alternative 2. We seek comment on what, if any, such additional changes to the rule would be needed.

Finally, the proposed regulation would make other employer responsibilities clear. When an employer receives a report from the MRO that there is a substituted or adulterated specimen, the employer must remove the affected employee immediately from safety-sensitive functions. When the MRO informs the employer of an unsuitable specimen, the employer must direct the employee involved to immediately submit a new specimen under direct observation. Likewise, when the employer receives a report from the BAT that there is a result 0.02 or above, the employer must remove the affected employee immediately from safety-sensitive functions.

Split Specimens

Section 40.173 again underlines that, where split specimen testing is required by DOT regulations, employers must make sure that a test of the split occurs every time that an employee makes a timely request. Payment or agreement by the employee to pay the cost of the test is not a prerequisite for conducting a test of the split specimen, though the employer may seek to recover the cost of the test. Laboratories conducting tests of split specimens must refer a specimen to a third laboratory for additional testing when necessary (§ 40.177(d)). The Department also seeks comment on whether (as proposed at § 40.183(d)(4)) there should be a retest under direct observation when a split specimen is unavailable for testing.

Split specimen tests are statutorily mandated only in FMCSA, FTA, FRA, and FAA. They are currently optional with employers in RSPA and USCG. The Department is interested in determining if continuing use of single specimen collections by RSPA and USCG causes confusion for collectors, employers, laboratories, and MROs in light of the fact that FMCSA, FTA, FRA, and FAA are required by the Omnibus Act to use split specimen collection methodology. Will there be fewer errors in the collection process if all DOT urine specimens are collected using split specimen procedures? Will employers covered under multiple rules (*e.g.,* RSPA and FMCSA) be less likely to order the wrong collection if all of DOT's OAs require split specimen procedures (e.g., a situation in which a pipeline repair person also drives a truck)? Is it sound policy to keep the current bifurcated specimen collection system that requires split specimen collection within some transportation

industries and permits single specimen collections for others?

''Problem'' Drug Tests

The NPRM would spell out the circumstances in which an employee's actions are considered to be a refusal to test (§ 40.191). The NPRM also includes a list of testing problems that must or may result in cancellation of a test, including instructions on how to correct problems that would otherwise result in cancellation (§ 40.201). This portion of the proposed rule also notes the effect of a canceled test (§ 40.205) and introduces the concept of a mistake in the process which must be documented when discovered but which does not result in cancellation of the test (§ 40.207). We also request information on whether there are other common mistakes that we should mention in this section.

In connection with the ''shy bladder'' provisions, the rule provides that a physician ''acceptable'' to the employer shall evaluate the employee (the same provision applies to inability to provide sufficient breath for an alcohol test). We understand that, in some cases, employers apparently do not check to determine the suitability of a physician to perform this evaluation. Should the language simply require the employer to ''select'' the physician? Should the rule establish criteria for this selection (*e.g.,* expertise in urology)?

The proposed rule also would incorporate 1998 DOT guidance concerning individuals whose tests are canceled on a pre-employment test because of a serious, long-term disability. These individuals could perform safety-sensitive functions after ''passing'' a physician's evaluation for signs or symptoms of drug abuse, which could include a blood test. Because pre-employment alcohol tests are no longer mandatory, is it necessary to include a similar provision in ''insufficient breath'' situations? The Department seeks comment on this question.

Alcohol Test Administration

Alcohol testing requirements are not proposed to be changed as much as the older drug testing requirements. Some of the changes proposed include mandatory retraining for BATs and STTs who make a mistake resulting in the cancellation of a test (§ 40.213(a)(3), new requirements for test site security (§ 40.223(a)), authorization for foreign-language testing forms (*e.g.,* in Spanish for use in Mexico), more specific instructions on the steps for beginning alcohol tests (§ 40.241) and clarifications concerning the timing of confirmation tests (§ 40.251). There are updated sections on ''fatal flaws'' and ''correctable flaws,'' and how to correct the latter (§ 40.271).

Section 40.233 requires quality assurance plans for evidential breath testing devices. Are these plans necessary or useful? Should the requirement be retained, changed, or eliminated? Can it be improved or modified? The Department also seeks comment on how well the current alcohol testing form is working for collection and other concerned personnel. Are there improvements we should make? We also seek comment on whether the provisions of the rule concerning the use of saliva devices (§ 40.245) adequately describe how these devices work, or whether we should modify this language.

Substance Abuse Professionals

The Department issued an Advance Notice of Proposed Rulemaking (ANPRM) in the **Federal Register** [June 3, 1999 (Volume 64, Number 106)] concerning the inclusion of additional groups of certified drug and alcohol addiction counselors in the definition of a SAP. The NPRM incorporates material from this ANPRM and the comments we received. An overwhelming number of respondents supported the Department's desire to streamline the process for reviewing certification groups' application materials and for evaluating the quality of those groups' certification testing processes. While some commenters favored maintaining the current review process and one favored individual certification for every SAP, the vast majority favored the Department's proposal to require National Commission for Certifying Agencies (NCCA) accreditation for certification agencies wishing to have their certified counselors included in the SAP definition. Because two counselor organizations—the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC) and the International Certification Reciprocity Consortium / Alcohol & Other Drug Abuse (ICRC)—have been through the current rigorous DOT evaluation process, the Department believes that NAADAC and ICRC will not need NCCA accreditation to have their certified counselors remain in the SAP definition.

The NPRM would add training requirements for SAPs (§ 40.281(c)). The NPRM also clarifies the role of the employer, employee, and SAP in the return-to-duty process (§§ 40.283 through 40.291), including a strengthened prohibition on waivers of liability. The NPRM would also incorporate into the rule text a number of existing interpretations concerning the SAP's role (*e.g.,* a SAP assessment must be face-to-face, an employer or employee cannot ''shop around'' for a favorable SAP evaluation, no one may modify or change a SAP's assessment of an employee (§§ 40.295 and 40.297); the SAP is to make a recommendation for a return to work agreement). The rule would also specify that recommendations for follow-up tests and post-return-to-duty follow-up treatment would be included in the SAP's recommendation, and that the employer must follow these recommendations (§§ 40.307 and 40.309). Finally, the NPRM lists the items that must be included in SAP reports on employee evaluations (§ 40.311).

Some SAPs have asked to receive reports of the quantity of drugs in an employee's system, to help them determine what sort of treatment might be appropriate. They do not receive quantitations in the normal course of business. Should SAPs be able to obtain this information from laboratories, much as MROs now can?

The NPRM, like the current rule, requires at least six follow-up tests over the period of one year following an individual's return to safety-sensitive duties after a rule violation (*e.g.,* positive drug test). From rehabilitation and safety viewpoints, is this minimum requirement adequate? For example, would it be better if there were a minimum requirement of twelve follow-up tests during the year? The Department seeks comment on this matter.

Finally, because of the Department's growing concern that no adverse consequences exist for most applicants for DOT safety-sensitive positions who test positive on or refuse to take a pre-employment drug test, we propose to prohibit those individuals from performance of any and all DOT safety-sensitive duties until and unless the person completes the SAP evaluation, referral, and treatment process. DOT agency regulations would be modified accordingly.

Confidentiality and Release of Information

The basic confidentiality provision of the existing part 40 would continue in effect: Information about an employee's drug or alcohol tests can be released to third parties only with the written consent of the employee. The NPRM specifies that this consent must be specific to the information in question, not a ''blanket'' release (§ 40.321(b)). However, a service agent (*e.g.,* an MRO)

can transfer their records to a successor without obtaining such consent, as long as no disclosure to outside parties occurs (§ 40.325(a)). MROs can, with employee consent, contact a prescribing physician to determine if an alternative medication not having side effects that adversely affect safety can be substituted (§ 40.327(c)).

The NPRM specifies that MROs would be required to report drug test information directly, and only, to actual employers. They could not report results via an intermediary, such as a consortium or third-party administrator. Use of intermediaries has the potential to delay the transmission of results and increase the likelihood of administrative error. There is one exception to this requirement: DOT agencies could have a regulatory provision authorizing the provision of results through an intermediary. At the present time, only the Coast Guard has such a provision. No other DOT agency authorizes this practice.

The proposed approach is based on the Department's 1995 guidance on the role of consortia and third-party administrators. As that guidance suggests, reporting through an intermediary might be appropriate in certain specific situations (*e.g.,* when use of a third party is the only practicable way to direct an owner-operator to cease performing safety-sensitive functions or to report a violation to a DOT agency for purposes of taking licence or certification action following a violation). The Department is reluctant to extend these provisions any wider. What are the advantages versus the disadvantages of the current system?

To resolve a dilemma that some MROs have faced, § 40.329 would authorize MROs who work for more than one DOT employer to inform Employer B that an employee has had a positive test or a refusal to test in his capacity as an employee of Employer A. This proposed exception to the employee consent rule has a number of protections to ensure that it is not abused or used too broadly. Should this provision be broadened (*e.g.,* so that the MRO could provide the information to an employer whom the MRO does not serve)? If so, how should a broadened provision be drafted in order to avoid an open-ended license to share information (*e.g.,* within an organization with many MROs and/or a large data base)? One purpose of part 40 is to maintain an appropriate balance between safety and privacy considerations, and we seek comment on how best to strike this balance in this situation.

The existing rule requires laboratories to provide certain information to employees about, among other things, their HHS certifications. Despite this requirement, laboratories have sometimes refused to provide the information. Section 40.331 specifies the scope of this requirement in greater detail and emphasizes the laboratories' obligation to comply. It should be noted that refusal by a laboratory to provide required information could subject the laboratory to public interest exclusion proceedings under subpart R.

The NPRM currently authorizes the provision of information about a post-accident drug or alcohol test to the National Transportation Safety Board (NTSB), in connection with an NTSB investigation of an accident to which the post-accident test pertained. The Department seeks comment on whether this provision should be broadened to apply to other types of tests (*e.g.,* pre-employment, random, follow-up) in the individual employee's past. Should the provision apply to the employee's urine specimens collected for the post-accident test (on which NTSB might want to conduct additional testing)? The issue involves how best to balance the potential relevance of the additional information to NTSB's investigation of the accident with the additional effects of broader dissemination of the information on the individual's privacy. If we do broaden the availability of such information to the NTSB, should the rule place conditions limiting further disclosure (*e.g.,* in the text of NTSB reports)?

Finally, in some situations a service agent may be aware that an individual is continuing to perform safety-sensitive functions despite having violated a DOT agency regulation. For example, a third-party administrator may learn that a truck driver is continuing to drive a commercial motor vehicle after having tested positive for drug use. There is no present requirement for the service agent to report such a situation to the DOT agency involved. In the interest of safety, should there be such a requirement?

Service Agent Roles and Responsibilities

Subpart Q of the rule is based in part on existing DOT guidance concerning the roles and responsibilities of service agents, such as third-party administrators and consortia. There is also new material, such as an explicit statement that service agents cannot impose requirements not authorized by DOT rulemaking, a reference to the subpart R public interest exclusion process and its consequences, and expanded provisions on the relationship between service agents and MROs.

The Department is concerned about any potential for conflicts of interest with all service agents and welcomes comments in this area. The Department has a long-standing prohibition against the laboratory and the MRO having an affiliation or financial arrangement with one another that may be construed as a conflict of interest. Should this prohibition be strengthened? If so, how? We are also interested in your comments on what limitations, if any, should be placed upon laboratories and MROs serving as third-party administrators. How can we ensure that there exists no conflict of interest in a laboratory-based third-party administrator's selection of an MRO? Or, in an MRO-based third-party administrator's selection of a laboratory?

Public Interest Exclusions (PIEs)

The Department of Transportation requires hundreds of thousands of transportation employers to conduct drug and alcohol tests on millions of employees performing safety-sensitive functions. As part of this program, the Department requires the employers to comply with the specific and detailed testing procedures in part 40. These procedures ensure the accuracy, integrity, and privacy of the testing process, and they contain significant safeguards for employers and employees alike. Employers who do not comply with these procedures are subject to sanctions, such as civil penalties or withdrawal of Federal funding.

Most DOT-regulated employers today do not use their own personnel to provide drug and alcohol testing services. Rather, they rely on a series of ''service agents'' (*e.g.,* collectors, BATs, laboratories, MROs, substance abuse professionals, testing consortia, third-party administrators), with whom they contract to provide these services. When service agents fail or refuse to carry out part 40 requirements, employers who engage their services in good faith are placed at risk of being found in noncompliance and subjected to DOT sanctions. The employers—especially the many small businesses involved—do not have the expertise or resources to determine whether the service agents are providing services in a way that meets part 40 requirements.

Relying on employer penalties alone to ensure service agent compliance does not adequately address the problem. For example, imposing a $1000 civil penalty on a small trucking company that has used a service agent that is not performing its functions properly does little to correct the service agent's

malfeasance. The service agent can go right on performing badly for the many other DOT employers with which it contracts. Attempting to address the problem through employer-by-employer sanctions is also a very inefficient use of the Department's resources. If a DOT agency must conduct separate civil penalty actions against 30 different employers to address the effects of a single service agent's malfeasance, its use of resources is much less efficient than if there is one DOT action focused on the service agent itself. Nor are educational efforts likely to be sufficient: existing DOT agency and private training efforts, while useful, have not prevented some recurring problems about which we know.

Noncompliance by service agents with part 40 requirements can have serious consequences that go beyond the possibility of DOT sanctions on employers. For example, if an MRO is unqualified, does not conduct verification interviews, or disregards DOT rules and guidance for making verification decisions, individuals who apparently have tested positive for drugs can have their test results invalidated and be put back to work in safety-sensitive positions, endangering transportation safety, or individuals can be unfairly identified as drug users. If a collector or BAT does not conduct the collection process as part 40 provides, then valid tests can be overturned, tests will have to be repeated, and hiring actions may be delayed (in the case of pre-employment tests), creating potential safety and cost problems. If a laboratory or MRO breaches confidentiality requirements, employees' privacy rights can be compromised, upsetting the program's carefully constructed balance between the government's interest in safety and the employee's interest in privacy.

To address these concerns, the Department is proposing a new subpart that would create a ''public interest exclusion'' mechanism. A public interest exclusion (PIE) would be a directive from the Department to its regulated employers to not use a service agent that fails or refuses to provide its services as part 40 requires. While a PIE obviously has adverse business consequences for the service agent involved, its imposition is not for the purpose of punishment. Its purpose is to serve the public interest by making it easier for employers to comply with our rules and to protect them from noncompliance with DOT regulations. We also believe it is important to protect employees from the consequences of services that do not meet DOT requirements. The proposed process would work as follows:

- When a DOT agency, ODAPC, or the Inspector General's office becomes aware of a problem with service agent performance, through an inspection or complaint, the office in question would first decide whether to pursue the matter through this process. This would be a ''prosecutorial discretion'' decision by the office, made in view of the seriousness of the problem and would, of course, be subject to the availability of DOT resources. We contemplate the use of this process only in cases having considerable significance, not for minor mistakes. In addition, in most cases, DOT offices would resort to this process only after having unsuccessfully tried other means of resolving the problem.
- Because the primary purpose of the process is compliance, the initiating office would first send a correction notice to the service agent, spelling out the problem and asking the service agent to fix it.
- If the service agent corrected its problem(s) within 60 days, no further proceedings would be necessary.
- If the problem(s) was not corrected, the initiating office would notify the service agent in writing that the Department was proposing to issue a PIE.
- To ensure that the service agent had administrative due process, it would have the opportunity to contest the issuance of a proposed PIE. This would include the opportunity to submit information and arguments in writing and to meet with the ODAPC Director in situations where there were material facts in dispute. (To ensure separation of functions, the ODAPC Director, as the decisionmaker, would not participate in the decision to initiate the proceeding, and there would be a firewall between the Director and other ODAPC, DOT agency, or IG staff concerning the case.)
- The Director would notify the service agent of the decision and the reasons for it in writing and issue a **Federal Register** notice to inform employers when a PIE was issued.
- The PIE would stay in effect for a period of from one to five years, depending on the seriousness of the problem. However, it could be lifted earlier if the service agent was able to show that the problem(s) resulting in the order had been corrected.

This process is analogous to the procedure for imposing suspension and debarment in nonprocurement situations (see 49 CFR part 29). It should be noted that this proposed provision is not a sweeping new assertion of regulatory authority over entities who were previously untouched by DOT regulations. Provisions of both part 40 and DOT agency drug and alcohol testing regulations already govern in detail the activities conducted by laboratories, MROs, collectors, substance abuse professionals, and other service agents. The proposed provision adds no new substantive requirements. Rather, it uses the Department's existing regulatory authority over transportation employers to direct the employers, in the public interest and in the interest of their own compliance with our regulations, not to use service agents whose conduct violates part 40. The General Counsel of the Department of Transportation has determined that the Department has sufficient legal authority to implement these proposed requirements.

The Department also seeks comment on three alternative methods to achieve the objective of this provision. We believe that all these alternative approaches could use due process procedures like those outlined above:

(1) The process would work as described above, but instead of issuing a PIE, the Department would issue an advisory notice to employers telling them that the service agent was not providing services as required by part 40, placing employers using the agent at peril of enforcement action.

(2) As a condition of participation, all service agents would be required to self-certify that they provide all services as required by Part 40. Instead of issuing a PIE, the Department would decertify service agents that failed to carry out requirements properly.

(3) A contract provision in all agreements between service agents and regulated employers (see § 40.11(d)) would bind service agents to providing services in compliance with Part 40. Noncompliance would breach this provision, leading to termination of the contract.

The Department seeks comment on all the alternatives, combinations of them, or other means to accomplish the purpose of the proposed Subpart R, as well as on the general concept of a mechanism to protect employers and employees from noncomplying service agents.

Table of Sources

As noted earlier in the preamble, this proposed rule would significantly change the organization of Part 40. To help readers follow the origin of the proposed provisions, we have created a table that lists a provision of the current Part 40 or other sources of each provision. The following are examples of some of the most common types of source notations:

• ''§ 40.33(b)''—The material in the proposed rule originated in § 40.33(b) of the existing rule. This does not mean that the proposed section is the same as the existing section, but simply that the proposed section addresses the same subject matter as the existing provision. Often, the language of the proposing and exiting provisions will be different.

• ''Interp.''—The material in the proposed rule text comes from an interpretation issued by the Department under the present Part 40.

• ''9/98 guidance''—The material in the proposed rule text comes from a guidance memorandum issued by the Department in September 1998.

• ''Modal regulation''—The material in the proposed rule text comes from a DOT agency regulation (*e.g.,* the FRA drug testing rule).

• ''New''—The material in the proposed rule would add material not found in the present Part 40 or in written interpretations or guidance.

• ''HHS''—The material in the proposed rule would incorporate material from the Department of Health and Human Services drug testing guidelines or HHS guidance interpreting those guidelines.

• ''Comment''—The material in the proposed rule responds to a comment on the ANPRM.

• ''Alcohol (or Drug) parallel''—The proposed rule text concerning drug testing procedures would be parallel to language on a similar provision in the alcohol testing procedures, or vice-versa.

Using the table, readers should be able to readily identify the source of a given provision and where the proposed rule differs from the present Part 40. This should help commenters determine whether they support proposed changes, support existing language, or whether they wish to recommend alternatives to the proposals. In a version of the NPRM on the Department's web site, we have placed these source notes in brackets after each section, for greater convenience to the reader (**Federal Register** format does not permit this placement in the published version of the document). The table follows:

Section of NPRM	Source
40.1	40.1
40.3	40.3, HHS, except ''alcohol test,'' ''designated employer representative,'' ''dilute specimen,'' ''notice,'' ''service agents,'' and ''substituted specimen,'' which are new.
40.5	New
40.7	49 CFR part 5, interp.
40.11	New
40.13(a)	New
(b)	Comment
40.15 (a), (b), (d), (e), (f)	Interp.
(c)	40.21(c)
40.17(a)	Guidance
(b), (c)	New
40.19	Interp.
40.21	New
40.31 (a), (b)	New
(c)	40.23(d)(3), interp.
(d)	40.23(d)(3)
40.33 (a)(1)	New
(a)(2)(i)	40.23(d)(2)
(a)(2)(iii)	40.23(d)(1)
(a)(3)–(5)	New
(b)	New
40.35	New
40.37	New
40.41 (a), (b)	New
(c)	40.25(a)(1)
(d)(1), (3)	40.25(a)(2)
(d)(2)	New
(e)	40.25(a)(2), HHS
(f), (g)	40.25(a)(1)
40.43(a)	40.25(b)
(b)(1)–(6)	40.25(b)(1)–(2)
(b)(7)–(8)	New
(c)	40.25(b)(2)
(d)(1)	40.25(d)
(d)(2)	40.25(g)
(d)(3)	40.25(d)
(d)(4)	40.25(f)(25)(ii)
(d)(5)	40.25(f)(25)(i)
(e)	40.25(d)
(e)(1)–(4)	New
40.45(a)	40.23(a)(1)(i)
(b)(1)	40.23(a)(1)(ii)
(b)(2)–(5)	Comments
(c)	40.23(a)(1)(ii)
(d)	40.23(a)(1)(iii)
(e)	New
40.47(a)	Interp.
(b)	Interp., new
40.49	New
40.51	Interp., new

Section of NPRM	Source
40.61(a)	40.25(f)(3), new
(b)	Interp.
(b)(1)	New
(b)(2)	40.25(j)
(b)(3)	Interp.
(c)	40.25(f)(2), HHS
(d)	40.25(f)(2), new
(e)	Alcohol parallel
(f)(1)–(2)	40.25(f)(4)
(f)(3)	Interp., HHS
(f)(4)–(6)	New
(g)	40.25(f)(22)(ii)
40.63 (a)	Alcohol parallel
(b)	40.25(f)(5)–(6), (11)
(c)	40.25(f)(7), HHS, interp.
(d)	40.25(f)(10), new
(e)	40.25(f)(8), new
40.65	Checklist format new
(a)	New, interp.
(b) (1)–(5)	40.25(e)(2)
(b)(6)	Interp.
(b)(7)	Interp., new
(c)	New, interp.
40.67(a)(1)	HHS
(a)(2)	New
(b)(1)	40.25(e)(2)(iv)
(b)(2)	9/98 guidance
(c)(1)	New
(c)(2)	40.25(e)(2)(iii); new
(c)(3)	40.25(e)(2)(i)
(c)(4)	40.25(e)(2)(iii)
(d)	HHS
(e)	New
(f)	40.25(f)(16), interp., HHS
(g)	New
(h)	Interp.
(i)	Interp., HHS
(j)	HHS
(k)	Interp.
40.69(a)	40.25(f)(9)
(b)–(c)	New
(d)–(h)	40.25(f)(9), Interp.
(i)	HHS
(j)	Interp.
40.71(a)	40.25(f)(10)(iii)
(b)	New
(c)	40.25(f)(19), HHS
(d)	40.25(f)(10)(iii), 40.25(f)(17)
(e)	40.25(f)(20)
(f)	New
40.73 (a)–(b)	40.25(f)(19)(ii)(B)(1), new
(c)	New
(d)	40.25(f)(19), HHS
(e)	40.25(f)(10)(iii), 40.25(f)(17)
(f)	40.25(f)(20)
40.75(a)(1)	40.25(f)(22)(i), HHS
(a)(2)	40.25(f)(23), HHS
(a)(3)–(4)	HHS
(a)(5)	New
(a)(6)–(7)	HHS
(a)(8)–(10)	New
(a)(11)	HHS
(b)	40.25(c), (h), (k)
(c)	New
40.81(a)	40.39(a)
(b)	40.39(b)
(c)–(d)	New
40.83(a)–(c)	40.25(k), 40.29(a)(2)
(d)	HHS, new
(e)	Interp.
(f)	Interp., new
(g)	New
40.85	40.21(a)
40.87(a)	40.29(e)(1), new

Section of NPRM	Source
(b)	40.29(f)
40.89(a)	40.29(e)(1) and (f)(1)
(b)–(c)	40.29(g)(2)
40.91 (a)–(b)	New, HHS
(c)	9/98 guidance
(d)	HHS
40.93	New, HHS
40.95(a)	40.29(g)(1)
(b)–(e)	HHS, new
40.97(a)	40.29(g)(4), new
(b)(1)	HHS, new
(b)(2)	40.29(g)(4), new
(c)	40.29(g)(4)
(d)–(e)	New
40.99(a)(1)	40.29(b)(2), HHS
(a)(2)	40.29(h), HHS
(b)	40.29(h)
(c)–(e)	New
40.101(a)	40.29(n)(6), new
(b)	New
40.103(a)	40.31(d)(1)–(2), new
(b)	40.31(d)(5), new
(c)	40.31(d)(3)
(c)(1)	HHS
(c)(2)	New
(d)	HHS, new
40.105(a)	40.31(d)(7)–(8), new
(b)	40.31(d)(8)
(c)	40.31(d)(7), new
(d)	40.31(d)(8), new
40.107	40.29(1)
40.109(a)–(b)	New
(c)	40.29(g)(6), 40.29(m)
(d)	40.29(m), new
(e)	HHS, new
40.111	40.29(g)(6), HHS, new
40.113	New
40.121(a)	40.33(b)(1)
(b)	40.33(a)
(c)–(f)	New
40.123	New
40.125	40.33(b)(2), new
40.127(a)	40.33(a)(2), new
(b)	Interp., new
(c)–(d)	New
(e)	9/98 guidance, new
40.129(a)(1)	40.33(a), interp.
(a)(2)	New
(a)(3)	40.33(c)(1)–(2)
(a)(4)	40.33(a)(2)
(a)(5)	New
(b)	Interp., new
(c)	9/98 guidance
(d)	Interp., new
40.131(a)–(c)	40.33(c)(2), new
(d)	40.33(c)(3)–(4), new
40.133(a)	40.33(c)(3), (c)(5)
(b)	New
(c)	40.33(c)(6)
40.135 (a)–(c)	New
(d)	40.33(i)(2)
40.137(a)–(b)	40.33(a), (b)(3), (c)
(c)–(d)	Interp.
40.139(a)	40.33(d)
(b)	New
(c)	40.33(d), new
(c)(1)–(4)	Interp., new, MRO training materials
40.141	New
(a)	40.33(a), (b)(3), new
(b)	40.33(b)(3), new
(c)	40.33(e)
40.143(a)	40.33(b)(3), interp.
(b)	New
(c)	Interp.

Section of NPRM	Source
(d)	Interp., MRO training materials
(e)	Interp.
(f)	Guidance
40.145(a)	New
(b)	40.33(e)–(f)
(c)	New
(d)	New, interp.
(e)	40.33(e)–(f)
(f)	Interp.
40.147(a)–(b)	9/98 guidance, new
(c)	Interp., new
40.149(a)–(b)	9/98 guidance, new
(c)	Interp., new
40.151(a)	9/98 guidance
(b)–(c)	Interp., new
40.153(a)	9/98 guidance, new
(b)	Interp., new
40.155	New
40.157 (a)–(b)	Alcohol parallel—40.65(i)
(c)	FMCSA regulation—49 CFR 382.407(a)(1)
(d)	New
40.159(a)	40.33(a)(1),interp., new
(b)	New
(c)–(f)	9/98 guidance, new
(g)	New
40.161(a)	Interp.
(b)	New
40.163	New
40.171(a)	40.33(f)
(b)	40.33(g)
(c)	Interp.
(d)	40.25(f)(10)(E)
40.173	Interp.
40.175(a)	40.129(b)(2), new
(b)	New
(c)	40.29(c)
(c)(1)–(2)	40.29(b)(2), new
(d)	40.25(f)(10)(F)
(e)	40.33(f)
(f)	Interp.
(g)	New
40.177(a)	HHS
(b)	40.29 (b)(3)
(c)–(d)	HHS
(e)	Interp.
40.179	New
40.181	HHS
40.183	9/98 guidance, new
40.185	New
40.187	New
40.191(a)(1)	Interp., comment
(a)(2)	Modal regulations
(a)(3)	Interp.
(a)(4)	40.25(f)(10)(iv)(2), 40.69(d)(2)(ii)
(a)(5)–(6)	Interp.
(a)(7)	40.67(a)
(b)	9/98 guidance
(c)	Modal regulations
(d)	40.67(a), interp.
(e)	Comment
40.193 (a)–(f), (h)–(i)	40.25(f)(10)(iv)
(g)	Guidance, new
40.195	Guidance, new
40.197	DOT and HHS guidance, interp.
40.199	Guidance, new
40.201	DOT and HHS guidance, interp., new
40.203(a)	40.67(b), new
(b)	New, interp.
40.205	Interp.
40.207	Interp., new
40.211(a)–(c)	40.51, 40.93
(d)	40.51(b), new
40.213(a)(1)	40.51(a)(1)
(a)(1)(i)	40.51(a)(2)

Section of NPRM	Source
(a)(1)(ii)	40.51(a)(3)
(a)(1)(iii)	Interp.
(a)(1)(iv)	Drug parallel
(a)(2)	40.93(c)
(a)(3)	New
(b)(1)	40.51(a)(1)
(b)(1)(i)	40.51(a)(2)
(b)(1)(ii)	40.51(a)(3)
(b)(1)(iii)	New
(b)(1)(iv)	Drug parallel
(b)(3)	New
(c)	Interp.
(d)	40.51(c)
(e)–(g)	New
40.215	New
40.217	New
40.221(a)–(b)	New
(c)–(d)	40.57(a)
(e)	40.57(e)
(f)	40.57(b)
40.223(a)	40.57, new
(b)	40.55(c)
(c)	40.57(c)
(d)	40.57(e), 40.99(b)
(d)(1)	New
(d)(2)	Interp.
(d)(3)	40.57(e), 40.99(b)
40.225(a)	40.59(a)
(b)(1)	Drug parallel–40.23(a)(1)(i) and CCF
(b)(2)	40.59(a)
(b)(3)–(6)	Comment
(c)	New
40.227(a)	Interp.
(b)	New
40.229	40.53, 40.91
40.231(a)	40.53(a), 40.91
(b)	40.53(b)
40.233(a)	40.55(a)
(a)(1)	40.55(a)(1)–(3)
(a)(2)	40.55(a)(4)
(b)	40.55(b), (b)(1), new
(c)	40.55(a)(1)
(d)	40.55(b)(2)
(e)	40.55(b)(4)
(f)	40.55(b)(3)
40.235(a)	40.95 (a), (a)(1)
(b)	40.95(b), (c)
(c)	New
(d)	40.55(a)(2)
40.241(a)	New
(b)(1)	New, Drug parallel—40.25(f)(3)
(b)(2), (b)(2)(i)	New
(b)(2)(ii)	Drug parallel—40.25(j)
(b)(3)	Drug parallel—40.25(f)(2)
(b)(4)	Drug parallel—40.25((f)(2), new
(b)(5)	40.61(b), 40.101(d)(1)
(b)(6)–(7)	40.63(a), 40.101(b)
40.243(a)	Drug parallel—40.25(f)(7), HHS, interp.
(b)	40.63(b)
(c)	40.63(c)
(d)	40.63(d)(2)(i), (d)(3), (d)(4)
(e)	New
(f)	40.63(d)(3)
(g)	40.63(d)(2)(i)
40.245(a)	40.101(d)(2)
(b)	40.101(d)(3)
(c)	New
(d)	40.101(d)(5)
(e)	40.101(d)(6)
(f)	40.101(d)(7)
(g)	40.101(d)(8)
(h)	40.101(d)(9)
(i)	40.101(d)(10)
40.247(a)	40.101(e)

Section of NPRM	Source
(b)(1)	40.63(e)(1), 40.101(e)
(b)(2)	40.62(e)(i)(3)
(b)(3)	40.63(e)(2)
(c)(1)	40.63(f)
(c)(2)	40.63(g), 40.101(e)
(c)(3)(i)–(iv)	40.63(h)(1)
(c)(3)(v)–(vii)	40.63(h)(2)
(c)(3)(viii)	New
(c)(3)(ix)	40.63(h)(3)
(d)	40.63(e)(4)
40.251(a)–(b)	40.65(b), new
(c)	40.63(a), 40.101(b)
(d)	40.65(b), new
40.253(a)	40.65(d)
(b)	40.63(b), 40.65(c)(2)
(c)	40.65(e)
(d)	40.63(b), 40.65(c)(2)
(e)–(f)	40.65(g)(1)–(2)
(g)	40.65(g)(1)
40.255(a)(1)	40.65(h)(1)
(a)(2)	40.65(h)(1)–(2)
(a)(3)	40.65(h)(3)
(a)(4)	40.65(i)(1)
(a)(4)(i)	40.65(i)(1)–(2)
(a)(4)(ii)	40.65(i)(4)
(b)(1)	40.65(i)(3)
(b)(2)	40.65(i)(4)
40.257	New, drug parallel
40.261(a)(1)	Interp., comment
(a)(2)	Modal regulations
(a)(3)	40.63(e)(3)
(a)(4)	40.69(d)(2)(ii), drug parallel–40.25(f)(10)(iv)(2)
(a)(5)	Interp.
(a)(6)	40.67(a), interp.
(b)	Modal regulations
(c)	40.67(a), interp.
40.263	40.105
40.265	40.69, 40.105
40.267(a)(1)	40.107(a)(1)
(a)(2)	40.107(a)(2)
(a)(3)	40.107(a)(3)
(b)	40.79(a)(7), 40.107(b)
(c)(1)	40.79(a)(2)
(c)(2)–(3)	40.79(a)(3)
(c)(4)	40.79(a)(6)
(c)(5)	40.79(a)(1)
40.269(a)	40.79(a)(4)
(b)	40.79(a)(5), 40.107(b)
(c)	40.107(a)(4)
(d)	New
40.271(a)	40.67(b), new
(b)	New, interp.
40.273	Interp.
40.275	New, interp.
40.277	Interp.
40.281	Interp., new, 40.3
40.283	Modal regulations, new
40.285	Modal regulations, new
40.287(a)	Modal regulations, interp.
(b)	Modal regulations, new
(c)–(e)	Interp.
40.289	Modal regulations, SAP guidelines
40.291	Interp.
40.293	Interp., SAP guidelines, modal regulations
40.295	Interp.
40.297	Interp., SAP guidelines
40.299(a)	SAP guidelines
(b)	SAP guidelines, modal regulations
(c)	Modal regulations, examples new
(d)	New
40.301	Interp., SAP guidelines, modal regulations
40.303	New
40.305	Interp., SAP guidelines
40.307	Modal regulations, interp., SAP guidelines

Section of NPRM	Source
40.309	Modal regulations, interp., SAP guidelines
40.311 all except	Interp., SAP guidelines
(e)(10), (f)	New
40.313	New
40.321	40.3(i), 40.35, 40.81(b), (g), (i)
(a)	New
(b)	Interp.
40.323	40.35, 40.81(H)
40.325	New
40.327 (a)	40.33(i)(1)—(2), new
(b)	40.33(i)(1)(ii)—(iii)
(c)	New
40.329	New
40.331(a)	40.37, 40.81(c)
(b)—(c)	Interp.
40.333 (a)	40.81(g), (i)
(b)(1)	40.81(d)
(b)(2)	40.81(e), new
(c)(1)	40.81(d)
(c)(2)	40.81(e), new
(d)	40.81(f)
(e)	New
40.335	40.81, 382.401
40.341—40.353	Consortium/third party administrator guidance
40.361—40.385	New

Regulatory Analyses and Notices

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

There are two features of the proposed regulation that would add new requirements that may have some economic impacts. The first is the requirement that laboratories test for dilute, substituted, and adulterated specimens. Existing regulations were devised before the widespread use of ''designer'' adulterants that some employees are putting into their urine to mask the results of positive drug tests. The DOT has worked with HHS and laboratory scientists to develop a set of appropriate forensic testing protocols for identifying these masking agents.

The revision expands existing regulations and guidance concerning these difficult testing situations by making mandatory laboratories' use of additional protocols for discovering adulteration, as well as for detecting situations in which an employee has substituted something other than normal human urine for the required urine specimen. As the result of work by HHS and the laboratories, these protocols are already in place and are being used by most laboratories, so we expect the incremental costs of this requirement to be modest. The Department believes that public safety is well-served by these steps to identify and hold accountable employees in safety-sensitive positions who attempt to cheat the testing process.

Second, the Department is proposing additional training requirements for some service agents. Errors in the testing process resulting from lack of training can lead to increased employer program costs and increased paperwork required to document the errors and repeat the testing process. The NPRM would upgrade requirements for urine collectors and other personnel. This additional training requirement can be met without formalized instruction to minimize the cost impact.

Also, MROs and SAPs would either attend a training session every two years to keep current on developments in the field or would be permitted to self-certify they have re-reviewed and understand the regulations in lieu of training. These training courses already exist and are widely attended. Again, we anticipate that overall net costs of these new training requirements and options would be quite modest because the requirement may be met without formalized instruction.

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

The Department has made some preliminary estimates of the cost increases and decreases that could be expected if the proposed rule's provisions are made final. It is important to understand that this is a big program, touching some 8.34 million employees working for about 673,413 employers. Around 30,000 individuals and organizations work as service agents.

In terms of new costs, the Department estimates an annual cost of about $902,000 for adulterant testing plus about $25,322 for training documentation. We believe there will not be any measurable additional costs for actual SAP and MRO training, because most SAPs and MROs already undergo such training as part of professional continuing education requirements. The option also exists for MROs and SAPs to self-administer training through study of DOT rules and guidance. In addition, we estimate that there will be one-time costs for a variety

of administrative requirements in the first year of implementation of approximately $1.93 million.

On the other hand, we anticipate saving at least $5.4 million annually from the proposed reduction in blind specimen testing (the savings will probably be somewhat greater, because fewer organizations will be required to submit blind specimens). By changing the current quarterly laboratory report requirement to require a semiannual report, we anticipate saving another $1.69 million annually. By permitting positive test results to be faxed rather than sent by overnight express, we project an annual $3.1 million saving. These annual savings are greater than the additional annual costs we anticipate for the proposed rule.

This NPRM does not have sufficient Federalism impacts to warrant a Federalism assessment under Executive Order 13132. With respect to the Regulatory Flexibility Act, the Department certifies that, if adopted, this rule would not have a significant economic impact on a substantial number of small entities, so a Regulatory Flexibility analysis has not been prepared. While this rule affects a large number of small entities, we do not expect the rule to have a significant economic impact on anyone.

This rulemaking involves a ''610 Review'' under the Small Business Regulatory Enforcement Fairness Act. We have reviewed the existing program to identify areas in which the rule can be improved with the effect of assisting small businesses to comply in a rational and cost-effective manner. In addition to the general clarification of the program this rule provides, we have identified some specific areas (e.g., blind specimen requirements, the addition of the public interest exclusion provision) that should be particularly helpful to small regulated employers. We seek comment on any changes that commenters might suggest to further assist small businesses who are affected by this rule.

Part 40 is one portion of a ''ONE-DOT'' drug and alcohol testing program that also involves regulations from six DOT agencies. The costs and impacts of Part 40 are intertwined with the costs and impacts of the DOT agency regulations. In connection with the 610 review, we are seeking comments on the effects of the entire program, including all its regulatory components, on small entities and on ways of improving the program from this point of view.

This proposed rule also contains information collection requirements. As required by the Paperwork Reduction Act of 1995 (the PRA, 44 U.S.C. 3507(d)), the Department has submitted these requirements to the Office of Information and Regulatory Affairs of the Office of Management and Budget for review, as required under the Paperwork Reduction Act.

As noted elsewhere in this preamble, this proposed rule would amend 49 CFR Part 40 to clarify and update the Department's alcohol and drug testing procedures. In the course of so doing, the proposal would increase some information collection requirements and decrease others, resulting in what we estimate to be a modest net reduction in information collection burdens, compared to the present regulation. The information collections involve such subjects as drug and alcohol specimen collection, quality control, and the reporting and retention of drug and alcohol testing information.

The regulated parties to whom these requirements apply are transportation employers and participants in the drug and alcohol testing industry, the numbers of which are summarized above. As summarized above, the Department anticipates that there will be new costs of $2.86 million and new savings of about $10.9 million, most of which represent costs involved with information collection. In terms of burden hours, we anticipate new collections amounting to 65,000 hours and savings on collections amounting to 168,888 hours, resulting in a net reduction of 103,888 hours compared to the present regulation.

The Department is soliciting comments to (1) evaluate whether the proposed collections are necessary for the functioning of the drug and alcohol testing program, including whether the information will have practical utility; (2) evaluate the accuracy of the Department's estimate of the burden; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of information collection for regulated parties, including through the use of appropriate automated, electronic, mechanical, or other technological information collection techniques or other forms of information technology (for example, permitting electronic submission of reports).

Individuals and organizations may submit comments on the information collection elements of this NPRM by April 7, 2000 and should direct them to the DOT docket specified at the beginning of the NPRM. According to OMB's regulations implementing the PRA (5 CFR 1320.8(b)(2)(vi)), an agency may not conduct or sponsor, and a person need not respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information will be published in the **Federal Register** after it is approved by OMB.

There are a number of other Executive Orders that can affect rulemakings. These include Executive Orders 13084 (Consultation and Coordination with Indian Tribal Governments), 12988 (Civil Justice Reform), 12875 (Enhancing the Intergovernmental Partnership), 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights), 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations), 13045 (Protection of Children from Environmental Health Risks and Safety Risks), and 12889 (Implementation of North American Free Trade Agreement). We have considered these Executive Orders in the context of this NPRM, and we believe that the proposed rule does not directly affect the matters that the Executive Orders cover.

We have prepared this rulemaking in accordance with the Presidential Directive on Plain Language.

List of Subjects in 49 CFR Part 40

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

Issued this 29th day of November, 1999, at Washington, DC.

Rodney E. Slater,

Secretary of Transportation.

For the reasons set forth in the preamble, the Department of Transportation proposes to revise part 40 of Title 49, Code of Federal Regulations, to read as follows:

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

Subpart A—Administrative Provisions

Subpart B—Participant Responsibilities

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

Subpart A—Administrative Provisions

§ 40.1 Whom does this regulation cover?

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

(b) This part covers transportation employers, safety-sensitive transportation employees (including self-employed individuals and volunteers), and everyone who provides drug or alcohol testing services to them, including, but not limited to, consortia, third-party administrators, medical review officers (MROs), substance abuse professionals (SAPs), urine collectors, breath alcohol technicians (BATs), screening test technicians (STTs), and laboratories.

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

When the terms listed in this section occur in this part, they have the following meanings:

Adulterated specimen. A urine specimen into which the employee has introduced a foreign substance.

Affiliate. Persons are affiliates of one another if, directly or indirectly, one controls or has the power to control the other, or a third party controls or has the power to control both. Indicia of control include, but are not limited to: interlocking management or ownership, identity of shared interest among family members, shared facilities or equipment, common use of employees, or a business entity organization following the issuance of a public interest exclusion which has the same or similar management, ownership, or principal employees as the service agent concerning whom a public interest exclusion is in effect.

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

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

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

Alcohol screening device (ASD). A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and placed on a conforming products list (CPL) for such devices. An ASD can be used only for screening tests for alcohol, and may not be used for confirmation tests.

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

Blind specimen or blind performance test specimen. A urine specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from employee specimens, and which is spiked with known quantities of specific drugs or which is blank, containing no drugs.

Breath Alcohol Technician (BAT). A trained and certified individual who instructs and assists individuals in the alcohol testing process and operates an evidential breath testing device.

Canceled test. In drug testing, a drug test that has been declared invalid by an MRO. A canceled test is neither a positive nor a negative test. For purposes of this part, a specimen that has been rejected for testing by a laboratory is treated the same as a canceled test. In alcohol testing, a test that is deemed to have a problem identified which cannot be or has not been corrected.

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

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

Collection site. A place selected by the employer where employees present themselves for the purpose of providing a urine specimen for a drug test and/or a breath or saliva specimen for an alcohol test.

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

Confirmation (or confirmatory) test. In drug testing: the test conducted by gas chromatography/mass spectrometry (GC/MS) to confirm the presence of drug(s) or drug metabolite(s) detected by the screening test at concentrations at or above cutoff concentrations established by the Department of Health and Human Services. In alcohol testing: a second test using an evidential breath testing device, following a screening test with a result of 0.02 or greater, that provides quantitative data of the alcohol concentration.

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

Designated employer representative (DER). An employer or individual(s) identified by the employer as able to receive communications and test results directly from medical review officers, BATs, screening test technicians, collectors, and substance abuse professionals, and who is authorized to take immediate actions to remove employees from safety-sensitive duties and to make required decisions in the testing and evaluation processes. Service agents cannot serve as DERs, except where a DOT agency has issued regulations permitting them to do so.

Dilute specimen. A urine specimen whose creatinine and specific gravity values are diminished by the employee through the introduction of fluid (usually water) into the specimen either directly or through excessive consumption of fluids.

DOT. Department of Transportation or any designee of the Secretary, Department of Transportation.

DOT agency. Any agency of the Department of Transportation administering regulations related to drug or alcohol testing, including but not limited to the United States Coast Guard (for drug testing purposes only), the Federal Aviation Administration, the Federal Railroad Administration, the Federal Motor Carrier Safety Administration, the Federal Transit Administration, the Research and Special Programs Administration, and the Office of the Secretary. This term includes a designee of the DOT agency.

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

Employee. An individual who is designated in a DOT agency regulation as subject to drug testing and/or alcohol testing. The term includes individuals currently occupying safety-sensitive positions designated in DOT agency regulations and applicants for employment subject to pre-employment testing.

Employer. An entity employing one or more employees (including an individual who is self-employed) that is subject to DOT agency regulations requiring compliance with this part. The term includes an employer's officers, representatives, and management personnel. The term, as used in this document, references the entity responsible for overall implementation of DOT drug and alcohol program

requirements, as well as those individuals employed by the entity who take personnel actions resulting from violations of this part and any applicable DOT agency regulations. Service agents are not regarded as employers, except where a DOT agency has issued regulations so designating them.

Evidential Breath Testing Device (EBT). A device approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential testing of breath, placed on NHTSA's Conforming Products List (CPL) for ''Evidential Breath Measurement Devices'' and identified on the CPL as conforming with the model specifications available from NHTSA, Office of Traffic Injury Control Programs.

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

Laboratory. Any laboratory which meets the minimum standards to engage in urine drug testing, as set forth in Subpart C of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. To participate in the DOT drug testing program, laboratories must be certified by HHS under the National Laboratory Certification Program or, in the case of foreign laboratories, be approved for participation by DOT. (The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs is available at *www.health.org/workpl.htm.* and at Division of Workplace Programs, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, MD 20856.)

Medical Review Officer (MRO). A licensed physician (doctor of medicine or osteopathy) responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate training to interpret and evaluate an individual's confirmed positive or ''unsuitable'' drug test results together with his or her medical history and any other relevant biomedical information. The MRO is also required to have a working knowledge of this part and the DOT agency regulations applicable to the employer(s) for which he or she evaluates drug test results.

Notice. In the context of a public interest exclusion proceeding, a written communication served in person or sent by certified mail, return receipt requested, or its equivalent, to the last known address of a service agent, its identified counsel, or agent for the service of process, or any partner, officer, director, owner, or joint venturer of the service agent. Notice, if undeliverable, shall be considered to have been received by the addressee five days after being properly sent to the last address known by the Department.

Primary specimen. In drug testing: the urine specimen that is opened and tested by a first laboratory to determine whether the employee has drug(s) or drug metabolite(s) in his or her system. The primary specimen is distinguished from the split specimen, defined in this section.

Screening test (or initial test). In drug testing: an immunoassay screen to eliminate ''negative'' urine specimens from further analysis. In alcohol testing: an analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath or saliva specimen.

Screening Test Technician (STT). A trained individual who instructs and assists individuals in the alcohol testing process and operates an alcohol screening device.

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

Service agents. All parties who provide services to employers in connection with DOT drug and alcohol testing requirements. This includes, but is not limited to, collection site personnel, BATs and STTs, laboratories, MROs, substance abuse professionals, consortia, and third-party administrators.

Shipping container. A container that is used for transporting and protecting one or more urine specimen bottle(s) and associated documents from the collection site to the laboratory.

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

Split specimen. A part of the urine specimen that is sent to the first laboratory and retained unopened, and which will be transported to a second laboratory in the event that the employee requests it be tested following a verified positive test of the primary specimen.

Substance Abuse Professional (SAP). A licensed physician (doctor of medicine or osteopathy); or a licensed or certified psychologist, social worker, or employee assistance professional; or an addiction counselor (certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission or by the International Certification Reciprocity Consortium / Alcohol & Other Drug Abuse). All must have knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled substances-related disorders. The SAP is also required to have a working knowledge of this part and the DOT agency regulation applicable to the employer(s) for which he or she evaluates employees who have engaged in a DOT drug and alcohol regulation violation.

Substituted specimen. A specimen, not consistent with human urine, that has been submitted by the employee in place of his or her own urine.

Verified drug test. A certified laboratory drug test result that has undergone review and final determination by the MRO.

§ 40.5 Who issues authoritative interpretations of this regulation?

The Department of Transportation (DOT) Office of Drug and Alcohol Policy and Compliance (ODAPC) and the DOT Office of General Counsel (OGC) provide written interpretations of the provisions of this part. Such interpretations are the only official and authoritative interpretations of DOT concerning the provisions of this part. DOT agencies may incorporate ODAPC/OGC interpretations in written guidance they transmit to parties they regulate. Only Part 40 interpretations issued after [effective date of the final regulation] shall be considered valid and binding.

§ 40.7 How are exemptions granted from this regulation?

(a) If you want an exemption from any provision of this part, you must request it in writing from the Office of the Secretary of Transportation, under the provisions and standards of 49 CFR part 5. The address to send requests for an exemption is the following: Department of Transportation, Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, Washington, DC 20590.

(b) Under the standards of 49 CFR part 5, we will grant the request only if the request documents special or exceptional circumstances, not likely to be generally applicable, and not contemplated in connection with the rulemaking that established this part, that make your compliance with a specific provision of this part impracticable.

(c) As the party granted the exemption, you must agree to take steps we specify to comply with the intent of the provision from which an exemption is granted.

(d) We will issue written responses to all exemption requests.

(e) When the Office of the Secretary grants or denies an exemption request, the decision is implemented as to

regulated employers through the DOT agency regulations that incorporate this part.

Subpart B—Participant Responsibilities

§ 40.11 What are the basic responsibilities of employers under this regulation?

(a) As an employer, you are responsible for making sure that everything required by this part occurs.

(b) You must conduct DOT tests of your employees in accordance with this part. This responsibility includes ensuring that all service agents you use comply with all requirements in this part.

(c) You are responsible for all actions of your officials, representatives, and agents in carrying out the requirements of the DOT agency regulations.

(d) You must include in each contract or agreement you enter into, renew, or modify with a service agent, the following statement:

Compliance With 49 CFR Part 40

[Name of service agent] agrees to provide all services concerning drug and/or alcohol tests required by Department of Transportation regulations in full compliance with the provisions of 49 CFR Part 40. Compliance with Part 40 is a mandatory term of this agreement. If the Department of Transportation determines that [name of service agent] is in noncompliance with Part 40 with respect to DOT regulated drug and alcohol programs, this agreement will be terminated for cause by the employer unless the noncompliance is corrected.

(e) If there is not a written agreement, you must ensure that the statement in paragraph (d) of this section is stipulated to in writing and signed by the service agent.

(f) The statement in paragraph (d) of this section shall be signed by the service agent.

§ 40.13 If an employer has employees subject to testing under both DOT and the Nuclear Regulatory Commission (NRC) regulations, what procedures does it follow?

(a) As an employer who has employees subject to both DOT agency drug and alcohol testing regulations and the NRC's drug and alcohol testing regulations, you may use either procedures in this part or procedures in NRC regulations to conduct DOT-required tests of those employees. For example, suppose you are a nuclear power plant that employs technicians subject to NRC testing. Some of these technicians are also truck drivers who are subject to testing under FMCSA regulations. You can follow either this part or NRC procedural regulations to test these double-covered employees, and DOT will regard you as complying with its testing procedure requirements.

(b) As an employer who has employees subject to both DOT agency drug and alcohol testing regulations and the NRC's drug and alcohol testing regulations, you are required to collect and maintain all drug and alcohol testing information, in accordance with either DOT or NRC regulations, and make arrangements for that information to be available for inspection or submission to representatives of either agency upon request.

§ 40.15 If an employer conducts non-DOT testing, under its own authority, as well as DOT testing, what Federal restrictions apply for the two tests?

(a) Non-DOT tests must be completely separate from DOT tests in all respects.

(b) The DOT tests must take priority and must be conducted and completed before a concurrent non-DOT test is begun.

(c) No tests may be performed on DOT urine or breath specimens other than those specifically authorized by this part or DOT agency regulations. For example, you may not test a DOT urine specimen for additional drugs, and a laboratory may not make a DOT urine specimen available for a DNA test or other types of specimen identity testing.

(d) The single exception to paragraph (c) of this section is when a DOT drug test collection is conducted as part of a physical examination required by DOT agency regulations. It is permissible to conduct required medical tests related to this physical examination on any urine remaining in the collection container after the drug test urine specimen has been sealed into the specimen bottles.

(e) No one may change or disregard the results of DOT tests based on the results of non-DOT tests. For example, an employer may not disregard a verified positive DOT drug test result because the employee presents a negative test result from a blood or urine specimen collected by the employee's physician or a DNA test result purporting to question the identity of the DOT specimen.

(f) Employers are prohibited from using the Federal Drug Testing Custody and Control Form (CCF) and the DOT Breath Alcohol Testing Form (BATF) in your non-DOT drug and alcohol testing programs. This prohibition includes the use of the DOT forms with references to DOT programs and agencies crossed out.

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

(a) As an employer, you are held fully responsible for compliance with this part and DOT agency drug and alcohol testing regulations. However, you may use a service agent to perform the tasks needed to comply with this part and DOT agency drug and alcohol testing regulations.

(b) As an employer, you must ensure that the service agent you use performs these tasks in accordance with DOT agency regulations.

(c) If a service agent fails to comply with DOT agency regulations, a DOT agency can subject you and/or the service agent to sanctions for the noncompliance of a service agent who works for you.

§ 40.19 May service agents impose requirements on employers that DOT agency regulations do not specifically authorize?

No. As a service agent, you must not impose conditions or requirements on employers that DOT regulations do not authorize. For example, as a consortium or third-party administrator serving employers in the pipeline or motor carrier industry, you may not require employers to have provisions in their DOT plans that RSPA or FMCSA regulations do not require.

§ 40.21 Do service agents have to comply with DOT drug and alcohol testing requirements?

(a) As a service agent, you must comply with this part and the DOT agency drug and alcohol testing regulations that apply to the transportation employer for whom you are providing services.

(b) If you do not comply, DOT may make you ineligible to participate in DOT drug and alcohol testing. DOT will use the procedures in Subpart R of this part to make decisions in eligibility cases.

Subpart C—Urine Collection Personnel

§ 40.31 Who collects urine specimens for DOT drug testing?

(a) Collectors meeting the requirements of this subpart are the only persons authorized to collect urine specimens for DOT drug testing.

(b) A collector must be trained to proficiency in correctly carrying out the urine collection requirements of this part.

(c) As the direct supervisor of a particular employee, you may not act as the collector when that employee is tested, unless no other collector is available and you are permitted to do so under DOT agency regulations.

(d) You may not act as the collector for a particular employee if you work for a HHS-certified laboratory (*e.g.,* as a technician or accessioner) and could

link the employee with a urine specimen, drug testing result, or laboratory report.

§ 40.33 What requirements must a collector meet?

(a) To be a collector, you must do the following:

(1) Read the drug testing procedures in this part and the current ''DOT Urine Specimen Collection Procedures Guidelines'' and attest in writing to your understanding of them. (The ''DOT Urine Specimen Collection Procedures Guidelines'' is available at ODAPC, Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590.)

(2) Be trained to proficiency on collection procedures in this part by another person(s) sufficiently knowledgeable in the applicable collection procedures of this part to be able to evaluate the collector's performance.

(i) The person providing the instruction must provide written documentation that you have demonstrated proficiency in collections under this part by your completing five consecutive error-free trial collections.

(A) The five trial collections must include both uneventful and problematic examples.

(B) In addition to two uneventful collection scenarios, one must address insufficient quantity of urine, one the temperature out of range, and one in which the employee refuses to sign the CCF.

(ii) The person providing the instruction will monitor, evaluate, and attest whether or not the trial collections are ''error-free.''

(iii) The person providing the instruction must emphasize that you are responsible for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(3) Meet the requirements of paragraph (b)(2) of this section by [date six months from the effective date of the final regulation], if you were a collector prior to [effective date of the final regulation]. Meet the requirements of paragraph (b)(2) of this section prior to your first collection, if you become a collector after [effective date of the final regulation].

(4) Receive additional training, as needed, to ensure proficiency as the technology you use changes.

(5) Be retrained to proficiency if you make a mistake in the collection process that has caused a test to be canceled.

(i) This retraining must be provided and your proficiency documented in writing by a person sufficiently knowledgeable in the applicable collection procedures of this part.

(ii) The instruction need only be in the general area of your deficiency that caused the test to be canceled.

(iii) As part of the retraining, you will have to demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free trial collections before you conduct another DOT collection of a safety-sensitive employee.

(iv) The person providing the instruction will monitor, evaluate, and attest whether or not the trial collections are ''error-free.''

(b) As a collector, you must be retrained in the elements of paragraph (a) of this section by [date one year from the effective date of the final regulation], or two years from the date you became a collector, whichever is later, and once every two years, thereafter.

(c) As a collector, you must maintain all documentation of training/retraining as long as you serve as a collector.

§ 40.35 What requirements must organizations employing collectors meet?

This section becomes effective [date six months from the effective date of the final regulation].

(a) As an organization employing the collector (*e.g.,* a transportation employer, third-party administrator, occupational health clinic), you must maintain in your files the following information:

(1) A signed statement by the collector that he or she has read and understood the drug testing procedures in this part and the current ''DOT Urine Specimen Collection Procedures Guidelines'; and (2) A signed statement by an official of the organization that the collector has received training/retraining and has demonstrated proficiency as required by this part.

(b) You must retain these signed statements as long as the person performs collector functions for the organization and for 2 years after the person ceases to perform these functions for the organization.

(c) You must provide to collectors the name and telephone number of a designated employer representative (DER) to contact about any problems or issues that may arise during the collection process.

§ 40.37 Where is other information on the role of collectors found in this regulation?

You can find other information on the role and functions of collectors in the following sections of this part:

§ 40.1—coverage.
§ 40.3—definition.
§ 40.43—steps to prepare and secure collection site.
§§ 40.45–40.47—use of CCF.
§§ 40.61–40.63—preliminary steps in collections.
§ 40.65—role in checking specimens.
§ 40.67—role in directly observed collections.
§ 40.69—role in monitored collections.
§ 40.71—role in single specimen collections.
§ 40.73—role in split specimen collections.
§ 40.75—chain of custody completion and finishing the collection process.
§ 40.191—action in case of refusals to take test.
§ 40.193—action in ''shy bladder'' situations.
§ 40.197–40.199—collector errors in tests, effects, and means of correction.

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

§ 40.41 Where does a urine collection for a DOT drug test take place?

(a) A urine collection for a DOT drug test must take place in a collection site meeting the requirements of this section.

(b) If you are operating a collection site, you must make sure that it meets the security requirements of § 40.43.

(c) If you are operating a collection site, you must have all needed personnel, materials, equipment, facilities and supervision to provide for the collection, temporary storage, and shipping of urine specimens to a laboratory, and a suitable clean surface for writing.

(d) Your collection site must include a closed room within which urination can occur.

(1) The room must provide visual and aural privacy to the employee and a toilet for completion of urination (unless a single-use collection container with sufficient capacity to contain the complete void is used).

(2) Whenever available, the closed room must be a single-toilet room with a full-length privacy door.

(3) No one but the employee may be present in the room during the collection, except for the observer in the event of a directly observed collection.

(e) If you are operating a collection site, you must have a source of water for washing hands, that, if practicable, should be external to the closed room where urination occurs. If a water source is not available, you may meet this requirement by providing moist towelettes outside the closed room.

(f) If a collection site fully meeting all the visual and aural privacy requirements and security requirements of paragraph (d) of this section is not readily available, the collection may take place at a site that partially meets these requirements.

(1) Such a site is one that provides substantial visual privacy but not aural privacy (*e.g.,* a toilet stall with a partial-length door in a multi-stall restroom) and meets all other requirements of this section.

(2) If you use a multi-stall restroom, you must secure all water sources and place bluing agent in all toilets or secure the toilets to prevent access.

(3) Such a site may be used only for monitored collections (see § 40.69). In this case, the site must afford aural privacy to the employee to the greatest extent practicable.

(g) A collection site can be in a medical facility, a mobile facility (*e.g.,* a van), a dedicated collection facility, or any other location meeting the requirements of this section.

§ 40.43 What steps must collection sites take to protect the security and integrity of urine collections?

(a) Collectors and collection sites must take the steps listed in this section to prevent unauthorized access which could compromise the integrity of collections.

(b) As a collector, you must do the following before each collection:

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

(2) Make sure that the water in the toilet is blue;

(3) Make sure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;

(4) Inspect the site to make sure that no foreign or unauthorized substances are present;

(5) Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;

(6) Make sure that undetected access (*e.g.,* through a door not in your view) is not possible;

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

(8) Recheck items in paragraphs (b) (1) through (7) of this section following each collection to ensure the site's continued integrity.

(c) If the collection site uses a facility normally used for other purposes, like a public rest room or hospital examining room, you must, as a collector, also make sure before the collection that:

(1) Access to collection materials and specimens is effectively restricted; and

(2) The facility is secured against access during the procedure to ensure privacy to the employee and prevent distraction of the collection site person and limited-access signs are posted.

(d) As a collector, you must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, make sure you have only one employee under your supervision at any time.

(2) To the greatest extent you can, keep an employee's collection container within view of both you and the employee before and after the employee has urinated.

(3) Make sure you are the only person in addition to the employee who handles specimens before they are secured in the shipping container.

(4) In the time between when the employee gives you the specimen and the time you seal the specimen, remain within the collection site.

(5) Maintain personal control over each specimen and CCF throughout the collection process.

(e) If you are operating a collection site, you must prevent unauthorized personnel from entering any part of the site.

(1) The only people you are to treat as authorized persons are employees being tested, collectors and other collection site workers, DERs, employee representatives authorized by the employer (*e.g.,* employer policy; labor-management agreement), and representatives of DOT.

(2) You must make sure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(3) You may remove any person who obstructs, interferes with, or causes a delay in the collection process.

(4) You must make sure that no one except the employee, collector, and monitor or direct observer enters the room in which urination occurs.

(f) If you are operating a collection site, you must minimize the number of persons handling specimens.

§ 40.45 What form is used to document a DOT urine collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every urine collection required by the DOT drug testing program. The CCF must be a seven-part carbonless manifold form. (The CCF is available at U.S. Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.)

(b) As a participant in the DOT drug testing program, you may not modify or revise the CCF except as follows:

(1) You may include other information needed for billing or other purposes necessary to the collection process.

(2) The CCF must include the employer's name, address and telephone number, which may be preprinted, typed, or handwritten. In addition, a consortium's or third-party administrator's name, address, and telephone number may be included.

(3) Instead of printing the entire pages of the CCF in the colors specified by HHS, you may use white pages with clearly discernible borders in the specified color for each page.

(4) As an employer, you may add, in the ''Remarks'' section of the CCF, the name of the DOT agency under whose authority the test occurred.

(5) As a collector, you may use a CCF with your name, address, and telephone number preprinted but under no circumstances are any signatures to be added before the collection event.

(c) Under no circumstances may the CCF transmit personal identifying information about an employee (other than a social security number or other employee identification number) to a laboratory.

(d) As the collector, you must make sure that medical information about the employee (*e.g.,* medications the employee has taken) appears only on the copy of the CCF given to the employee.

(e) As an employer outside the United States, you may use a foreign-language (equivalent) version of the CCF approved by ODAPC (*e.g.,* in French for use in Canada or Spanish for use in Mexico).

§ 40.47 May employers use the CCF for non-DOT collections or non-Federal forms for DOT collections?

(a) No. As an employer, you are prohibited from using the CCF for non-DOT urine collections. You are also prohibited from using non-Federal forms for DOT urine collections. Doing either subjects you to enforcement action under DOT agency regulations.

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

form was not discovered by the laboratory.

§ 40.49 What materials are used to collect urine drug specimens?

For each DOT drug test, you must use a collection kit meeting the requirements of Appendix A of this part.

§ 40.51 What materials are used to send urine specimens to the laboratory?

(a) A shipping container (*e.g.,* standard courier cardboard box, small cardboard box) must be used that adequately protects the specimen bottles from shipment damage in the transport of specimens from collection site to the laboratory.

(b) A shipping container box is not necessary if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

Subpart E—Drug Test Collections

§ 40.61 What are the preliminary steps in the collection process?

As the collector, you must take the following steps before actually beginning a collection:

(a) If an employee does not show up at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the employer has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee is a ''no show.''

(b) Make sure that, when the employee enters the collection site, you begin the testing process without delay. For example, you must not wait because the employee says he or she is not ready or is unable to urinate or because an authorized employer or employee representative is delayed in arriving.

(1) If the employee is also going to take a DOT alcohol test, you must make sure that the alcohol test is completed before the urine collection process begins.

(2) If the employee needs medical attention (*e.g.,* an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to collect a specimen.

(3) You may not collect (*e.g.,* by means of catheterization) urine from an unconscious employee for purposes drug test under this part.

(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer or a Federal, state, or local government agency for this purpose. You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(d) If the employee asks, provide identification to the employee. Your identification must include your name and your employer's name, address, and telephone number but does not have to include your picture, address, or telephone number.

(e) Explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF.

(f) Direct the employee to remove outer clothing (*e.g.,* coveralls, jacket, coat, hat) and to leave these garments and any briefcase, purse, or other personal belongings with you.

(1) If the employee asks for a receipt for any belongings left with you, you must provide one.

(2) You must allow the employee to keep his or her wallet.

(3) You must not ask the employee to remove other clothing (*e.g.,* shirts, pants, dresses, underwear), to remove all clothing, or to change into a hospital or examination gown (unless the urine collection is being accomplished simultaneously with a DOT agency-authorized medical examination).

(4) You must direct the employee to empty his or her pockets and display the items in them to ensure that no items are present which could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee can place the items back into the pockets. The employee must allow you to make this observation.

(5) You must require an employee who is wearing boots (*e.g.,* work boots or cowboy boots) to remove the boots and allow you to look into the boots to ensure that no items are present which could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee can put the boots back on. The employee must allow you to make this observation.

(6) If, in your duties under paragraphs (f)(4) and (5) of this section, you find a material or materials that could be used to alter a specimen, you must:

(i) If the material appears to be brought to the collection site with the intent to alter the specimen, conduct a directly observed collection using direct observation procedures (see § 40.67); or

(ii) If the material appears to be inadvertently brought to the collection site, secure and maintain it until the collection process is completed and conduct a normal (*i.e.,* unobserved) collection.

(g) You must not require the employee to sign a consent, release, or waiver of liability, or indemnification agreement with respect to any part of the collection or testing process.

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

As the collector, you must take the following steps before the employee provides the urine specimen:

(a) Complete Step 1 of the CCF.

(b) Instruct the employee to wash and dry his or her hands at this time. You must tell the employee not to wash his or her hands again until after delivering the specimen to the collector. You must not give the employee any further access to water or other materials that could be used to adulterate or dilute a specimen.

(c) Select, or allow the employee to select, an individually wrapped or sealed collection container from collection kit materials. Either you or the employee, with both of you present, must unwrap or break the seal of the collection container. You must not unwrap or break the seal at this time on any specimen bottle. You must not allow the employee to take anything from the collection kit into the room used for urination except the collection container.

(d) Direct the employee to go into the room used for urination, provide a specimen of at least 45 mL (split specimen collections) or 30 mL (single specimen collections), not flush the toilet, and return to you with the specimen as soon as the employee has completed the void. Except in the case of an observed or a monitored collection (see §§ 40.67 and 40.69), neither you nor anyone else may go into the room with the employee.

(e) You must pay careful attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to substitute or adulterate a specimen (*e.g.*, substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute.). If you detect such conduct, you must direct that a collection take place immediately under direct observation (see § 40.67) and note the conduct and the fact that the collection was observed in the ''Remarks'' section of the CCF. You must also, as soon as possible, inform the DER and collection site supervisor that the collection took place under direct observation and the reason for doing so.

§ 40.65 What does the collector check for when the employee presents a specimen?

As a collector, you must check the following when the employee gives the collection container to you:

(a) *Sufficiency of specimen.* You must check to make sure that the specimen contains a sufficient amount of urine (45 mL for a split specimen collection; 30 mL for a single specimen collection).

(1) If it does not, you must follow ''shy bladder'' procedures (see § 40.193).

(2) When you follow ''shy bladder'' procedures, you must discard the original specimen, unless another problem (*i.e.*, temperature out of range, apparent adulteration) also exists.

(3) You are never permitted to combine urine collected from separate voids to create a specimen.

(b) *Temperature.* You must check the temperature of the specimen no later than four minutes after the employee has given you the specimen.

(1) The acceptable temperature range is 32–38°C/90–100°F.

(2) You must determine the temperature of the specimen by reading the temperature strip attached to the collection container.

(3) If the specimen temperature is within the acceptable range, you must mark the ''Yes'' box on the CCF.

(4) If the specimen temperature is outside the acceptable range, you must mark the ''No'' box on the CCF.

(5) If the specimen temperature is outside the acceptable range, you must immediately conduct a new collection using the direct observation procedures (see § 40.67).

(6) In a case where a specimen is collected under direct observation because of the temperature being out of range, you must process both the original specimen and the specimen collected using direct observation and send them to the laboratory. This is true even in a case in which the original specimen has insufficient volume but the temperature is out of range.

(7) In a case where the employee refuses to provide another specimen (see § 40.191(a)(3)) or does not provide the requisite amount of urine (see § 40.193(b)(4)) under direct observation, you must notify the DER. As soon as you have notified the DER, you may discard the previous specimen.

(c) *Signs of adulteration or substitution.* You must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of adulteration (*e.g.*, if you notice any unusual odor).

(1) If it is apparent from this inspection that the employee has adulterated or substituted the specimen (*e.g.*, blue dye in the specimen, excessive foaming when shaken, smell of bleach), you must immediately conduct a new collection using direct observation procedures (see § 40.67).

(2) In a case where a specimen is collected under direct observation because of showing signs of adulteration or substitution, you must process both the original specimen and the specimen collected using direct observation and send them to the laboratory. This is true even in a case in which the original specimen has insufficient volume but it shows signs of adulteration or substitution.

(3) In a case where the employee refuses to provide another specimen (see § 40.191(a)(3)) or does not provide the requisite amount of urine (see § 40.193(b)(4)) under direct observation, you must notify the DER. As soon as you have notified the DER, you may discard the previous specimen.

§ 40.67 When and how is a directly observed collection conducted?

(a) As an employer you must direct an immediate collection under direct observation with no advance notice to the employee, if:

(1) The laboratory reported a specimen as unsuitable for testing, and the MRO reported to you that there was not an adequate medical explanation for the unsuitability; or

(2) The MRO reported to you that the original positive test result had to be canceled because the test of the split specimen was not performed.

(b) As an employer you may direct a collection under direct observation of an employee if:

(1) The drug test is a return-to-duty test or a follow-up test; or

(2) The MRO reports that the employee's immediately prior drug test result was dilute.

(c) As a collector, you must conduct a collection under direct observation under the following circumstances if:

(1) You are directed by the DER to do so (see paragraphs (a) and (b) of this section); or

(2) You observed materials brought to the collection site or employee conduct clearly indicating an attempt to adulterate or substitute a specimen (see §§ 40.61(f)(6)(i) and 40.63(e)); or

(3) The temperature on the original specimen was out of range (see § 40.65(b)(5)); or

(4) The original specimen appeared to have been adulterated or substituted (see § 40.65(c)(1)).

(d) As the collector, you must complete a new CCF for the directly observed collection. You must enter the reason (*e.g.*, suspected adulteration, prior specimen dilute) for conducting the directly observed collection in the ''Remarks'' section of the CCF.

(e) In a case where two specimens (or sets of specimens, where the split specimen method of collection is used) are being sent to the laboratory because of suspected adulteration or substitution at the collection site, enter in the ''Remarks'' section of the CCF for each specimen a notation to this effect (*e.g.*, collection 1 of 2, or 2 of 2.).

(f) As the collector, you must make sure that the observer is the same gender as the employee. You must never permit an opposite gender person to act as the observer. The observer can be a different person from the collector and need not be a qualified collector.

(g) As the collector, if someone else is to observe the collection, you must verbally instruct that person to follow procedures at paragraphs (h) and (i) of this section. If you, the collector, are the observer, you too must follow these procedures.

(h) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to watch the urine go from the employee's body into the collection container.

(i) As the observer but not the collector, you must not take the collection container from the employee, but you must observe the specimen as the employee takes it to the collector.

(j) As the collector, when someone else has acted as the observer (*e.g.*, in order to ensure a same gender observer), you must include the observer's name in the remarks section of the CCF.

(k) As the employee, if you decline to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.

§ 40.69 When and how is a monitored collection conducted?

(a) As a collector, you are permitted to conduct a monitored collection only if these conditions are met:

(1) A collection site fully meeting all the visual and aural privacy requirements and security requirements of § 40.41(d) is not readily available; and

(2) The available collection site does offer substantial visual privacy but not aural privacy (*e.g.*, a toilet stall with a partial-length door in a multi-stall restroom) and meets the other requirements of § 40.41.

(b) No one is permitted to conduct a monitored collection under any other circumstances.

(c) As the collector, you must enter the reasons for conducting the monitored collection in the ''Remarks'' section of the CCF.

(d)(1) As the collector, you must secure the room being used for the

monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

(2) You must also put bluing agent into the toilet's water before the collection takes place and direct the employee not to flush the toilet until after giving the specimen to the collector.

(e) As the collector, you must make sure that the monitor is the same gender as the employee. You may permit an opposite gender person to act as the monitor only if that person is a medical professional (*e.g.*, nurse, doctor, physician's assistant). The monitor can be a different person from the collector and need not be a qualified collector.

(f) As the collector, if someone else is to monitor the collection, you must verbally instruct that person to follow procedures at paragraph (g) of this section. If you, the collector, are the monitor, you too must follow these procedures.

(g) As the monitor, you must not watch the employee urinate into the collection container. However, you must stand near the enclosure in which the collection is taking place and listen for any sounds that could indicate an attempt to substitute or adulterate a specimen (e.g., opening of a plastic package or tube, an object dropping to the floor). If you hear such sounds or make other observations indicating an attempt to substitute a specimen, there must be an additional collection under direct observation (see §§ 40.63(e) and 40.67(c)).

(h) As the monitor, you must ensure that the employee takes the collection container directly to the collector as soon has the employee has exited the enclosure.

(i) As the collector, when someone else has acted as the monitor (e.g., in order to ensure a same gender monitor), you must include the name of the monitor in the remarks section of the CCF.

(j) As the employee, if you decline to permit a collection required or permitted to be monitored under this section to be monitored, this is a refusal to test.

§ 40.71 How does the collector process a single specimen collection?

As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you:

(a) You, not the employee, must—in the employee's presence—pour at least 30mL of urine from the collection container into the specimen bottle.

(b) You, not the employee, must place and secure (i.e., tighten or snap) the lid/cap on the bottle.

(c) You, not the employee, must write the date on the tamper-evident bottle seal.

(d) You, not the employee, must seal the bottle by placing the tamper-evident bottle seal over the bottle cap/lid and down the sides of the bottle.

(e) You must then make sure that the employee initials the tamper-evident bottle seal for the purpose of certifying that the bottle contains the specimen he or she provided.

(f) You must dispose of the extra tamper-evident bottle seal if it was included in the collection kit or on the CCF.

§ 40.73 How does the collector process a split specimen collection?

As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you:

(a) You, not the employee, must—in the presence of the employee—first pour 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.

(b) You, not the employee, must—in the presence of the employee—then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.

(c) You, not the employee, must place and secure (i.e., tighten or snap) the lids/caps on the bottles.

(d) You, not the employee, must write the date on the tamper-evident bottle seals.

(e) You, not the employee, must seal the bottles by placing the tamper-evident bottle seals over the bottle caps/lids and down the sides of the bottles.

(f) You must then make sure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the specimens he or she provided.

§ 40.75 How is the collection process completed?

(a) As the collector, you must do the following things to complete the collection process:

(1) Direct the employee to read and sign the certification statement on Copy 4 of the CCF and provide date of birth, printed name, and day and evening contact telephone numbers. If the employee refuses to sign the CCF, you must note this in the ''Remarks'' section of the CCF.

(2) Complete the collector certification section of the CCF (Step 5) by printing the name, address, and telephone number of the collection site (Note: You may pre-print this information); checking the box indicating whether this was a split specimen collection; printing your name; recording the time and date of the collection; and signing the certification statement.

(3) Sign the first line of the chain of custody block of the CCF (Step 6), indicating that you received the specimen from the employee, and print your name and the date.

(4) Complete the second line of the chain of custody by printing and signing your name in the ''Specimen Released By'' block and completing the ''Specimen Received By'' block by printing the specific name of the courier or shipping service and the date. You must also complete the ''Purpose of Change'' block to indicate the reason for transfer (e.g., ''shipment to lab'').

(5) Ensure that all copies of the CCF are legible and complete.

(6) Remove Copy 5 of the CCF, give it to the employee.

(7) Place the specimen bottle(s) and Copies 1 and 2 (plus Copy 3 in the case of a split specimen collection) of the CCF in the appropriate pouches of the plastic bag.

(8) Using the tamper-evident seal for the plastic bag, secure both pouches of the plastic bag, initial the seal and enter the collection date.

(9) Advise the employee that he or she may leave the collection site.

(10) To prepare the sealed plastic bag containing the specimens and CCFs for shipment you must:

(i) Place the sealed plastic bag in a shipping container (e.g., standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier process.

(11) Send Copy 4 of the CCF to the MRO and Copy 7 to the DER. Keep Copy 6 for the period of time specified by applicable DOT agency regulations.

(b) Each time a specimen is handled or transferred, the date and purpose of the action, as well as the individual taking the action, must be documented on the CCF. The following are exceptions to this general rule:

(1) The activity of couriers, express carriers, postal service personnel, and other persons who are involved only with the transportation of the specimen

to a laboratory is not required to be documented on the CCF.

(2) When a specimen already in the sealed plastic bag is put into or taken out of secure storage before transportation personnel pick it up, documentation on the CCF is not required.

(c) As a collector or collection site, you must make sure that each specimen you collect is shipped to a laboratory as expeditiously as possible, the same day preferably. You must also make sure that all copies of the CCF are sent to the persons designated on the bottom of the CCF as soon as the specimen is sent to the laboratory.

Subpart F—Drug Testing Laboratories

§ 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP).

(b) As a drug testing laboratory located outside of the U.S. which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has certified your laboratory as meeting HHS laboratory certification standards or deemed your laboratory fully equivalent to a laboratory meeting HHS laboratory certification standards; or

(2) The DOT, based on a written recommendation from HHS, has recognized a foreign certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the foreign certifying organization has certified your laboratory under those equivalent standards and procedures.

(c) As a laboratory participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.

(d) If DOT determines that you are in noncompliance with this part, you will be ineligible to participate in the DOT drug testing program, and employers covered by DOT agency regulations will be prohibited from using your services for DOT drug testing. You will be ineligible to participate under these circumstances even if you continue to meet the requirements of paragraph (a) or (b) of this section.

§ 40.83 How do laboratories process incoming specimens?

As the laboratory, you must do the following when you receive a DOT specimen:

(a) Use the chain of custody on the CCF and an internal chain of custody document(s) to maintain control and accountability of the specimen from the time you receive it until you ultimately dispose of it. The provisions of § 40.75(b) apply to your use of chain of custody documentation.

(b) Inspect each specimen and CCF for the following ''fatal flaws'' and take the appropriate reporting actions outlined in § 40.95(d)(4):

(1) The specimen ID numbers on the specimen bottle and the CCF do not match;

(2) There is no specimen ID number on the specimen bottle;

(3) The specimen bottle seal is broken or shows evidence of tampering (unless a split specimen can be redesignated, see paragraph (f) of this section); and

(4) There is insufficient amount of urine in the primary or single specimen bottle for analysis and any necessary reanalysis for quality control (unless the specimens can be redesignated, see paragraph (f) of this section) and, in the case of a single specimen, reconfirmation of results.

(c) Inspect each specimen and CCF for the following ''correctable flaws'' and take the appropriate actions as noted in § 40.203(b):

(1) The collector's signature is omitted on the certification statement on the CCF.

(2) The chain of custody block on the CCF is incomplete.

(3) The employee's social security number or ID number is omitted from the CCF, unless the employee's refusal to provide the information is noted in the ''Remarks'' section.

(d) Inspect each specimen for integrity and consistency (e.g., foreign material or color differences between the primary and the split specimens).

(1) If, as a result of your receipt-inspection protocol, you note that the primary specimen contains a visible foreign material and you are unable to test the specimen, take appropriate reporting actions outlined in § 40.95(d)(3) and (4)(viii).

(2) If, as a result of your receipt-inspection protocol, you note that the primary specimen shows a marked color difference (e.g., light vs. dark, blue vs. yellow) from the split specimen, do not test the specimen but take appropriate reporting actions outlined in § 40.95(d)(3) and (4)(viii).

(e) If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, follow appropriate procedures outlined in § 40.175(b) regarding the unavailability of the split specimen for testing.

(f)(1) The primary specimen and the split specimen can be redesignated (i.e., Bottle B is redesignated as Bottle A, and vice versa) if:

(i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(ii) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

(iii) The laboratory opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing. You must also follow appropriate procedures outlined in § 40.175(b) regarding the unavailability of the split specimen for testing.

(2) In situations outlined in paragraph (f)(1) of this section, the laboratory shall mark through the ''A'' and write ''B,'' then initial and date the change. A corresponding change shall be made to the other bottle by marking through the ''B'' and writing ''A,'' and initialing and dating the change. A notation shall be made on the original CCF (Copy 1) and on the split specimen copy (Copy 3).

(g) Comply with all applicable provisions of the HHS Guidelines concerning accessioning and processing of urine drug specimens.

§ 40.85 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test ''DOT specimens'' for any other drugs.

(a) Marijuana metabolites.

(b) Cocaine metabolites.

(c) Amphetamines.

(d) Opiate metabolites.

(e) Phencyclidine (PCP).

§ 40.87 What methods do laboratories use for screening and confirmation tests?

As a laboratory, you must use the following methods for a DOT drug test.

You may not use any other testing methods.

(a) For the screening test, you must use an immunoassay test that meets Food and Drug Administration requirements for commercial distribution, and has had its application in the laboratory approved by HHS inspection criteria or validation.

(b) For the confirmation test, you must use gas chromatography/mass spectrometry (GC/MS) and perform a quantitative analysis.

§ 40.89 What are the cutoff concentrations for screening and confirmation tests?

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

Type of drug	Screening test	Confirmation test
(1) Marijuana metabolites	50	
(i) Delta-9-Tretrahydrocannabinol-9-carbolic acid (THC)		15
(2) Cocaine metabolites	300	
(i) Benzoylecgonine		150
(3) Phencyclidine (PCP)	25	25
(4) Amphetamines	1000	
(i) Amphetamine		500
(ii) Methamphetamine		500 (Specimen must also contain amphetamine at a concentration greater than or equal to 200 ng/mL.)
(5) Opiate metabolites	2000	
(i) Codeine		2000
(ii) Morphine		2000 (Test for 6-acetylmorphine (6–AM) in the specimen)
(iii) 6-acetylmorphine (6–AM)		10 (Conduct this test only when specimen contains morphine at a concentration greater than or equal to 2000 ng/mL.)

(b) On a screening test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.

(c) On a confirmation test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

§ 40.91 What additional testing must be done by laboratories on primary specimens?

(a) As a laboratory, you must subject each primary specimen to specimen validity testing. Specimen validity testing is the evaluation to determine if the specimen is consistent with normal human urine. Specifically, you will determine if certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.

(1) Each primary specimen must be tested for creatinine, pH, and nitrite concentration. You must also determine the specific gravity of the primary specimen if you find that the creatinine level is <20 mg/dL.

(2) Each primary specimen may also be tested for, but not limited to, pyridine, glutaraldehyde, bleach, and soap.

(3) When you suspect the presence of an interfering substance/adulterant (e.g., glutaraldehyde, surfactant, bleach) that could make a specimen unsuitable for testing, you may, using scientifically suitable validity tests, conduct tests to identify the interfering substance/adulterant. If you are unable to identify it, you may send the specimen to another HHS certified laboratory that has the capability of doing so. Such specimen transfers must be documented with appropriate chains of custody.

(b) Specimen validity must be conducted on the split specimen if the split specimen fails to reconfirm the presence of the drug/analyte that was determined to be present in the primary specimen.

(c) You must not use the split specimen to verify the primary specimen results for a substituted or adulterated result.

(d) You must make every effort to conserve the specimen volume for possible future testing.

§ 40.93 What methods and criteria do laboratories use for validity testing?

(a) Specimen validity can be determined by establishing parameters that are consistent with normal human urine and/or by testing for the presence of an abnormal or foreign substance in the urine.

(b) For dilute specimens, at a minimum, creatinine and specific gravity must be measured by quantitative procedures at a cutoff of 20 mg/dL and 1.003, respectively.

(1) As a laboratory you must consider the primary specimen to be dilute if the creatinine is <20 mg/dL *and* the specific gravity is <1.003, unless the criteria for a substituted specimen are met.

(2) [Reserved]

(c) For substituted specimens, at a minimum, creatinine must be measured by at least one quantitative procedure on two different aliquots both utilizing the specified cutoff of 5 mg/dL. At a minimum, specific gravity must be performed on one of these aliquots utilizing the specified cutoffs of 1.001 or 1.020.

(1) As a laboratory you must consider the primary specimen to be *substituted* (*i.e.,* the specimen does not exhibit the clinical signs or characteristics associated with normal human urine) if the creatinine concentration is ≤5 mg/dL and the specific gravity is ≤1.001 or ≤1.020.

(2) [Reserved]

(d) For adulterated specimens, concerning pH and nitrites, at a minimum, two procedures must be performed for pH and nitrites. One procedure must be quantitative and utilize the specified cutoff. The second procedure may be qualitative, must be at least as sensitive as the quantitative procedure, and must be performed on a separate aliquot.

(1) As a laboratory you must consider the primary specimen to be *adulterated* if the nitrite concentration is ≤500 μg/mL.; or if the pH is ≤3 or ≤11; or if an exogenous substance (i.e., a substance which is not a normal constituent of urine) or an endogenous substance at a higher concentration than normal physiological concentration is present in the specimen.

(2) [Reserved]

(e) For adulterant analytes without a specified cutoff (e.g., glutaraldehyde, bleach, soap), at least one procedure must be performed on two separate aliquots.

(f) All specimen validity testing methods must be characterized by demonstrating precision and accuracy. Where cutoffs are specified, the limit of quantitation (LOQ) and linearity must be determined. The limit of detection (LOD) must be experimentally determined for qualitative methods.

(g) All specimen validity tests must be performed using methods that are validated by the laboratory. All methods used to characterize and validate these tests must be documented in the laboratory's SOP.

§ 40.95 What do laboratories need to report to MROs regarding primary specimen results?

As a laboratory, the following applies to your reports of individual primary specimen drug test results:

(a) Before reporting a result, you must ensure that it has been reviewed and certified as accurate by the certifying scientist.

(b) You will report drug test results as either Negative, Positive (for a specific drug), or Test Not Performed.

(c) Additionally, you must include an appropriate comment on the ''Remarks'' line in Step 7 on the CCF when the specimen is dilute, adulterated, substituted, or not tested for drugs (e.g., presence of a fatal flaw or uncorrected flaw). If the additional comments cannot be fully described on the ''Remarks'' line, you may attach a separate sheet describing the problem, and reference the attachment on the ''Remarks'' line.

(d) When a specimen is reported as Negative, Positive, or Test Not Performed:

(1) *Negative.* Check the ''Negative'' box in Step 7 on the CCF when a negative drug test result is obtained on the initial test or on the confirmatory test. If the specimen is also dilute, include the statement, ''Dilute Specimen'' on the ''Remarks'' line.

(2) *Positive.* Check the ''Positive'' and the specific drug(s)/drug metabolite(s) boxes in Step 7 on the CCF when a positive drug test result is obtained on an initial test and a confirmatory test. If the specimen is also dilute, include the statement, ''Dilute Specimen'' on the ''Remarks'' line.

(3) *Test Not Performed.* Check the ''Test Not Performed'' box in Step 7 on the CCF if the specimen is not tested because of a fatal flaw (*e.g.,* broken seal; specimen ID numbers do not match); not tested because of an uncorrected flaw (*e.g.,* a collector's signature was omitted and a signed statement is not received to correct the error); rejected for testing (*e.g.,* significant color difference between the primary and split specimens); unsuitable for testing or contains an unidentified interfering substance and a valid drug test result cannot be obtained; adulterated; or substituted.

(e) If the ''Test Not Performed'' box in Step 7 on the CCF is checked, include one of the following statements (as appropriate) on the ''Remarks'' line:

(1) ''Fatal Flaw'' (with the flaw stated).

(2) ''Uncorrected Flaw'' (with the flaw stated).

(3) ''Specimen Unsuitable: Cannot obtain valid drug test result''.

(4) ''Specimen Adulterated: Nitrite is too high''.

(5) ''Specimen Adulterated: pH is too high (or too low)''.

(6) ''Specimen Adulterated: Presence of (specify) detected''.

(7) ''Specimen Substituted: Not consistent with normal human urine''.

(8) ''Specimen Rejected for Testing'' (with reason stated).

(f) You may not routinely report the quantitative results for validity tests (*e.g.,* nitrite concentration, creatinine concentration, actual specific gravity, or actual pH) to the MRO, but may do so upon MRO request on a case-by-case basis.

§ 40.97 Through what methods and to whom must a laboratory transmit results?

(a) As a laboratory, you must transmit laboratory results directly, and only, to the MRO at his or her place of business (not to the MRO through a consortium or third-party administrator). You must not transmit results to or through the DER or another service agent (*e.g.,* consortia, third-party administrators).

(b) In transmitting these laboratory results:

(1) You must fax, courier, or mail a copy of the original and fully-completed (as outlined in § 40.95) Copy 2 of the CCF, which has been signed by the individual responsible for day-to-day management of your laboratory or the individual responsible for attesting to the validity of test results.

(2) In addition, you may elect to forward a results report that includes only the test result, remarks line items, the specimen number as it appears on the CCF, and the laboratory specimen identification number (accession number), and the cutoff concentrations for screening and confirmation tests. This report can be transmitted through any means that ensures accuracy and confidentiality (*e.g.,* courier, mail, fax, computer link), but never verbally by telephone.

(c) In transmitting these laboratory results to the MRO, you, the MRO, and the employer must ensure the security of the transmission and limit access to any transmission, storage, or retrieval system.

(d) In the case of a negative test, you must transmit the laboratory result so that it reaches the MRO within 72 hours from the time of the result.

(e) In the case of a positive test, a test not performed, or a negative test that is dilute, you must transmit the laboratory result so that it reaches the MRO within 24 hours from the time of the result.

§ 40.99 How long does the laboratory retain specimens after testing?

(a) As a laboratory, you must keep positive urine specimens in long-term frozen storage ($-20°C$ or less) for at least one year.

(1) Where there is a split specimen, you must keep it as well as the positive primary specimen for the one-year period.

(2) You must keep these specimens in their original specimen bottles.

(b) As a laboratory, you must keep a positive specimen indefinitely if you know that there is a pending legal proceeding (*e.g.,* unemployment or workers' compensation proceeding, unjust discharge or personal injury lawsuit) for which the specimen may be evidence. You must also keep a positive specimen beyond the one-year period if the employee (through the MRO), employer or a DOT agency asks you. Otherwise, you may discard the specimen at the end of the one-year period.

(c) When you determine that a specimen is unsuitable, adulterated, or substituted, you must keep it the same way you keep a positive specimen.

(d) Once you have reported a negative result, a rejected for testing result, a fatal flaw result, or an uncorrected flaw result on the primary specimen to the MRO, you may discard the primary specimen as well as the split specimen.

(e) As a laboratory testing the split specimen, you must keep a split specimen that does not reconfirm the primary specimen in the same way as you keep a positive specimen.

§ 40.101 What relationship may a laboratory have with an MRO?

(a) As a laboratory, you may not enter into any relationship with an employer's MRO that creates a conflict of interest or the appearance of a conflict of interest with the MRO's responsibilities for that employer. You may not derive any financial benefit by having an employer use a specific MRO.

(b) As a laboratory, you must maintain a statement, signed by the responsible

person for laboratory management, for review by a DOT agency. The statement will certify that the laboratory has no apparent financial or potentially conflicting relationship with any MRO. The statement will remain in effect until its conditions change, at which time you must amend the statement to reflect current status.

§ 40.103 What blind specimens must be sent to a laboratory?

(a) As an employer, consortium, or third-party administrator with 2000 or more DOT-covered employees, you must send blind specimens to laboratories you use. If you have fewer than 2000 DOT-covered employees, you are not required to provide blind specimens.

(b) To each laboratory to which you send at least 100 specimens in a year, you must transmit a number of blind specimens equivalent to one percent of the specimens you send to that laboratory, up to a maximum of 50 blind specimens in each quarter (*i.e.,* January–March, April–June, July–September, October–December). As a consortium or third-party administrator, you must apply this percentage to the total number of DOT-covered employees for whom you provide services. Your blind specimen submissions must be evenly spread throughout the year. The following examples illustrate how this requirement works:

(1) *Example 1.* You send 1500 specimens to Lab X in Year 1. In this case, you would send 15 blind specimens to Lab X in Year 1. To meet the even distribution requirement, you would send 4 in each of three quarters and 3 in the other.

(2) *Example 2.* You send 1000 specimens to Lab X and 500 specimens to Lab Y in Year 1. In this case, you would send 10 blind specimens to Lab X and 5 to Lab Y in Year 1. The even distribution requirement would apply in a similar way to that described in Example 1.

(3) *Example 3.* Same as Example 2, except that you also send 10 specimens to Lab Z. In this case, while you would send blind specimens to Labs X and Y as in Example 2, you would not have to send any blind specimens to Lab Z, because you sent fewer than 100 specimens to Lab Z.

(4) *Example 4.* You are a consortium sending 1000 specimens to Lab X in Year 1. These 1000 specimens represent 150 small employers who have an average of 15 covered employees each. In this case you—not the individual employers—send 10 blind specimens to Lab X in Year 1, again ensuring even distribution. The individual employers you represent are not required to provide any blind specimens on their own.

(5) *Example 5.* You are a large third-party administrator that sends 40,000 specimens to Lab Y in Year 1. One percent of that figure is 400. However, the 50 blind specimen per quarter ''cap'' means that you need send only 50 blind specimens per quarter, rather than the 100 per quarter you would have to send to meet the one percent rate. Your annual total would be 200, rather than 400, blind specimens.

(c) Approximately 80 percent of the specimens you submit must be blank (*i.e.,* containing no drugs). The rest must be positive for one or more of the five drugs involved in DOT tests.

(1) The blind specimens that you submit must be certified by immunoassay and GC/MS and have stability data that verifies the materials' performance over time.

(2) You may not obtain blind specimens from the laboratory to which they are being sent, or knowingly, from any affiliate of that laboratory.

(d) You must make sure that each blind specimen is indistinguishable to the laboratory from a normal specimen.

(1) You must submit blind specimens to the laboratory through the same channels (*e.g.,* via a regular collection site) that employees' specimens are sent to the laboratory.

(2) You must make sure that the collector uses a CCF, placing fictional initials on the specimen bottle label/seal, indicating on Copy 4 that the specimen is a blind specimen, and discarding Copy 5.

(3) If you normally send split specimens to the laboratory, the blind specimens you send must be split specimens.

§ 40.105 What happens if there is a laboratory error on any test?

(a) If a laboratory error (either a false positive or false negative) occurs, the MRO or other party discovering the error must promptly notify ODAPC.

(b) When an error is brought to its attention, ODAPC will notify HHS. HHS will take any appropriate action under its Guidelines.

(c) If the error is determined to be the result of an administrative problem (*e.g.,* specimen mix-up, clerical mistake), the laboratory, at the direction of ODAPC and in consultation with HHS, must take corrective action. If there is reason to believe that the error could have been systematic, ODAPC may also require review and reanalysis of previous specimens.

(d) If the error is determined to be technical or methodological in origin, the laboratory, at the direction of ODAPC and in consultation with HHS, must submit all quality control and subject data from the batch of specimens that included the error.

(1) The laboratory, at the direction of ODAPC and in consultation with HHS, may be required to retest all specimens for the drug(s)/drug metabolite(s) involved in the error from the time the error is resolved back to the time of the last satisfactory performance test cycle.

(2) The individual responsible for day-to-day management of the laboratory's drug testing program must document this retesting through a signed statement.

(3) ODAPC may require an unannounced on-site review of the laboratory.

§ 40.107 Who may inspect laboratories?

As a laboratory, you must permit an inspection, with or without prior notice, by ODAPC or a DOT agency.

§ 40.109 What documentation must the laboratory keep, and for how long?

(a) As a laboratory, you must keep for at least one year all records pertaining to each DOT urine specimen for which you obtain a negative test result or did not test because of a fatal flaw or an uncorrected flaw.

(b) As a laboratory, you must keep for at least five years all records pertaining to each DOT urine specimen for which you obtain a positive test result, determine that the specimen is unsuitable, or determine that the specimen is substituted or adulterated.

(c) As a laboratory, you must keep for two years employer-specific data required in § 40.111.

(d) As a laboratory, you must keep for two years personnel files on individuals with access to specimens; quality assurance and quality control records; procedure manuals; performance records on performance testing; and results of certification inspections. You must maintain these longer if asked to do so in writing by a DOT agency.

(e) As a laboratory, you must keep documents for any specimen known to be under legal challenge for an indefinite period.

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary of the data listed in Appendix B of this part to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is reasonably likely that information about a employee's test

result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) When the condition in paragraph (a)(2) of this section exists, you must send the employer a report indicating that insufficient testing was conducted to warrant a summary.

(4) The summary must be sent by January 15 of each year for the last 6 months (*i.e.,* July 1 through December 31) of the prior year.

(5) The summary must be sent by June 15 of each year for the last 6 months (*i.e.,* January 1 through June 30) of the current year.

(b) You must also provide the summary when the employer needs it in response to an inspection, audit, or review by a DOT agency.

(c) You must also release information to appropriate parties as provided in §§ 40.331 and 40.333.

§ 40.113 Where is other information concerning laboratories found in this regulation?

You can find more information concerning laboratories in several sections of this part:

§ 40.3—definition.
§ 40.15—prohibition on making specimens available for other purposes.
§ 40.31—conflicts of interest concerning collectors.
§ 40.47—laboratory rejections of test for improper form.
§ 40.125—conflicts of interest concerning MROs.
§ 40.175—role of first laboratory in split specimen tests.
§ 40.177—role of second laboratory in split specimen tests.
§ 40.179—40.181—transmission of split specimen test results to MRO.
§ 40.199—40.203—role in correcting errors.
§ 40.331—provision of records to interested parties.
§ 40.333—limits on release of information.
§ 40.351—role with respect to other service agents.

Subpart G—Medical Review Officers (MROs)

§ 40.121 Who is qualified to act as an MRO?

You are qualified to act as an MRO in the DOT drug testing program only if you meet each of the following criteria:

(a) You are a licensed physician (Doctor of Medicine or Osteopathy).

(b) You have knowledge of and clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed positive drug tests.

(c) You have working knowledge of laboratory results relating to adulterated and substituted specimens as well as the possible medical causes of specimens being unsuitable for testing.

(d) You have a working knowledge of this part, the DOT MRO Guidelines, and the DOT agency regulation applicable to the employers for which you evaluate drug test results.

(e) You participate in and document training (*e.g.*, a course) at least once every two years that relates directly to the MRO responsibilities of the DOT program, or self-certify that you have re-reviewed and understand this part and the applicable DOT guidelines. You must retain these records for two years.

(f) If you were an MRO prior to the date these regulations are published, you must meet the requirements of paragraph (e) of this section by [date six months from the effective date of the final regulation]. If you become an MRO after [effective date of the final regulation], you must meet the requirements of paragraph (e) of this section prior to acting as an MRO.

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

As an MRO, you have the following basic responsibilities:

(a) You must act as an independent and impartial ''gatekeeper'' for the accuracy and integrity of the drug testing process.

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

(1) Ensuring the review of the CCF on all specimen collections for the purposes of determining whether there is a problem that may cause a test to be canceled (see §§ 40.197 and 40.201);

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

(3) Reporting to the ODAPC or a relevant DOT agency any program issue for which you need assistance in resolving.

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

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

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

(f) You must protect the confidentiality of the testing process.

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

§ 40.125 What relationship may an MRO have with a laboratory?

(a) As an MRO, you may not enter into any relationship with an employer's laboratory that creates a conflict of interest or the appearance of a conflict of interest with your responsibilities for that employer. You may not derive any financial benefit by having an employer use a specific laboratory.

(b) As an MRO, you must maintain a statement for review by a DOT agency. The statement will certify that you do not have any financial or potentially conflicting relationship with any laboratory. The statement will remain in effect until its conditions change, at which time you must amend the statement to reflect current status.

§ 40.127 What are the MRO's functions in reviewing negative test results?

As the MRO, you must do the following with respect to negative drug test results you receive from a laboratory, prior to verifying the result and releasing the result to the DER:

(a) Review Copy 4 of the CCF to determine if there are any errors in the chain of custody or elsewhere that may require you to cancel the test (see §§ 40.197, 40.199, and 40.201).

(1) Staff under your direct, personal supervision may conduct this administrative review for you (including the steps set forth in paragraphs (b) through (e) of this section), but only you can cancel a test.

(2) On specimen results that are reviewed by your staff, you are responsible for assuring the quality of their work.

(i) You are required to personally review at least 10 percent of the CCFs reviewed by your staff on a quarterly basis, and take corrective action as necessary to ensure compliance with this part.

(ii) You must attest to the quality assurance review by initialing the CCFs which you reviewed.

(iii) You must mark these CCFs to make them easily identifiable for review by DOT agencies.

(b) You may report a negative test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF, or you are in possession of the laboratory results report that conveys the negative laboratory test result. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature.

(c) If the copy of the documentation provided to you by the laboratory appears unclear or erroneous, you must request that the laboratory send you an original or certified true copy.

(d) On Copy 4 of the CCF, place a check mark in the ''Negative'' box in Step 8 and sign, initial, or stamp and date the verification statement.

(e) Report the result directly to the DER in a confidential manner.

§ 40.129 What are the MRO's functions in reviewing laboratory confirmed positive drug test results?

(a) As the MRO, you must do the following with respect to confirmed positive drug tests you receive from a laboratory, prior to verifying the result and releasing the result to the DER:

(1) Review the CCF to determine if there are any errors in the chain of custody or elsewhere that may require you to cancel the test (see §§ 40.197. 40.199, and 40.201). Staff under your direct, personal supervision may conduct this administrative review for you, but only you may cancel a test.

(2) If the copy of the documentation provided to you by the laboratory appears unclear or possibly erroneous, you must request that the laboratory send you an original or certified true copy.

(3) Except in the circumstances spelled out in § 40.133, conduct a verification interview. This interview must include direct contact in person or by telephone between you and the employee.

(4) Verify the test result as either positive or negative, or cancel the test, consistent with the requirements of §§ 40.135 through 40.139.

(5) Report verified positive drug test results directly to the DER in a confidential manner, consistent with the requirements of § 40.157.

(b) You may only report a positive test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature.

(c) Place a check mark in the ''Positive'' box in Step 8 on Copy 4 of the CCF, indicate the drug(s)/drug metabolite(s) detected on the ''Remarks'' line, sign and date the verification statement, and report the result directly to the DER.

Alternative 1 for Paragraph (d)

(d) As the MRO, you must never inform the employer that you have received an employee's laboratory confirmed positive test result. You are prohibited from reporting any information to the DER or other persons until you verify the test result. For example, as an MRO employed directly by a company, you must not tell anyone on the company's staff or management that you have received an employee's laboratory confirmed positive test result, and you must structure the way in which this information is received and stored to make sure that other personnel of the company do not have access to it.

Alternative 2 for Paragraph (d)

(d)(1) As the MRO, except as provided in paragraph (d)(2) of this section, you must never inform the employer that you have received an employee's laboratory confirmed positive test result. You are prohibited from reporting any information to the DER or other persons until you verify the test result. For example, as an MRO employed directly by a company, you must not tell anyone on the company's staff or management that you have received an employee's laboratory confirmed positive test result, and you must structure the way in which this information is received and stored to make sure that other personnel of the company do not have access to it.

(2) If an employer has a stand-down policy that meets the requirements of § 40.159(a), you may report to the DER that you have received an employee's laboratory confirmed positive laboratory test result.

§ 40.131 How is the employee notified of the verification process after a confirmed positive test result?

(a) When, as the MRO, you receive a confirmed positive test result from the laboratory, along with the appropriate collection documentation (see Appendix C of this part), you must contact the employee directly, on a confidential basis, and determine whether the employee wants to discuss the test result. In making this contact, you must explain to the employee that, if he or she declines to discuss the result, you will verify the test as positive.

(b) As the MRO, staff under your personal supervision may conduct this initial contact for you.

(1) This staff contact must be limited to explaining the consequences of the employee's declining to speak with you and scheduling the discussion between you and the employee.

(2) A staff person must not gather any medical information or information concerning possible explanations for the confirmed positive test result.

(3) A staff person may advise an employee to have medical information ready to present at the interview with the MRO.

(4) Since you are required to speak personally with the employee, your staff must not inquire if the employee wishes to speak with you.

(c) As the MRO, if you cannot reach the employee directly after making reasonable efforts (at a minimum, two attempts) to reach the employee at the day and/or evening telephone numbers listed on the CCF over a period of at least 24 hours, you must:

(1) Document the efforts you made to contact the employee, including dates and times.

(2) Contact the DER, instructing the DER to contact the employee.

(i) You must simply direct the DER to inform the employee to contact you.

(ii) You must not inform the DER that the employee has a confirmed positive test result.

(iii) You must document the dates and times of your attempts to contact the DER, and you must document the name of the DER you contacted and the date and time of the contact.

(d) As the DER, you must attempt to contact the employee immediately, using procedures that protect, as much as possible, the confidentiality of the MRO's request that the employee contact the MRO. If you contact the employee, you must document the date and time of the contact, and inform the MRO.

(1) As the DER, you must not inform anyone else working for the employer that you are seeking to contact the employee on behalf of the MRO.

(2) If, as the DER, you have made all reasonable efforts to contact the employee but failed to do so, you may place the employee on temporary medically unqualified status or medical leave.

(i) Reasonable efforts include, as a minimum, two attempts to reach the employee at the day and/or evening telephone numbers listed on the CCF over a period of 24 hours. As the DER, you must document the dates and times of these efforts.

(ii) If, as the DER, you are unable to contact the employee within this 24-hour period, you must leave a message for the employee by any practicable means (*e.g.*, voice mail, E-mail, letter) to contact the MRO and inform the MRO of the date and time of this attempted contact.

§ 40.133 Under what circumstances may the MRO verify a test as positive without interviewing the employee?

(a) As the MRO, you normally may verify a confirmed positive test result only after interviewing the employee as provided in §§ 40.135 through 40.143. However, there are three circumstances

in which you may verify a confirmed positive test result (regardless of which drugs are involved) without such an interview:

(1) You may verify a test result as positive if the employee expressly declines the opportunity to discuss the test with you. Complete documentation of this occurrence must be made, including notation of informing, or attempting to inform, the employee of the consequences of not exercising the option to speak with the MRO.

(2) You may verify a test result as positive if neither you nor the DER, after making all reasonable efforts, has been able to contact the employee within 14 days of the date on which the MRO receives the confirmed positive test result from the laboratory.

(3) You may verify a test result as positive if you or the DER has successfully made and documented a contact with the employee and instructed the employee to contact the MRO (see § 40.131(c) and (d)), and more than 72 hours have passed since the time DER contacted the employee.

(b) As the MRO, when you verify a test result as positive under this section, you must document the date, time and reason.

(c) As the MRO, if you verify a test result as positive under this section, you must allow the employee to present information to you documenting that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/or DER in the times provided.

(1) On the basis of such information, you may reopen the verification, allowing the employee to present information concerning a legitimate medical explanation for the confirmed positive test result.

(2) If you conclude that there is a legitimate medical explanation for the positive test result, you must change the verified result to negative, and report the change directly to the DER.

§ 40.135 What does the MRO tell the employee at the beginning of the verification interview?

As the MRO, you must provide the following information to the employee at the beginning of the verification interview:

(a) You must tell the employee that the laboratory has determined that the employee's test result was positive. You must also tell the employee of the drugs for which his or her specimen tested positive.

(b) You must explain the verification interview process to the employee, and that you will decide whether to verify the test result as positive based on information the employee provides in the interview.

(c) You must explain that, if further medical evaluation is needed for the verification process, the employee must comply with your request for this evaluation and that failure to do so is equivalent of expressly declining to discuss the drug test result.

(d) You must tell the employee that you are authorized to provide to the employer, DOT, or another Federal safety agency any positive test result or medical information he or she provides during the interview under the circumstances stated in § 40.327. This may include providing information to employers concerning medication or medical conditions that could adversely affect the employee's safety-sensitive duties.

§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, and PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/drug metabolite(s) in his or her system.

(b) You must offer the employee an opportunity to present a legitimate medical explanation in all cases.

(c) The employee has the burden of presenting evidence that a legitimate medical explanation exists. If you determine that there is such an explanation, you must verify the test result as negative. Otherwise, you must verify the test result as positive.

(d) In determining whether a legitimate medical explanation exists, you may consider the employee's use of a medication from a foreign country where it can be substantiated that the medication was legally obtained and used.

§ 40.139 On what basis does the MRO verify test results involving opiates?

As the MRO, you must proceed as follows when you receive laboratory confirmed positive opiate results:

(a) If the laboratory detects the presence of 6-acetylmorphine (6–AM) in the specimen, you must verify the test result positive.

(b) In the absence of the 6–AM, if the laboratory detects the presence of either morphine or codeine at 15,000 ng/mL or above, you must verify the test result positive unless the employee presents a legitimate medical explanation for the presence of the drug metabolite in his or her system, as in the case of other drugs (see § 40.137). Consumption of food products (*e.g.,* poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine at these levels.

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

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

(i) Recent needle tracks;

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

(iii) Clinical history of unauthorized use, such as an admission by the employee that an opiate drug was ingested without legal authorization; or

(iv) Use of a medication from a foreign country where it cannot be substantiated that the medication was legally obtained and legally used.

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

(i) Therefore, you, as the MRO, must conduct, or cause to be conducted, a face-to-face interview with the employee.

(ii) No face-to-face interview is needed in establishing the clinical evidence referenced in paragraphs (c)(1)(iii) and (iv) of this section.

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

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

§ 40.141 How does the MRO obtain information for the verification decision?

As an MRO, you must do the following as you make the determinations needed for verification decision.

(a) You must conduct a medical interview. You may review the employee's medical history and any other relevant biomedical factors. You may direct the employee to undergo further medical evaluation by you or another physician.

(b) When the employee asserts that the presence of a drug(s)/drug metabolite(s) in his or her system results from taking prescription medication, you must review all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information.

(c) Before completing the verification process, and at your sole discretion, you may direct the laboratory to conduct a reanalysis of the primary specimen. (You may do so regardless of whether a single specimen or split specimen collection is involved.) You may choose the laboratory that tested the primary specimen or another HHS-certified laboratory for this reanalysis. The purpose of this reanalysis is to gather further information concerning any questions you have about the technical or scientific validity of the laboratory's test.

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

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

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

(b) In reviewing the CCF, you must not consider evidence inessential to the documents in determining whether the test is valid. For example, you must review only what is on the face of the CCF for this purpose, not assertions by the employee that the CCF does not accurately reflect what happened at the collection site.

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

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

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

(f) You must never accept an assertion of consumption or other use of a hemp or other marijuana-related product as a basis for verifying a marijuana test negative. Consuming or using such a product is not a legitimate medical explanation.

§ 40.145 How does the MRO notify employees of their right to a test of the split specimen or to a retest of a single specimen?

(a) You must notify the employee of procedures for requesting a retest of the specimen (single specimen collections) or a test of the split specimen (split specimen collections). The purpose of these tests is to determine whether drug(s)/drug metabolite(s) are present in the specimen tested.

(b) You must inform the employee that he or she has 72 hours to make a timely request for the additional test.

(c) You must tell the employee how to contact you in order to make a timely request. You must provide telephone numbers or other information that will allow the employee to make this request. As the MRO, you must have the ability to receive the employee's calls at all times during the 72 hour period (*e.g.,* by use of an answering machine with a time stamp feature when there is no one in your office to answer the phone).

(d) You must tell the employee that if he or she requests the additional test in a timely manner, the employer must ensure that the test takes place, and that the employee is not required to pay for the test from his or her own funds before the test takes place. You must also tell the employee that the employer may seek reimbursement for the cost of the test (see § 40.173).

(e) You must tell the employee that, when the test resulted from a split specimen collection, a retest of the primary specimen is not authorized.

(f) You must tell the employee that additional tests of the specimen (*e.g.,* DNA tests) are not authorized.

§ 40.147 What happens when a negative or positive test result is also dilute?

(a) As the MRO, when the laboratory reports that the specimen was dilute, you must report directly to the DER that, in addition to the specimen being negative or positive, the specimen was dilute and that the next time the employee is selected for a drug test the employer may require the specimen to be collected under direct observation.

(b) You must note that the specimen is dilute on the ''Remarks'' line in Step 8 on Copy 4 of the CCF.

(c) You may only report a dilute test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature.

§ 40.149 What happens when a test is not performed because of a fatal or uncorrected flaw?

(a) As the MRO, when the laboratory reports that a specimen test must be canceled because of a fatal or uncorrected flaw, you must place check marks in the ''Test Not Performed'' and ''Test Canceled'' boxes in Step 8 Copy 4 of the CCF and enter, ''Fatal Flaw, _____'' (with the flaw stated) or ''Uncorrected Flaw, _____'' (with the flaw stated), as appropriate, on the ''Remarks'' line.

(b) Report directly to the DER that the test is canceled, the reason for cancellation, and that no further action is required unless a negative test result is required (*e.g.,* pre-employment, return-to-duty, follow-up).

(c) You may only report a fatal or uncorrected flaw test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature.

§ 40.151 What happens when a drug test specimen is unsuitable for testing?

(a) As the MRO, when the laboratory reports that the test result is ''Test Not Performed—Specimen Unsuitable: Cannot obtain valid drug test result,'' you must do the following:

(1) Discuss the laboratory results with the certifying scientist to obtain more specific information.

(2) Contact the employee and inform the employee that the specimen was not suitable for testing or contained an unexplained interferant.

(3) After explaining the limits of disclosure (see § 40.327), you should inquire as to medications the employee may have taken that may interfere with some immunoassay tests.

(4) If the employee gives an explanation that is acceptable, you must:

(i) Place check marks in the ''Test Not Performed'' and ''Test Canceled'' boxes in Step 8 on Copy 4 of the CCF and enter ''Specimen Unsuitable: Cannot obtain valid drug test result'' on the ''Remarks'' line.

(ii) Report directly to the DER that the test is canceled, the reason for cancellation, and that no further action is required unless a negative test result is required (*e.g.,* pre-employment, return-to-duty, follow-up).

(5) If the employee is unable to provide an explanation and/or a valid prescription for a medication that interfered with the immunoassay test but denies having adulterated the specimen, you must:

(i) Place check marks in the ''Test Not Performed'' and ''Test Canceled'' boxes in Step 8 on Copy 4 of the CCF and enter ''Specimen Unsuitable: Cannot obtain valid drug test result'' on the ''Remarks'' line.

(ii) Report directly to the DER that the test is canceled, the reason for cancellation, and that a second collection must take place immediately under direct observation.

(b) You may only report an unsuitable for testing test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature.

(c) If the employee admits to having adulterated the specimen, you must follow procedures outlined in § 40.153.

§ 40.153 What happens when a drug test specimen is adulterated or substituted?

(a) As the MRO, when the laboratory reports that the test result is ''Test Not Performed—Specimen Adulterated/Substituted,'' you must do the following:

(1) Check the ''Test Not Performed'' box in Step 8 on Copy 4 of the CCF and enter ''Adulterated,'' or ''Substituted,'' and ''Refusal to test'' on the ''Remarks'' line.

(2) Report directly to the DER that the specimen was adulterated or substituted, either of which constitutes a refusal to test.

(3) Also, inform the DER that the employee has no right to have the split specimen tested (or to have a retest of a single specimen). You must not authorize a test of a split specimen or a retest of the primary specimen following an adulterated or substituted test result. The laboratory has already tested two aliquots of the primary specimen to confirm the accuracy of their result.

(b) You may only report an adulterated or substituted testing test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature.

§ 40.155 What happens when a drug test specimen is rejected for testing?

(a) As the MRO, when the laboratory reports that the test result is ''Test Not Performed—Specimen Rejected for Testing,'' you must do the following:

(1) Rule out collector error as the reason the specimen was rejected for testing. You may consult with the laboratory and must consult with the collection site in making this determination.

(2) If the rejection is a result of collector error, you must:

(i) Place check marks in the ''Test Not Performed'' and ''Test Canceled'' boxes in Step 8 on Copy 4 of the CCF and enter ''Specimen Rejected for Testing: Collection Error_____'' (with reason stated) on the ''Remarks'' line.

(ii) Report directly to the DER that the test is canceled, the reason for the cancellation, and that a second collection must take place immediately. This collection is not to be conducted under direct observation.

(3) If you determine that the rejection is not a result of collector error, you must:

(i) Place check marks in the ''Test Not Performed'' and ''Test Canceled'' boxes in Step 8 on Copy 4 of the CCF and enter ''Specimen Rejected for Testing: _____'' (with reason stated) on the ''Remarks'' line.

(ii) Report directly to the DER that the test is canceled, the reason for cancellation, and that a second collection must take place immediately under direct observation.

(b) You may only report a specimen rejected for testing test result when you are in possession of a copy of Copy 2 or the original Copy 2 of the CCF. In addition, you must have a copy of Copy 4 or the original Copy 4 of the CCF, or any copy of the CCF containing the employee's signature.

§ 40.157 How does the MRO report test results to the employer?

As the MRO, you must report all drug test results (*e.g.,* positive, negative, test not performed, canceled) directly to the DER in a confidential manner.

(a) You must make the reports and other communications concerning test results directly to the DER.

(b) You must as expeditiously as possible, the same day preferably, report directly to the DER verified positive test results, results requiring an immediate collection under direct observation, and adulterated or substituted specimen results.

(1) Direct telephone contact with the DER is the preferred method of immediate reporting.

(2) You are responsible for identifying yourself to the DER, and the DER must have a means to confirm your identification.

(3) Your report shall contain all of the information in paragraph (c) of this section.

(c) In all cases, verified test results must be provided directly to the DER in writing. The report must include the following information:

(1) A statement that the test was conducted in accordance with this part;

(2) The full name, as indicated on the CCF, of the employee tested;

(3) The type of test as indicated on the CCF (*e.g.,* random, post-accident);

(4) The date and location of the collection;

(5) The identities of the persons or entities performing the collection, analyzing the specimen, and serving as the MRO for the test;

(6) The result of the test (*e.g.,* positive, negative, test not performed, and canceled) and the date the result was verified; and (7) For verified positive tests, the substance for which the test was positive.

(d) Within three days of your verification of the result, you must provide the DER the signed, written report of the verified test result.

(1) For any result (positive, negative, test not performed, or canceled), you may use Copy 4 of the CCF or a legible photocopy of it. If you provide a written report to the employer using any means other than Copy 4, you must retain a signed (for positive, test not performed, or canceled tests) or stamped (for a negative test) Copy 4 in your records.

(2) For a negative test, if you do not use Copy 4 of the CCF or a legible photocopy of it, you may use such means as a letter listing negative results for a group of specimens, each identified by its specimen ID number, or an individual letter providing each test result.

(3) You must not use Copy 1 or Copy 2 to report negative drug test results. Your signature must be on the report; you may sign or rubber-stamp the report of the result (or a staff member can rubber-stamp it for you with your written authorization). You may not use electronic signatures for this purpose.

(4) For a positive test, you must make sure that your signature and the substance(s) for which the test was positive are legibly noted in Step 8 of the CCF. You must sign the report; rubber stamps are not acceptable. You may not use electronic signatures for this purpose.

(5) For a test not performed or for a canceled test, you must make sure that your signature and the required explanation(s) for the result are legibly noted in Step 8 of the CCF. You must sign the report; rubber stamps are not acceptable. You may not use electronic signatures for this purpose.

§ 40.159 When MROs send reports of positive, dilute, unsuitable, substituted, or adulterated test results to employers, what is an employer to do?

Alternative 1 for Paragraph (a)

(a) As an employer, you must never take any personnel or disciplinary action, permanent or temporary, related to a DOT drug test (including removing the employee from safety-sensitive functions) before receiving a verified positive test result from the MRO. Specifically, you are prohibited from standing-down an employee on the basis of information or belief that the employee has a laboratory confirmed positive drug test result. You may, however, temporarily medically disqualify an employee in the circumstances spelled out in § 40.131(d)(2).

Alternative 2 for Paragraph (a)

(a) As an employer, you must never take any permanent personnel or disciplinary action, related to a DOT drug test, before receiving a verified positive drug test result from the MRO.

(1) However, you may stand-down an employee (*i.e.,* temporarily remove the employee from the performance of safety-sensitive functions) after your DER is informed by the MRO that the individual has a laboratory confirmed positive drug test result, pending the completion of the MRO's verification process.

(2) If you choose to stand-down an employee, you must ensure that information about the laboratory confirmed positive test result or the reason for the employee's temporary removal from performance of safety-sensitive functions is not made available by the MRO or DER to any other employees of your organization or other persons.

(3) If the MRO reports to you that the test has been verified negative or has been canceled, you must immediately return the employee to the performance of safety-sensitive duties, without any adverse consequences to the employee and with no notation of the stand-down or the laboratory confirmed positive test result retained in any records pertaining to the employee. You may also temporarily medically disqualify an employee in the circumstances referenced in § 40.131(d)(2).

(b) As an employer who receives a verified positive test result from the MRO, you must immediately remove the employee involved from performing safety sensitive functions. You must take this action upon receiving the initial report from the MRO. Do not wait to receive the written report or the result of a split specimen test.

(c) As an employer who receives a test result from the MRO indicating that the employee's specimen was adulterated or substituted, you must consider this a refusal to test and immediately remove the employee involved from performing safety sensitive functions. You must take this action on receiving the initial report from the MRO. Do not wait to receive the written report.

(d) As an employer who receives a test result from the MRO indicating that the employee's specimen was dilute, the next time the employee is selected for a drug testing, you may require the specimen to be collected under direct observation.

(e) As an employer who receives a test result from the MRO indicating that the employee's specimen was unsuitable for testing or rejected for testing and that a second collection must take place under direct observation—

(1) You must immediately direct the employee to provide a new specimen under direct observation.

(2) You must not attach consequences to the finding of unsuitability other than collecting a new specimen under direct observation.

(3) You must not give any advance notice of this test requirement to the employee and can only notify the employee immediately before the collection.

(4) You must instruct the collector to note on the CCF the same reason (*e.g.* random test, post-accident test) as for the original collection.

(f) As an employer who receives a canceled test result when a negative result is required (*e.g.,* pre-employment, return-to-duty, or follow-up test), you must direct the employee to provide another specimen.

(g) As an employer, you may also be required to take additional actions required by DOT agency regulations (*e.g.,* FAA requires some positive drug tests to be reported to the Federal Air Surgeon).

§ 40.161 May the employer or MRO change a verified drug test result?

(a) As the employer, you must not change a test result that you have received from the MRO.

(b) As the MRO, you may change a verified drug test result only in the following situations:

(1) When you have reopened a verification that was done without an interview with an employee, as in § 40.133(c).

(2) If you receive information, not available to you at the time of the original verification, demonstrating that the laboratory made an error in identifying (*e.g.,* a paperwork mistake) or testing (*e.g.,* a false positive or negative) the employee's primary or split specimen. For example, suppose the laboratory originally reported a positive test result for Employee X and a negative result for Employee Y. You verified the test results as reported to you. Then the laboratory notifies you that it mixed up the two test results, and X was really negative and Y was really positive. You would change X's test result from positive to negative and contact Y to conduct a verification interview.

(3) If you receive, within 60 days of the original verification decision, information that could not reasonably have been provided to you at the time of the decision demonstrating that there is a legitimate medical explanation for the presence of drug(s)/ drug metabolite(s) in the employee's specimen. For example, if the employee's physician provides you a valid prescription that he or she failed to find at the time of the original verification, you may change the test result from positive to negative if you conclude that the prescription provides a legitimate medical explanation for the drug(s)/drug metabolite(s) in the employee's specimen. If you receive the information after the 60 day period, you must consult with ODAPC prior to changing the result.

(4) When you have made an administrative error and reported an incorrect result.

(c) As the MRO, in any case where you change a result, you must notify the DER of the changed result as provided in § 40.157.

§ 40.163 Where is other information concerning the role of MROs found in this regulation?

You can find more information concerning the role of MROs in several sections of this part:

§ 40.3—definition.
§ 40.67—role in direct observation and other atypical test situations.
§ 40.83—corrective actions in atypical test situations.
§ 40.95—receipt of laboratory reports.
§ 40.99—authorization of longer laboratory retention of specimens.
§ 40.101—relationship with laboratories; avoidance of conflicts of interest.
§ 40.107—notification of laboratory errors.
§ 40.171—request for test of split specimen.
§ 40.183—action concerning split specimen test results.
§ 40.191—role in ''shy bladder'' situations.
§ 40.193—role in canceling tests.
§§ 40.199–40.203—documenting errors in tests.
§ 40.325—transfer of records.
§ 40.327—confidentiality and release of information.
§ 40.329—providing information to other employers.
§ 40.351—relationships with service agents.

Subpart H—Split Specimen Tests And Retests

§ 40.171 How does an employee request a test of a split specimen?

(a) As an employee, when the MRO has notified you that you have a verified positive test, you have 72 hours from the time of notification to request a test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen.

(b)(1) If, as an employee, you have not requested a test of the split specimen within 72 hours, you may present to the MRO information documenting that serious injury, illness, lack of actual notice of the verified positive test, inability to contact the MRO (e.g., there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented you from making a timely request.

(2) As the MRO, when you conclude from the employee's information that there was a legitimate reason for the employee's failure to contact you within 72 hours, you must direct that the test of the split take place, just as you would when there is a timely request.

(c) As an employer, you may authorize the MRO to act on a request for the test of a split specimen that an employee makes later than 72 hours from the time of notification.

(d) When the employee makes a valid request for a test of the split specimen under paragraphs (a) through (c) of this section, as the MRO, you must immediately provide written notice to the laboratory that tested the primary specimen, directing the laboratory to forward the split specimen to a second HHS-certified laboratory and identifying the drug(s)/drug metabolite(s) to be tested for. You must also document the date and time of the employee's request.

§ 40.173 Who is responsible for paying for the test of a split specimen?

(a) As the employer, you are responsible for making sure that the MRO, first laboratory, and second laboratory perform the functions noted in §§ 40.175 and 40.177 in a timely manner, once the employee has made a timely request for a test of the split specimen.

(b) As the employer, you must not condition your compliance with these requirements on the employee's direct payment to the MRO or laboratory or the employee's agreement to reimburse you for the costs of testing. For example, if you ask the employee to pay for some or all of the cost of testing the split specimen, and the employee is unwilling or unable to do so, you must make sure that the test takes place in a timely manner, even though this means that you pay for it.

(c) As the employer, you may seek payment or reimbursement of all or part of the cost of the split specimen by the employee. This regulation takes no position on who ultimately pays the cost of the test, so long as the employer ensures that the testing is conducted as required.

§ 40.175 What steps does the first laboratory take with a split specimen?

(a) As the laboratory at which the primary and split specimen first arrive, you must check to see whether the split specimen as well as the primary specimen is available for testing.

(b) If the split specimen is unavailable or appears insufficient, you must still test the primary specimen. You must then do the following:

(1) Report the results for the primary specimen without providing the MRO information regarding the unavailable split specimen.

(2) Upon receiving a letter from the MRO instructing you to forward the split specimen to another laboratory for testing, report to the MRO that the split specimen is unavailable for testing, and provide as much information as you can as to the cause of the unavailability.

(c) If the split specimen is available and appears sufficient, you must keep it in secure, short-term refrigerated storage (with temperatures not to exceed 6 °C) until you have completed the test of the primary specimen.

(1) If the test of the primary specimen is negative, you may discard the primary and split specimens.

(2) If the test of the primary specimen is a confirmed positive, or is adulterated or substituted, you must retain the primary and split specimens for one year unless you are requested to keep it longer.

(d) As the laboratory that tested the primary specimen, you are not authorized to open the split specimen under any circumstances.

(e) When you receive written notice from the MRO that the employee has made a valid request (i.e., for a verified positive test result, not an adulterated or substituted test result) for a test of the split specimen, you must forward the following things to a second laboratory.

(1) The split specimen in its original specimen bottle, with the seal intact.

(2) A copy of the MRO's written request, which identifies the drug(s)/drug metabolite(s) to be tested for.

(3) The split specimen copy of the CCF with appropriate chain of custody entries.

(4) Your external chain of custody for specimen transfer.

(f) You must not send to the second laboratory any information about the identity of the employee. Inadvertent disclosure does not cause a fatal flaw.

(g) This subpart does not prescribe who gets to decide which laboratory is used to test the split specimen. That decision is left to the parties involved.

§ 40.177 What does the second laboratory do with the split specimen?

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) detected in the primary specimen.

(b) You must conduct this test, using GC/MS, at the level of detection without regard to the cutoff concentrations of § 40.89.

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that was reported positive in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/drug metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.91.

(d) If unable to conduct the validity tests, you must send the split specimen and Copy 3 of the CCF using chain of custody procedures to a third laboratory that has the capability to conduct the validity tests. If the validity tests conducted by the third laboratory do not determine the reason for being unable to reconfirm the presence of the drug(s)/drug metabolite(s) in the split specimen, the third laboratory must test the split specimen for the drug(s)/drug metabolite(s) found in the primary specimen by the first laboratory.

(e) You must not conduct tests of the split specimen for any purposes (*e.g.* for adulterants found in the primacy specimen) other than reconfirming the presence of the drug(s)/drug metabolite(s) detected in the primary specimen or conducting the validity tests in paragraphs (c) and (d) this section.

§ 40.179 Through what methods and to whom must a laboratory transmit split specimen results?

(a) As the laboratory testing the split specimen, you must transmit laboratory results directly, and only, to the MRO at his or her place of business (not to the MRO through a consortium or third-party administrator). You must not transmit results to or through the DER or another service agent (*e.g.,* consortia, third-party administrators).

(b) You must fax, courier, or mail a copy of the original and fully-completed Copy 3 of the CCF, which has been signed by the individual responsible for day-to-day management of your laboratory or the individual responsible for attesting to the validity of split specimen test results.

(c) You must transmit the laboratory result so that it reaches the MRO within 24 hours from the time of the split specimen test result.

§ 40.181 What information do laboratories need to report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results as either Reconfirmed [notating the specific drug in the appropriate drug(s)/drug metabolite(s) box(es)], Failed to Reconfirm, or Test Not Performed in Step 7 on Copy 3 of the CCF.

(b) Additionally, you must include an appropriate comment on the ''Remarks'' line if you find that the specimen is adulterated or substituted, or if the drug test was not performed.

(c) You must check the ''Failed to Reconfirm'' box in Step 7 on Copy 3 of the CCF if the drug(s)/drug metabolite(s) is not detected, the specimen is adulterated, or the specimen is substituted.

(d) If you check the ''Failed to Reconfirm'' box, one of the following statements must be included (as appropriate) on the ''Remarks'' line:

(1) ''Drug/Drug Metabolite Not Detected''.

(2) ''Specimen Adulterated: Nitrite is too high''.

(3) ''Specimen Adulterated: pH is too high (or too low)''.

(4) ''Specimen Adulterated: Presence of _____ (specify) Detected''.

(5) ''Specimen Substituted: Not consistent with normal human urine''.

(e) You must check the ''Test Not Performed'' box in Step 7 on Copy 3 of the CCF if the specimen is not tested or if the testing could not be completed successfully.

(f) If you check the ''Test Not Performed'' box one of the following statements must be included (as appropriate) on the ''Remarks'' line:

(1) ''Fatal Flaw, _____ (with the flaw stated)''.

(2) ''Uncorrected flaw, _____ (with the flaw stated)''.

(3) ''Specimen Unsuitable: Cannot obtain valid confirmatory test result''.

(4) ''Specimen Unsuitable: Insufficient specimen volume to complete testing''.

§ 40.183 What does the MRO do with the split specimen laboratory results?

As an MRO, you must take the following actions when a laboratory reports:

(a) *Reconfirmed.* (1) Check the ''Reconfirmed'' box in Step 8 on Copy 3 of the CCF.

(2) Indicate the specific drug/drug metabolite detected on the ''Remarks'' line.

(3) Report the reconfirmation directly to the DER and the employee.

(b) *Failed to Reconfirm: Drug/Drug Metabolite Not Detected.* (1) Check the ''Failed to reconfirm: Both tests canceled'' box in Step 8 on Copy 3 of the CCF.

(2) Report directly to the DER and the employee that both tests must be canceled.

(3) Using a format that includes the items in Appendix E, inform ODAPC of the failure to reconfirm.

(c) *Failed to Reconfirm: Specimen Adulterated/Substituted.* (1) Check the ''Failed to Reconfirm'' box.

(2) Line through the accompanying phrase, ''Both tests canceled.''

(3) Enter (as appropriate) ''Adulterated'' or ''Substituted,'' and ''Refusal to test'' on the ''Remarks'' line in Step 8 on Copy 3 of the CCF.

(4) Report directly to the DER and the employee that the specimen was adulterated or substituted, either of which constitutes a refusal to test. Therefore, ''refusal to test'' becomes the final, single result for both tests.

(d) *Test Not Performed.* (1) Check the ''Test not performed: Both tests canceled'' box in Step 8 on Copy 3 of the CCF.

(2) Provide the reason for the test not being performed on the ''Remarks'' line.

(3) Report directly to the DER and the employee that both tests must be canceled and the reason for cancellation.

(4) Order an immediate collection of another specimen from the employee under direct observation and inform the DER that no advance notice should be given to the employee of this collection requirement, until immediately before the collection.

(5) Using a format that includes the items in Appendix E of this part, inform ODAPC of the failure to reconfirm.

§ 40.185 Are employees' requests for reanalysis of the specimen from a single specimen collection handled the same way as requests for the test of the split specimen?

(a) Yes. When an employee makes a request for a reanalysis of the specimen from a single specimen collection, all the provisions of this subpart apply just as they do in the case of the request for a test of a split specimen.

(b) Such reanalysis may be conducted in the same laboratory that originally tested the specimen, or may be conducted in another HHS laboratory.

§ 40.187 Where is other information concerning split specimens found in this regulation?

You can find more information concerning split specimens in several sections of this part:

§ 40.3—definition.
§§ 40.63–40.65—quantity of split specimen.
§ 40.67—directly observed test when split specimen is unavailable.
§§ 40.73–40.75—collection process for split specimens.
§ 40.83—laboratory accessioning of split specimens.
§ 40.95—laboratory reports of unavailability.
§ 40.99—laboratory retention of split specimens.
§ 40.103—blind split specimens.
§ 40.145—MRO notice to employees on tests of split specimen.
§ 40.153—use for other purposes prohibited.
§ 40.157—employer actions.
§§ 40.193–40.205—MRO actions on insufficient or unavailable split specimens.
§ 40.329—MRO provision of information to other employers.

Subpart I—Problems in Drug Tests

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

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

(1) Fail to show up for any test within a reasonable time after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a third-party administrator or consortium. (see § 40.61(a));

(2) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations;

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

(4) Fail to provide a sufficient amount of urine when directed, unless the physician has determined, through a required medical evaluation, that there was an adequate medical explanation for the failure (see § 40.193(d)(2));

(5) Fail to drink fluids as directed by the collector following a failure to provide a sufficient amount of urine (see § 40.193(b)(2));

(6) Fail to undergo an additional medical examination, as directed by the MRO as part of the verification process, or as directed by the physician conducting the evaluation as part of the ''shy bladder'' procedures of this part; or

(7) Fail to cooperate (*e.g.,* leave the test site before the collection process is completed, refuse to empty pockets or boots) with any part of the testing process.

(b) As an employee, you are also considered to have refused to take a drug test if your specimen is found to have been adulterated or substituted.

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

(d) As a collector or an MRO, or as the physician evaluating a ''shy bladder'' condition, when an employee refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the CCF (or in a separate document which you cause to be attached to the form), and notify the DER.

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

§ 40.193 What happens when an employee is unable to provide a sufficient amount of urine for a drug test?

(a) If an employee is unable to provide a sufficient amount of urine to permit a valid drug test (*i.e.,* 30 mL of urine for a single specimen collection or 45 mL of urine for a split specimen collection), the following steps must be taken.

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

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

(2) Direct the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a new sufficient amount of urine, whichever occurs first.

(3) If the employee refuses to drink fluids as directed or to provide a new urine specimen, you must discontinue the collection, note the fact in the ''Remarks'' section of the CCF, and immediately notify the DER. This is a refusal to test.

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

(c) As the DER when the collector informs you that the employee has not provided a sufficient amount of urine (see paragraph (b)(4) of this section), you must direct the employee to obtain, within five working days, an evaluation from a licensed physician who is acceptable to the employer concerning the employee's medical ability to provide a sufficient amount of urine. This physician may, but need not, be the MRO. DOT agency regulations may specify a different time period within which this evaluation must take place.

(d) As the examining physician, you must make one of the following determinations, in your reasonable medical judgment:

(1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. In this case, the test is canceled.

(2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. This is a refusal to test.

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

(f) As the examining physician, after making your determination, you must provide a written statement of your conclusions to the MRO. You must not include in this statement detailed information on the employee's medical condition.

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

(h) As the MRO, you must report the examining physician's determination directly to the DER in writing as soon as you receive it.

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

§ 40.195 What happens when an individual is unable to provide a sufficient amount of urine for a pre-employment drug test because of a permanent or long-term disability?

(a) When it is determined, through the required medical evaluation outlined in § 40.193(d) that an individual has a medical condition that precluded him or her from providing the requisite amount of urine during a pre-employment test event and that the condition is documented as being permanent or long-term, as an MRO:

(1) You must determine if there is clinical evidence that would indicate the individual is an illicit drug user. You will accomplish this by personally conducting a medical examination and through consultation with the employee's physician and/or the physician who conducted the § 40.193(d) medical evaluation.

(2) If unable to personally conduct the medical examination, you must ensure that one is conducted by a licensed physician. This physician must be suitable to the employer.

(b) For purposes of this section, DOT will offer no objection if the MRO or examining physician believes a blood test to be one of the medically-appropriate procedures in determining clinical evidence of drug use.

(c) If the medical examination reveals no clinical evidence of drug use, as the MRO, you will report the result to the employer as a negative test with written notations regarding results of both the § 40.193(d) evaluation and the medical examination—one determining that a permanent or long-term medical condition exists making requisite urination impossible, the other determining that no signs and symptoms of drug use exist.

(d) If the medical examination reveals clinical evidence of drug use, as the MRO, you will report the result to the employer as a canceled test with written notations regarding results of both the § 40.193(d) evaluation and the medical examination—one determining that a permanent or long-term medical condition exists making requisite urination impossible, the other determining that signs and symptoms of drug use exist.

(e) For purposes of this section, permanent or long-term medical conditions are those physiologic, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever.

(1) Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; a severe psychiatric disorder focused on genito-urinary matters.

(2) Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in paragraph (e)(1) of this section.

§ 40.197 What problems will always result in a drug test being canceled?

As the MRO, you must cancel a drug test if any of the following problems occur. These are ''fatal flaws.'' You must inform the DER that the test was canceled and must be treated as if the test never occurred. These problems are:

(a) The specimen ID numbers on the specimen bottle and the CCF do not match;

(b) There is no specimen ID number on the specimen bottle;

(c) The specimen bottle seal is broken or shows evidence of tampering (unless a split specimen can be redesignated, see § 40.83(f)); or

(d) Because of leakage or other causes, there is insufficient amount of urine in the primary or single specimen bottle for analysis and any necessary reanalysis for quality control and, in the case of a single specimen, reconfirmation of results.

§ 40.199 What problems will always result in a drug test being canceled and may result in a requirement for another collection?

As the MRO, you must cancel a drug test if any of the following problems occur. You must inform the DER that the test was canceled and must be treated as if the test never occurred. You must also direct the DER to ensure that an additional collection occurs, when required by the appropriate procedures specified in paragraphs (a) through (d) of this section.

(a) The laboratory reports result test as ''Test Not Performed: Specimen Unsuitable.'' You must follow appropriate procedures outlined at § 40.151.

(b) The laboratory reports the result as ''Test Not Performed: Specimen Rejected for Testing.'' You must follow appropriate procedures outlined at § 40.155.

(c) The laboratory's test of the primary specimen is positive and the split specimen is reported by the laboratory as either ''Failure to Reconfirm: Drug/Drug Metabolite Not Detected'' or ''Test Not Performed.'' You must follow appropriate procedures outlined at § 40.183(b) and (d).

(d) The examining physician has determined that there is an acceptable medical explanation of the employee's failure to provide a sufficient amount of urine (see § 40.193(d)(1)).

§ 40.201 What problems will result in the drug test being canceled unless they are corrected?

As an MRO, you must cancel a drug test if any of the following problems occur, unless they are corrected. These are ''correctable flaws.'' If the problems are not corrected, you must inform the DER that the test was canceled and must be treated as if the test never occurred.

(a) The collector's signature is omitted on the certification statement on the CCF (see § 40.75(a)(2)).

(b) The chain of custody block on the CCF is incomplete. (To be complete, the block must include, as a minimum, two signed entries by the collector, both dated, and a shipping/storage entry (see § 40.75(a)(3)and (4)).

(c) The employee's signature is omitted from the certification statement, unless the employee's refusal to sign is noted in the ''Remarks'' section of the CCF (see § 40.75(a)(1)).

(d) The employee's social security number or ID number is omitted from the CCF, or is incorrect, unless the employee's refusal to provide the information is noted in the ''Remarks'' section of the CCF.

(e) The certifying scientist's signature is omitted on the laboratory copy of the CCF for a positive test result.

(f) The collector uses a non-DOT form for the test, provided that the testing process is conducted in a HHS-certified laboratory in accordance with DOT screening and confirmation test criteria (see §§ 40.45 and 40.47).

§ 40.203 How are drug test problems corrected?

(a) As a collector, you have the responsibility of trying to successfully complete a collection procedure for each employee.

(1) If, during or shortly after the collection process, you become aware of any event that prevents the completion of a valid test or collection (*e.g.,* a procedural or paperwork error), you must try to correct the problem promptly, if doing so is practicable. You may conduct another collection as part of this effort.

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

(b) If, as a collector, laboratory, MRO, employer, or other person implementing these drug testing regulations, you become aware of a problem that may be corrected (see § 40.201), but which has not already been corrected under paragraph (a) of this section, you must take all practicable action to correct the problem so that the test is not canceled.

(1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply, in writing, the missing information and a statement that it is true and accurate. For example, suppose you are a collector, and you forgot to make a notation in the ''Remarks'' section of the CCF that the employee refused to sign the certification. You would, when the problem is called to your attention, supply a written statement that the employee refused to sign the certification, and you would certify, in writing, that your statement is true and accurate.

(2) If the problem is the use of a non-DOT form, you must, as the person responsible for the use of the incorrect form, certify in writing that the incorrect form contains all the information needed for a valid DOT test and does not contain information prohibited in DOT tests. You must also provide a written statement that the incorrect form was used inadvertently or out of

necessity, as the only means of conducting a test, in circumstances beyond your control and the steps you have taken to prevent future use of non-DOT forms for DOT tests. For this flaw to have been corrected, the test of the specimen must have occurred at a HHS-certified laboratory where it was tested using the testing protocol in this part.

(3) The written documentation of a correction must be maintained with the CCF.

§ 40.205 What is the effect of a canceled drug test?

(a) A canceled drug test is neither positive nor negative.

(1) As an employer, you must not attach to a canceled test the consequences of a positive test (*e.g.,* removal from a safety-sensitive position).

(2) As an employer, you must not use a canceled test for the purposes of a negative test (*e.g.,* in the case of a pre-employment, a return-to-duty, or a follow-up test, to authorize the employee to perform safety-sensitive functions).

(b) A canceled test does not count toward compliance with DOT requirements, such as a minimum random testing rate.

§ 40.207 What is the effect of procedural problems that are not sufficient to cancel a drug test?

(a) As a collector, laboratory, MRO, employer or other person administering the drug testing process, you must document any errors in the testing process of which you become aware, even if they are not considered problems that will cause a test to be canceled as listed in this subpart. Decisions about the ultimate impact of these errors will be determined by other administrative or legal proceedings, subject to the limitation of paragraph (b) of this section.

(b) No person concerned with the testing process may declare a test canceled 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. For example, it is inconsistent with these regulations to cancel a test based on a minor administrative mistake (*e.g.,* the omission of the employee's middle initial) or an error that does not affect employee protections under this part (*e.g.,* the collector's failure to add bluing agent to the toilet bowl, which adversely affects only the ability of the collector to detect tampering with the specimen by the employee).

(c) As an employer, these errors, even though not sufficient to cancel a drug test result, may subject you to enforcement action under DOT agency regulations.

Subpart J—Alcohol Testing Personnel

§ 40.211 Who conducts DOT alcohol tests?

(a) Screening test technicians (STTs) and breath alcohol technicians (BATs) meeting their respective requirements of this subpart are the only people authorized to conduct DOT alcohol tests.

(b) An STT or a BAT must be trained to proficiency in correctly carrying out the alcohol testing requirements of this part.

(c) An STT can only conduct alcohol screening tests, but a BAT can conduct alcohol screening and confirmation tests.

(d) As the direct supervisor of a particular employee, you may not act as the STT or BAT when that employee is tested, unless no other STT or BAT is available and you are permitted to do so under DOT agency regulations.

§ 40.213 What requirements must STTs and BATs meet?

(a) To be an STT, you must do the following:

(1) Be trained to proficiency on the alcohol testing procedures of this part and in the operation of the particular alcohol screening device(s) (ASD) you are using by an instructor(s) sufficiently knowledgeable in the DOT Model Course and in the use of the ASD(s) that you will be using to be able to evaluate STT performance. (The DOT Model Course is available at U.S. Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.)

(i) The training must be provided using the DOT Model Course for STTs or a course of instruction equivalent to it, as determined by ODAPC. On request, ODAPC will review STT instruction courses for equivalency.

(ii) The course of instruction must provide written documentation by the instructor that you have demonstrated proficiency on the specific ASD(s) you will use.

(iii) The demonstration of proficiency must be done in front of the instructor, in order that he or she can accurately determine if you are qualified to be an STT.

(iv) The instruction must emphasize that you are responsible for maintaining the integrity of the testing process, ensuring the privacy of employees being tested, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(2) Be able to discern changes, contrasts, or readings correctly if you are using an ASD that indicates readings by changes or contrasts, or other readings in color.

(3) Be retrained to proficiency if you have made a mistake in the testing process that has caused a test to be canceled.

(i) This retraining must be provided and your proficiency documented in writing by a person sufficiently knowledgeable in the applicable alcohol testing procedures of this part to be able to evaluate STT performance.

(ii) The instruction need only be in the general area of your deficiency that caused the test to be canceled.

(iii) As part of the retraining, you will have to demonstrate your proficiency in alcohol testing under this part by completing three consecutive error-free trial tests before you conduct another DOT alcohol test.

(iv) The person providing the instruction will monitor, evaluate, and attest whether or not the trial tests are ''error-free.''

(b) To be a BAT, you must do the following:

(1) Be trained to proficiency on the alcohol testing procedures of this part and in the operation of the particular evidential breath testing device(s) (EBTs) you are using, by an instructor(s) sufficiently knowledgeable in the DOT Model Course and in the use of the EBT(s) that you will be using to be able to evaluate BAT performance.

(i) The training must be provided using the DOT Model Course for BATs or a course of instruction equivalent to it, as determined by ODAPC. On request, ODAPC will review BAT instruction course for equivalency.

(ii) The course of instruction must provide written documentation by the instructor that you have demonstrated proficiency on the specific EBT(s) you will use.

(iii) The demonstration of proficiency must be done in front of the instructor, in order that he or she can accurately determine if you are qualified to be a BAT.

(iv) The instruction must emphasize that you are responsible for maintaining the integrity of the testing process, ensuring the privacy of employees being tested, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(2) Be retrained to proficiency if you have made a mistake in the testing process that has caused a test to be canceled.

(i) This retraining must be provided and your proficiency documented in writing by a person sufficiently

knowledgeable in the applicable alcohol testing procedures of this part to be able to evaluate BAT performance.

(ii) The instruction need only be in the general area of your deficiency that caused the test to be canceled.

(iii) As part of the retraining, you will have to demonstrate your proficiency in alcohol testing under this part by completing three consecutive error-free trial tests before you conduct another DOT alcohol test.

(iv) The person providing the instruction will monitor, evaluate, and attest whether or not the trial test collections are ''error-free.''

(c) Anyone meeting the requirements of § 40.213 to be a BAT may act as an STT, provided that the individual has demonstrated proficiency in the operation of the ASD that he or she is using.

(d) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. In order for a test conducted by such an officer to be accepted under DOT alcohol testing requirements, the officer must have been certified by a state or local government to use the EBT or ASD that was used for the test.

(e) As an STT or BAT, you must receive additional training, as needed, to ensure proficiency on new or additional devices or changes in technology that you will use.

(f) As an STT or BAT, you must read the alcohol testing procedures in this part and the current DOT Model Course, as applicable, and attest in writing to your understanding of them. You will have to demonstrate your proficiency in alcohol testing of this part by completing three consecutive error-free trial tests in front of a person sufficiently knowledgeable in the applicable alcohol testing procedures of this part to be able to evaluate STT or BAT performance. That person will monitor, evaluate, and attest whether or not the trial tests are ''error-free.'' You must complete the requirements of this paragraph by [date one year from the effective date of the final regulation], or two years from the date you became an STT or BAT, whichever is later, and once every two years, thereafter.

(g) As an STT or BAT, you must maintain all documentation of training/retraining as long as you serve as an STT and/or BAT.

§ 40.215 What requirements must organizations employing STTs and/or BATs meet?

This section becomes effective [date one year from the effective date of the final regulation].

(a) As an organization employing the STT and/or BAT (*e.g.,* a transportation employer, third-party administrator, occupational health clinic), you must maintain in your files documentation, signed by the person providing the training or retraining, that the STT and/or BAT has demonstrated proficiency as required by this subpart.

(b) You must retain this documentation as long as the person performs STT and/or BAT functions for the organization and for two years after the person ceases to perform these functions for the organization.

(c) You must provide to the STTs and BATs the name and telephone number of the appropriate DER to contact about any problems or issues that may arise during the testing process.

§ 40.217 Where is other information on the role of STTs and BATs found in this regulation?

You can find other information on the role and functions of STTs and BATs in the following sections of this part:

§ 40.1—application of rule to STTs and BATs.
§ 40.3—definitions.
§ 40.223—responsibility for supervising employees being tested.
§§ 40.225–40.227—use of the alcohol testing form.
§§ 40.241–40.243—screening test procedures.
§ 40.243—use of ASDs.
§ § 40.251–40.255—confirmation test procedures.
§ 40.261—refusals to test.
§§ 40.263–40.265—insufficient saliva or breath.
§ 40.267—problems requiring cancellation of tests.
§§ 40.267–40.271—correcting problems in tests.

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

§ 40.221 Where does an alcohol test take place?

(a) A DOT alcohol test is required to take place at an alcohol testing site meeting the requirements of this section.

(b) If you are operating an alcohol testing site, you must make sure that it meets the security requirements of § 40.223.

(c) If you are operating an alcohol testing site, you must make sure that it provides visual and aural privacy to the employee being tested, sufficient to prevent unauthorized persons from seeing or hearing test results.

(d) If you are operating an alcohol testing site, you must make sure that it has all needed personnel, materials, equipment, facilities, and supervision to provide for the collection and analysis of breath and/or saliva samples, and a suitable clean surface for writing.

(e) If an alcohol testing site fully meeting all the visual and aural privacy requirements of paragraph (c) of this section is not readily available, this regulation allows a reasonable suspicion or post-accident test to be conducted at a site that partially meets these requirements. In this case, the site must afford visual and aural privacy to the employee to the greatest extent practicable.

(f) An alcohol testing site can be in a medical facility, a mobile facility (*e.g.,* a van), a dedicated collection facility, or any other location meeting the requirements of this section.

§ 40.223 What steps must be taken to protect the security of alcohol testing sites?

(a) If you are operating an alcohol testing site, you must prevent unauthorized personnel from entering the testing location.

(1) The only people you are to treat as authorized persons are employees being tested, BATs, STTs, and other alcohol site workers, DERs, employee representatives authorized by the employer (*e.g.,* on the basis of employer policy or labor-management agreement), and DOT agency representatives.

(2) You must make sure that all persons are under the supervision of a BAT or STT at all times when permitted into the site.

(3) You may remove any person who obstructs, interferes with, or causes unnecessary delay in the testing process.

(b) If you are operating an alcohol testing site, you must make sure that when an EBT is not being used for testing, you store it in a secure place.

(c) If you are operating an alcohol testing site, you must make sure that no one other than BATs or other employees of the site have access to the site when an EBT is unsecured.

(d) As a BAT or STT, to avoid distraction that could compromise security, you may have only one employee under your direct supervision at any time.

(1) When an EBT screening test on an employee indicates a result at the 0.02 concentration or higher, and the same EBT will be used for the confirmation test, you are not allowed to use the EBT for a screening test on another employee before completing the confirmation test on the first employee.

(2) As a BAT who will conduct both the screening and the confirmation test, you are to complete the entire screening and confirmation process on one employee before starting the screening process on another employee.

(3) You are not allowed to leave the alcohol testing site while the testing process for a given employee is in progress.

§ 40.225 What form is used for an alcohol test?

(a) The DOT Breath Alcohol Testing Form (BATF must be used for every DOT alcohol test. The BATF must be a three-part carbonless manifold form. (The BATF is available at U.S. Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.)

(b) As an employer in the DOT alcohol testing program, you may not modify or revise the BATF except as follows:

(1) You may include other information needed for billing or other purposes necessary to the collection process.

(2) You may use a BATF directly generated by an EBT which omits the space for affixing a separate printed result to the BATF, provided the EBT prints the result directly on the BATF.

(3) You may use a BATF that has the employer's name, address, and telephone number preprinted.

(4) Instead of printing the entire pages of the BATF in the colors specified by DOT, you may use white pages with clearly discernible borders in the specified color for each page.

(5) As a BAT or STT, you may add, in the ''Remarks'' section of the BATF, the name of the DOT agency under whose authority the test occurred.

(6) As a BAT or STT, you may use a BATF that has your name, address, and telephone number preprinted, but under no circumstances can your signature be preprinted.

(c) As an employer outside the United States, you may use an equivalent foreign-language version of the BATF approved by ODAPC (e.g., in French for use in Canada or Spanish for use in Mexico).

§ 40.227 May employers use the BATF for non-DOT tests, and vice-versa?

(a) No. As an employer, you are prohibited from using the BATF for non-DOT alcohol tests. You are also prohibited from using non-DOT forms for DOT alcohol tests. Doing either subjects you to enforcement action under DOT agency regulations.

(b) If the STT or BAT, either by mistake, or as the only means to conduct a test under difficult circumstances (e.g., post-accident test with insufficient time to obtain the BATF), uses a non-DOT form for a DOT test, the use of a non-DOT form does not, in and of itself, require the employer or service agent to cancel the test. However, in order for the test to be considered valid, a signed statement must be obtained from the STT or BAT stating the reason why the BATF was not used for the DOT test.

§ 40.229 What devices are used to conduct alcohol screening tests?

EBTs and ASDs on the National Highway Traffic Safety Administration's (NHTSA) conforming products lists (CPL) for evidential and non-evidential devices are the only devices you are allowed to use to conduct alcohol screening tests under this part.

§ 40.231 What devices are used to conduct alcohol confirmation tests?

(a) EBTs on the NHTSA CPL for evidential devices that meet the requirements of paragraph (b) of this section are the only devices you may use to conduct alcohol confirmation tests under this part.

(b) To conduct a confirmation test, you must use an EBT that has the following capabilities:

(1) Provides a printed triplicate result (or three consecutive identical copies of a result) of each breath test;

(2) Assigns a unique, sequential number to each completed test, which the BAT and employee can read before each test and which is printed on each copy of the result;

(3) Prints, on each copy of the result, the manufacturer's name for the device, its serial number, and the time of the test;

(4) Distinguishes alcohol from acetone at the 0.02 alcohol concentration level;

(5) Tests an air blank; and

(6) Performs an external calibration check.

§ 40.233 What are the requirements for proper use and care of EBTs?

(a) As an EBT manufacturer, you must submit, for NHTSA approval, a quality assurance plan (QAP) for your EBT before NHTSA places the EBT on the CPL.

(1) Your QAP must specify the methods used to perform external calibration checks on the EBT, the tolerances within which the EBT is regarded as being in proper calibration, and the intervals at which these checks must be performed. In designating these intervals, your QAP must take into account factors like frequency of use, environmental conditions (e.g., temperature, humidity, altitude) and type of operation (e.g., stationary or mobile).

(2) Your QAP must also specify the inspection, maintenance, and calibration requirements and intervals for the EBT.

(b) As the manufacturer, you must include, with each EBT, instructions for its use and care consistent with the QAP. As an employer, you must follow these instructions, including performance of external calibration checks at the intervals the instructions specify.

(c) As an employer conducting external calibration checks, you must use calibration devices listed on NHTSA's CPL for ''Calibrating Units for Breath Alcohol Tests.''

(d) If an EBT fails an external check of calibration, as an employer you must take the EBT out of service. You may not use the EBT again for DOT alcohol testing until it is repaired and passes an external calibration check.

(e) As an employer, you must maintain records of the external calibration checks of EBTs as provided in § 40.335(a)(v).

(f) As an employer, you must ensure that inspection, maintenance, and calibration of the EBT are performed by its manufacturer or a maintenance representative certified either by the manufacturer or by a state health agency or other appropriate state agency.

§ 40.235 What are the requirements for proper use and care of ASDs?

(a) As an ASD manufacturer, you must submit, for NHTSA approval, a QAP for your ASD before NHTSA places the ASD on the CPL. Your QAP must specify the methods used for quality control checks, temperatures at which the ASD must be stored and used, the shelf life of the device, and environmental conditions (e.g., altitude, humidity) that may affect the ASD's performance.

(b) As a manufacturer, you must include, with each ASD, provided to an employer, instructions for its use and care consistent with the QAP. The instructions must include directions on the proper use of the ASD, the time within which the device must be read, and the manner in which the reading is made.

(c) As the employer, you must follow the QAP instructions.

(d) As an employer, you are not permitted to use an ASD that does not pass the specified quality control checks or that has passed its expiration date.

Subpart L—Alcohol Screening Tests

§ 40.241 What are the first steps in any alcohol screening test?

(a) This section lists the procedures used to begin any alcohol screening test, no matter whether an ASD or EBT is being used.

(b) As the BAT you will take the following steps:

(1) If an employee does not show up at the testing site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee is a ''no show.''

(2) Make sure that, when the employee enters the alcohol testing site, you begin the alcohol testing process without delay. For example, you must not wait because the employee says he or she is not ready or because an authorized employer or employee representative is delayed in arriving.

(i) If the employee is also going to provide a urine specimen, you must complete the alcohol test before the urine collection process begins.

(ii) If the employee needs medical attention (e.g., an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to conduct a test.

(3) Require the employee to provide positive identification. You must see a photo ID issued by the employer or a Federal, state, or local government agency for this purpose. You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(4) If the employee asks, provide identification to the employee. Your identification must include your name, your employer's name, address, and telephone number but does not have to include your picture, address, or telephone number.

(5) Explain the testing procedure to the employee, including showing the employee the instructions on the back of the BATF.

(6) Complete Step 1 of the BATF.

(7) Direct the employee to complete Step 2 on the BATF and sign the certification.

(i) If the employee refuses to sign this certification, you must document this refusal in the remarks section and immediately notify the DER.

(ii) The employer must treat the event described in paragraph (b)(7)(i) of this section as a refusal to test on the part of the employee.

§ 40.243 What is the procedure for an alcohol screening test using an EBT or non-evidential breath ASD?

As the BAT or STT, you must take the following steps:

(a) Select, or allow the employee to select, an individually wrapped or sealed mouthpiece from the testing materials.

(b) Open the individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

(c) Instruct the employee to blow steadily, and forcefully, into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

(d) Show the employee the displayed test result.

(e) If the device is one that prints the test number, testing device name and serial number, time and result directly onto the BATF, you must check to ensure that the information has been printed correctly onto the BATF.

(f) If the device is one that prints the test number, testing device name and serial number, time and result, but on a separate printout rather than directly onto the BATF, you must affix the printout of the information to the designated space on the back of the BATF with tamper-evident tape.

(g) If the device is one that does not print the test number, testing device name and serial number, time, and result, or it is a device not being used with a printer, you must record this information in Step 3 of the BATF.

§ 40.245 What is the procedure for an alcohol screening test using a saliva ASD?

As the STT, you must take the following steps:

(a) Check the expiration date on the device and show it to the employee. You may not use the device after its expiration date.

(b) Open an individually wrapped or sealed package containing the device in the presence of the employee.

(c) Offer the employee the opportunity to use the device. If the employee uses it, you must instruct the employee to insert it into his or her mouth and use it in a manner described by the device's manufacturer.

(d) If the employee chooses not to use the device, or in all cases in which a new test is necessary because the device did not activate (see paragraph (g) of this section), you must insert the device into the employee's mouth and gather saliva in the manner described by the device's manufacturer. You must wear single-use examination or similar gloves while doing so and change them following each test.

(e) When the device is removed from the employee's mouth, you must follow the manufacturer's instructions regarding necessary next steps in ensuring that the device has activated.

(f)(1) If you were unable to successfully (e.g., the device breaks, you drop the device on the floor) follow the procedures of paragraphs (c) through (e) of this section, you must discard the device and conduct a new test using a new device.

(2) The new device you use must be one that has been under your control or that of the employer before the test.

(3) You must note in the ''Remarks'' section of the BATF the reason for the new test. (Note: You may continue using the same BATF with which you began the test.)

(4) You must offer the employee the choice of using the device or having you use it unless the employee, in the opinion of the STT or BAT, was responsible (e.g., the employee dropped the device) for the new test needing to be conducted.

(5) If you are unable to successfully follow the procedures of paragraphs (c) through (e) of this section on the new test, you must end the collection and put an explanation in the ''Remarks'' section of the BATF.

(6) You must then direct the employee to take a new test, using an EBT for the screening test.

(g) If you are able to successfully follow the procedures of paragraphs (c) through (e) of this section, but the device does not activate, you must discard the device and conduct a new test, in the same manner as provided in paragraph (f) of this section. In this case, you must place the device into the employee's mouth to collect saliva for the new test.

(h) You must read the result displayed on the device no sooner than the device's manufacturer instructs. In all cases the result displayed must be read within 15 minutes of the test. You must then show the device and its reading to the employee and enter the result on the BATF.

(i) You must never re-use devices, swabs, gloves or other materials used in saliva testing.

§ 40.247 What happens next after the alcohol screening test result?

After the ASD or EBT has displayed or printed a result on an alcohol screening test, you must, as the STT or BAT, take the following additional steps:

(a) In the case of a screening test using an ASD, you must write in the ''Remarks'' section of the BATF whether you used a saliva device or a non-evidential breath device.

(b) If the test result is an alcohol concentration of less than 0.02, you must do the following:

(1) Sign and date Step 3 of the BATF;

(2) Instruct the employee to sign and date Step 4 of the BATF. If the employee does not do so, you must note this in the ''Remarks'' section of the BATF. You must not treat the employee's failure to sign Step 4 as a refusal to test; and

(3) Transmit the result directly to the DER in a confidential manner, as provided in § 40.255.

(c) If the test result is an alcohol concentration of 0.02 or higher, you must do the following:

(1) Direct the employee to take a confirmation test and conduct the test using procedures beginning at § 40.251; or

(2) If you are not the BAT who will conduct the confirmation test, direct the employee to take a confirmation test, sign and date Step 3 of the BATF, and give the employee Copy 2 of the BATF; and

(3) If the confirmation test will be performed at a different site from the screening test, you must take the following additional steps:

(i) Advise the employee not to eat, drink, put anything (e.g., cigarette, chewing gum) into his or her mouth, or belch;

(ii) Tell the employee the reason for the waiting period (i.e., to prevent an accumulation of mouth alcohol from leading to an artificially high reading);

(iii) Explain that following your instructions concerning the waiting period is to the employee's benefit;

(iv) Explain that the confirmation test will be conducted at the end of the waiting period, even if the instructions have not been followed;

(v) Note in the remarks section of the BATF that the waiting period instructions were provided;

(vi) Advise the employee not to drive, operate heavy equipment, or perform safety-sensitive functions, and show the employee the warning to this effect in Step 4 of the BATF;

(vii) Instruct the employee to sign and date Step 4 of the BATF. If the employee does not do so, you must note this in the ''Remarks'' section of the BATF. You must not treat the employee's failure to sign Step 4 as a refusal to test;

(viii) Instruct the employee to carry a copy of the BATF to the BAT who will perform the confirmation test; and

(ix) Make sure that you or another BAT, STT, or employer representative observe the employee as he or she is transported to the confirmation testing site.

(d) If the screening test is invalid, you must tell the employee the test is canceled and note the problem in the ''Remarks'' section of the BATF. If practicable, conduct a re-test (see § 40.271).

Subpart M—Alcohol Confirmation Tests

§ 40.251 What are the first steps in an alcohol confirmation test?

As the BAT for an alcohol confirmation test, you must follow these steps to begin the confirmation test process:

(a) You must carry out a requirement for a waiting period before the confirmation test, by taking the following steps:

(1) You must ensure that the waiting period lasts at least 15 minutes, but not more than 30 minutes, starting with the completion of the screening test.

(i) If the confirmation test is taking place at a different location from the screening test (see § 40.247(c)(3)) the time of transit between sites counts toward the waiting period if the STT or BAT who conducted the screening test provided the waiting period instructions.

(ii) If you cannot verify, through review of the BATF, that waiting period instructions were provided, then you must carry out the waiting period requirement.

(2) Concerning the waiting period, you must tell the employee:

(i) Not to eat, drink, put anything (e.g., cigarette, chewing gum) into his or her mouth, or belch;

(ii) The reason for the waiting period (i.e., to prevent an accumulation of mouth alcohol from leading to an artificially high reading);

(iii) That following the instructions concerning the waiting period is to the employee's benefit; and

(iv) That the confirmation test will be conducted at the end of the waiting period, even if the instructions have not been followed.

(3) If you become aware that the employee has not followed the instructions, you must note this in the ''Remarks'' section of the BATF.

(b) If you did not conduct the screening test for the employee, you must require positive identification of the employee, explain the confirmation procedures, and use a new BATF. You must note in the ''Remarks'' section of the BATF that a different BAT or STT conducted the screening test.

(c) Complete Step 1 of the BATF.

(1) Direct the employee to complete Step 2 on the BATF and sign the certification.

(2) If the employee refuses to sign this certification, you must document this refusal in the remarks section and immediately notify the DER. This is considered a refusal to test.

(d) Even if more than 30 minutes have passed since the screening test result was obtained, you must begin the confirmation test procedures in § 40.253, not another screening test.

(1) You must note in the ''Remarks'' section of the BATF the time that elapsed between the two events and the reason why the confirmation test could not begin within 30 minutes of the screening test.

(2) Beginning the confirmation test procedures after the 30 minutes have elapsed does not invalidate the screening or confirmation tests, but may constitute a regulation violation subject to DOT agency sanction.

§ 40.253 What are the procedures for conducting an alcohol confirmation test?

As the BAT for an alcohol confirmation test, you must follow these steps in order to complete the confirmation test process:

(a) In the presence of the employee, you must conduct an air blank on the EBT you are using before beginning the confirmation test and show the reading to the employee.

(1) If the reading is 0.00, the test may proceed. If the reading is greater than 0.00, you must conduct another air blank.

(2) If the reading on the second air blank is 0.00, the test may proceed. If the reading is greater than 0.00, you must take the EBT out of service.

(3) If you take an EBT out of service for this reason, no one may use it for testing until the EBT is found to be within tolerance limits on an external check of calibration.

(4) You must proceed with the test of the employee using another EBT, if one is available.

(b) You must open a new individually wrapped or sealed mouthpiece in view of the employee and insert it into the device in accordance with the manufacturer's instructions.

(c) You must make sure that you and the employee read the sequential test number displayed on the EBT.

(d) You must instruct the employee to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

(e) You must show the employee the result displayed on the EBT.

(f) You must show the employee the result and sequential test number that the EBT prints out either directly onto the BATF or onto a separate printout.

(g) If the EBT provides a separate printout of the result, you must attach the printout to the designated space on the back of the BATF, using tamper-evident tape.

§ 40.255 What happens next after the alcohol confirmation test result?

(a) After the EBT has printed the result of an alcohol confirmation test, you must, as the BAT, take the following additional steps:

(1) Sign and date Step 3 of the BATF.

(2) Direct the employee to sign and date Step 4 of the BATF. If the employee does not do so, you must note this in the ''Remarks'' section of the BATF. You must not treat the employee's failure to sign Step 4 as a refusal to test.

(3) If the test is invalid, tell the employee the test is canceled and note the problem in the ''Remarks'' section of the BATF. If practicable, conduct a re-test. (see § 40.271).

(4) Transmit the result directly to the DER in a confidential and immediate manner.

(i) You may transmit the results in writing (using Copy 1 of the BATF), in person, by telephone, or by electronic means. In any case, you must immediately notify the DER of any result of 0.02 or greater by any means (e.g., telephone or secure facsimile machine) that ensures the result is immediately received by the DER.

(ii) If you do not make the initial transmission in writing, you must follow up the initial transmission with Copy 1 of the BATF.

(b) As an employer, you must take the following steps with respect to the receipt and storage of alcohol test result information:

(1) If you receive any test results that are not in writing (e.g., by telephone or electronic means), you must establish a mechanism to establish the identity of the BAT sending you the results.

(2) You must store all test result information in a way that protects confidentiality (as outlined in subpart P of this part).

§ 40.257 When BATs report test results of 0.02 or greater to employers, what is an employer to do?

(a) As an employer who receives a test result of 0.04 or greater from the BAT, you must immediately remove the employee involved from performing safety sensitive functions. You must take this action upon receiving the initial notification from the BAT. Do not wait to receive a written report.

(b) As an employer who receives a test result of 0.02 through 0.039 from the BAT, you must immediately remove the employee involved from performing safety sensitive functions under the conditions stipulated by the appropriate DOT agency regulation. You must take this action upon receiving the initial notification from the BAT. Do not wait to receive a written report.

Subpart N—Problems in Alcohol Testing

§ 40.261 What is a refusal to take an alcohol test, and what are its consequences?

(a) As an employee, you are considered to have refused to take an alcohol test if you:

(1) Fail to show up for any test within a reasonable time after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a third-party administrator or consortium. (see § 40.241(b)(1));

(2) Fail to provide a saliva or breath specimen, as applicable, for any test required by this part or DOT agency regulations;

(3) Refuse to sign the certification in Step 2 of the BATF (see § 40.241(b)(7));

(4) Fail to provide a sufficient breath specimen, unless the physician has determined, through a required medical evaluation, that there is an adequate medical explanation for the failure (see § 40.265(c));

(5) Fail to undergo an additional medical examination, as directed by the physician conducting the evaluation as part of the insufficient breath procedures outlined at § 40.265(c); or

(6) Fail to cooperate with any part of the testing process.

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

(c) As a BAT or an STT, when an employee refuses to take an alcohol test, you must terminate the portion of the testing process in which you are involved, document the refusal on the BATF, and immediately notify the DER by any means (e.g., telephone or secure facsimile machine) that ensures the refusal notification is immediately received by the DER.

§ 40.263 What happens when an employee is unable to provide an adequate amount of saliva for an alcohol screening test?

(a) As the STT, you must take the following steps if an employee is unable to provide sufficient saliva to complete a test on a saliva screening device (*e.g.,* the employee does not provide sufficient saliva to activate the device).

(1) You must conduct a new screening test using a new screening device.

(2) If the employee refuses to complete the new test, you must discontinue testing, note the fact in the ''Remarks'' section of the BATF, and immediately notify the DER.

(3) If the employee has not provided a sufficient amount of saliva to complete the new test, you must note the fact in the ''Remarks'' section of the BATF and immediately notify the DER.

(b) As the DER, when the STT informs you that the employee has not provided a sufficient amount of saliva (see paragraph (a)(3) of this section), you must immediately arrange to administer an alcohol test to the employee using an EBT or other breath testing device.

§ 40.265 What happens when an employee is unable to provide a sufficient amount of breath for an alcohol test?

(a) If an employee does not provide a sufficient amount of breath to permit a valid breath test, you must take the steps listed in this section.

(b) As the BAT or STT, you must instruct the employee to attempt again to provide a sufficient amount of breath.

(1) If the employee refuses to make the attempt, you must discontinue the test, note the fact in the ''Remarks'' section of the BATF, and immediately notify the DER.

(2) If the employee again attempts and fails to provide a sufficient amount of breath, you must note the fact in the ''Remarks'' section of the BATF and immediately notify the DER.

(3) If you are using an EBT that has the capability of operating manually, you may attempt to conduct the test in manual mode.

(4) If you are qualified to use a saliva ASD and you are in the screening test stage, you may change to a saliva ASD only to complete the screening test.

(c) As the employer, when the BAT or STT informs you that the employee has not provided a sufficient amount of breath (see paragraph (b)(2) of this section), you must direct the employee to obtain, within five working days, an evaluation from a licensed physician who is acceptable to you concerning the employee's medical ability to provide a sufficient amount of breath.

(1) You are required to provide the physician who will conduct the evaluation with the following information and instruction:

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

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

(iii) That the physician must provide you with a written statement of his or her conclusions; and

(iv) That the physician, in his or her reasonable medical judgment, must base those conclusions on one of the following determinations:

(A) A medical condition has, or with a high degree of probability could have,

precluded the employee from providing a sufficient amount of breath. The physician must not include in the written statement detailed information on the employee's medical condition. In this case, the test is canceled.

(B) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have precluded the employee from providing a sufficient amount of breath. This constitutes a refusal to test.

(C) For purposes of paragraphs (c)(1)(iv)(A) and (B) of this section, a medical condition includes an ascertainable physiological condition (e.g., a respiratory system dysfunction) or a documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or hyperventilation.

(2) Upon receipt of the report from the examining physician, you must immediately inform the employee and take appropriate action based upon your DOT agency regulations.

§ 40.267 What problems always cause an alcohol test to be canceled?

As an employer, a BAT, or an STT, you must always cancel an alcohol test if any of the following problems occur. These are ''fatal flaws'' that always cause an alcohol test to be canceled and cannot be corrected:

(a) In the case of a screening test conducted on a saliva ASD:

(1) The STT reads the result either sooner than or later than the time allotted by the manufacturer (see § 40.245(h));

(2) The device does not activate (see § 40.245(e), (f), and(g)); or

(3) The device is used for a test after the expiration date printed on its package (see § 40.245(a)).

(b) In the case of a screening or confirmation test conducted on an EBT, the sequential test number or alcohol concentration displayed on the EBT is not the same as the sequential test number or alcohol concentration on the printed result (see § 40.253(c)).

(c) In the case of a confirmation test:

(1) The BAT conducts the confirmation test before the end of the minimum 15-minute waiting period (see § 40.251(a)(1));

(2) The BAT does not conduct an air blank before the confirmation test (see § 40.253(a));

(3) There is not a 0.00 result on the air blank conducted before the confirmation test (see § 40.253(a)(1) and(2));

(4) The EBT does not print the result (see § 40.253(f)); or

(5) The next external calibration check of the EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this case, every result of 0.02 or above obtained on the EBT since the last valid external calibration check is canceled (see § 40.233(a)(1) and (d)).

§ 40.269 What problems cause an alcohol test to be canceled unless they are corrected?

You must treat an alcohol test as canceled if any of the following problems occur, unless they are corrected. These are ''correctable flaws.''

(a) The BAT or STT does not sign the BATF (see §§ 40.247(c)(2) and 40.255(a)(1)).

(b) The BAT or STT fails to note in the remarks section of the BATF that the employee has failed or refused to sign the BATF after the result is obtained (see §§ 40.247(b)(2) and 40.255(a)(2)).

(c) In the case of a screening test using an ASD, the BAT or STT fails to note in the remarks section of the BATF, whether the test was conducted using a saliva or non-evidential breath ASD (see § 40.247(a)).

(d) The BAT or STT uses a non-DOT form for the test (see § 40.225(a)).

§ 40.271 How are alcohol testing problems corrected?

(a) As a BAT or STT, you are responsible for completing successfully an alcohol test for each employee.

(1) If, during or shortly after the testing process, you become aware of any event that will cause the test to be canceled (see § 40.267), you must try to correct the problem promptly, if practicable. You may repeat the testing process as part of this effort.

(2) If repeating the testing process is necessary, you must begin a new test as soon as possible. You must use a new BATF, a new sequential test number, and, if needed, a new ASD and/or a new EBT.

(b) If, as an STT, BAT, employer or other service agent administering the testing process, you become aware of a ''correctable flaw'' (see § 40.269) that has not already been corrected, you must take all practicable action to correct the problem so that the test is not canceled.

(1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply, in writing, the missing information and a signed statement that it is true and accurate. For example, suppose you are a BAT and you forgot to make a notation in the ''Remarks'' section of the BATF that the employee refused to sign the certification. You would, when the problem is called to your attention, supply a written statement that the employee refused to sign the certification, and you would certify, in writing, that your statement is true and accurate.

(2) If the problem is the use of a non-DOT form, you must, as the person responsible for the use of the incorrect form, certify in writing that the incorrect form contains all the information needed for a valid DOT. You must also provide a written statement that the incorrect form was used either by mistake, or as the only means to conduct a test under difficult circumstances (e.g., post-accident test with insufficient time to obtain the BATF), and the steps you have taken to prevent future use of non-DOT forms for DOT tests.

§ 40.273 What is the effect of a canceled alcohol test?

(a) A canceled alcohol test is neither positive nor negative.

(1) As an employer, you must not attach to a canceled test the consequences of a test result that is 0.02 or greater (e.g., removal from a safety-sensitive position).

(2) As an employer, you must not use a canceled test for the purposes of a test result that is below 0.02 (*e.g.,* in the case of a pre-employment, return-to-duty, or follow-up test to authorize the employee to perform safety-sensitive functions).

(b) A canceled test does not count toward compliance with DOT requirements, such as a minimum random testing rate.

§ 40.275 What is the effect of procedural problems that are not sufficient to cancel an alcohol test?

(a) As an STT, BAT, employer or other service agent administering the testing process, you must document any errors in the testing process of which you become aware, even if they are not ''fatal flaws'' or ''correctable flaws'' listed in this subpart. Decisions about the ultimate impact of these errors will be determined by administrative or legal proceedings, subject to the limitation of paragraph (b) of this section.

(b) No person concerned with the testing process may declare a test canceled based on a mistake in the process that does not have a significant adverse effect on the right of the employee to a fair and accurate test. For example, it is inconsistent with these regulations to cancel a test based on a minor administrative mistake (e.g., the omission of the employee's middle initial,) or an error that does not affect employee protections under this part.

(c) As an employer, these errors, even though not sufficient to cancel an

alcohol test result, may subject you to enforcement action under DOT agency regulations.

§ 40.277 Are alcohol tests other than saliva or breath for screening and breath for confirmation permitted under these regulations?

No. Other types of alcohol tests (i.e., blood and urine) are not authorized for testing done under this part. Only saliva or breath for screening tests and breath for confirmation tests are permitted.

Subpart O—Return-to-duty Process And Role of Substance Abuse Professionals (SAPs)

§ 40.281 Who is qualified to act as a SAP?

You are qualified to act as a SAP in DOT drug and alcohol testing programs if you meet each of the following criteria:

(a) You have knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled substances-related disorders, and:

(1) You are a licensed physician; or

(2) You are a licensed or certified social worker; or

(3) You are a licensed or certified psychologist; or

(4) You are a licensed or certified employee assistance professional; or

(5) You are a drug and alcohol counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission or by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse.

(b) You have a working knowledge of this part, the current ''Substance Abuse Professional Procedures Guidelines'' and the DOT agency regulations applicable to the employers for which you evaluate employees. In addition, you are cognizant of the SAP function as it relates to employer interests in safety-sensitive duties. (The ''Substance Abuse Professional Procedures Guidelines'' is available at ODAPC, Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590.)

(c) You participate in and document training (e.g., a course) at least once every two years that relates directly to the SAP responsibilities of the DOT program, or self-certify that you have re-reviewed and understand this part and applicable DOT agency regulations. You must maintain these records for two years.

(d) If you were a SAP prior to [effective date of the final regulation], you must meet the requirements of paragraph (c) of this section by [date six months from the effective date of the final regulation]. If you become a SAP after [effecitve date of the final regulation], you must meet the requirements of paragraph (c) of this section prior to acting as a SAP.

(e) If you represent a certification organization that wants DOT to authorize its certified drug and alcohol counselors to be included in paragraph (a)(5) of this section, you may submit a written petition to DOT requesting a review of your petition for inclusion.

(1) You must obtain the National Commission for Certifying Agencies (NCCA) accreditation as a prerequisite for having the DOT review your petition.

(2) You must meet the minimum requirements at Appendix F of this part as a prerequisite for having the DOT review your petition.

(3) If you are a certification organization with a petition already submitted for DOT review, you must obtain NCCA accreditation before the review can continue.

(4) If you were a certification organization listed in paragraph (a)(5) of this section prior to [effective date of the final regulation], you are not required by DOT to have NCCA accreditation.

§ 40.283 When is a SAP evaluation required?

(a) When an employee has violated DOT drug and alcohol regulations, the employee cannot again perform any DOT safety-sensitive duties until and unless he or she completes the SAP evaluation, referral, and treatment process set forth in this subpart and in applicable DOT agency regulations. (In some cases, DOT agency regulations may prohibit your return to work in safety-sensitive functions.) The first step in this process is to be evaluated by a SAP.

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

§ 40.285 What information is an employer required to provide concerning SAP services to an employee who has a DOT drug and alcohol regulation violation?

As an employer, you must provide to each employee who engages in a DOT drug and alcohol regulation violation, a listing of SAPs readily available to the employee, with names, addresses, and telephone numbers. You cannot charge the employee any fee for compiling or providing this list.

§ 40.287 Are employers required to provide SAP and treatment services to employees?

(a) As an employer, you are not required to provide a SAP evaluation or any subsequent recommended education or treatment for an employee who has violated a DOT drug and alcohol regulation.

(b) However, if you offer that employee an opportunity to return to a DOT safety-sensitive duty following a violation, then before the employee again performs that duty, you must first ensure that the employee receives an evaluation by a SAP suitable to you and that the employee successfully complies with the SAP's evaluation recommendations.

(c) As an employer, you must ensure that the selected SAP is qualified to do the job, and is aware of the SAP role and function as it relates to your interests in safety sensitive duties.

(d) You must, as an employer, use as a SAP only someone who is knowledgeable about this part, the DOT SAP guidelines, and the appropriate DOT agency regulation under which you conduct your drug and alcohol program.

(e) SAP and treatment payment matters are left for employers and employees to decide and may be governed by existing management-labor agreements and insurance coverage.

§ 40.289 What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has violated the DOT drug and alcohol regulations?

As a SAP, you are charged with:

(a) Making a face-to-face clinical assessment and evaluation to determine what assistance, if any, is needed by the employee to resolve problems associated with alcohol and/or drug use.

(b) Referring the employee to an appropriate education and/or treatment program(s) if assistance is needed.

(c) Conducting a face-to-face follow-up evaluation to determine if the employee has actively participated in the education and/or treatment program and has demonstrated successful compliance with the initial assessment and evaluation recommendations (if assistance was needed).

(d) Providing the DER with a follow-up drug and/or alcohol testing plan for the employee.

§ 40.291 Can employees who are referred for SAP evaluations be required to waive liability with regard to negligence or malpractice on the part of the SAP?

(a) As a SAP, you must not ask or require an employee or employer to waive liability with regard to negligence and/or malpractice related to the SAP

evaluation, referral, treatment, and follow-up evaluation processes, nor indemnify any person or group for the negligence of others in the SAP process.

(b) As a service agent or service agent representative, you must not ask or require an employee or employer to sign any form, statement, or authorization with regard to waiving SAP liability.

§ 40.293 What is the SAP's function in conducting the initial evaluation of an employee?

As a SAP, when an employee comes to you following a DOT drug and alcohol regulation violation, you must accomplish the following:

(a) Provide a comprehensive face-to-face assessment and clinical evaluation to determine if the employee needs assistance resolving problems associated with alcohol and/or drug use.

(b) If you find the employee is in need of assistance as a result of your evaluation, recommend a course of education and/or treatment with which the employee must demonstrate successful compliance prior to returning to DOT safety-sensitive duty.

(1) Appropriate education modalities may include, but are not limited to, self-help groups (e.g., Alcoholics Anonymous) and community lectures, where attendance can be independently verified, and *bona fide* drug and alcohol education courses.

(2) Appropriate treatment modalities may include, but are not limited to, in-patient hospitalization, partial in-patient treatment, out-patient counseling programs, and aftercare.

(3) You must provide a written report directly to the DER highlighting your specific recommendations for assistance (see § 40.311(c)).

(c) If you find the employee needs no assistance as a result of your evaluation, you must follow the instructions for follow-up testing at § 40.307(b), and provide a written report (see § 40.311(d)) directly to the DER. You have no additional responsibilities with regard to §§ 40.301, 40.303, and 40.311(c) and (e).

§ 40.295 Can employees or employers seek a second SAP evaluation if they disagree with the first SAP's recommendations?

(a) As an employee with a DOT drug and alcohol regulation violation, when you have been evaluated by a SAP suitable to the employer, you cannot seek a second SAP's evaluation in order to obtain another recommendation.

(b) As an employer, you cannot seek a second SAP's evaluation if the employee has already been evaluated by a SAP suitable to you.

§ 40.297 Does anyone have the authority to change a SAP's initial assessment recommending assistance?

No one (e.g., an employer, employee, a managed-care coordinator, or any service agent or service agent network) has the authority to change, append, or modify the SAP's evaluation recommendation for assistance. This is most important in cases where a third party wishes to lessen or downgrade a SAP's recommendation by changing the SAP's evaluation or seeking another SAP's evaluation. In situations where the third party wishes a more stringent recommendation, the same basic principle applies.

§ 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) As a SAP, upon your determination of the best recommendation for assistance, you will serve as a referral source to assist the employee's entry into a treatment and/or education program.

(b) To prevent the appearance of a conflict of interest, you must not refer an employee requiring assistance to your private practice or to a person or organization from which you receive remuneration or to a person or organization in which you have a financial interest. You are precluded from making referrals to entities with which you are financially associated.

(c) There are four exceptions to the prohibitions contained in paragraph (b) of this section. You may refer an employee to any of the following providers of assistance, regardless of your relationship with them:

(1) A public agency (e.g., treatment facility) operated by a state, county, or municipality;

(2) The employer or a person or organization under contract to the employer to provide alcohol or drug treatment services (e.g., the employer's contracted treatment provider);

(3) The sole source of therapeutically appropriate treatment under the employee's health insurance program (e.g., the single substance abuse in-patient treatment program made available by the employee's insurance coverage plan); or

(4) The sole source of therapeutically appropriate treatment reasonably available to the employee (e.g., the only appropriate treatment facility reasonably located within the general commuting area).

(d) As a SAP, you must maintain a signed statement that you will not make treatment referrals covered under this DOT program to yourself or to persons and entities with which you are financially associated. The statement will remain in effect and be maintained until its conditions change, at which time you will so notify the employer of the change. This signed statement will be made available for review by employers.

§ 40.301 What is the SAP's function in the follow-up evaluation of an employee?

(a) As a SAP, when you have prescribed assistance under § 40.293, you must re-evaluate the employee to determine if the employee has successfully carried out your education and/or treatment recommendations.

(1) This is your way to gauge for the employer the employee's ability to demonstrate successful compliance with the education and/or treatment plan.

(2) Your evaluation may serve as one of the reasons the employer decides to return the employee to safety-sensitive duty.

(b) As the SAP making the follow-up evaluation determination, you must:

(1) Confer with the appropriate education or treatment program professionals where the employee was referred;

(2) Conduct a face-to-face clinical interview with the employee to determine if the employee demonstrates successful compliance with your initial evaluation recommendations; and

(3) Provide a written report directly to the DER highlighting your clinical determination whether the employee has demonstrated successful compliance with your initial evaluation recommendation (see § 40.311(e)).

(c) You may determine that an employee has successfully demonstrated compliance even though the individual has not completed the full regimen of treatment you recommended or needs additional treatment or continuing care. For example, if the employee has successfully completed the 30-day in-patient program you prescribed, you may make a ''successful completion'' determination even though you conclude that the employee has not completed the out-patient counseling you recommended or should continue in an aftercare program.

(d) As a SAP, if you believe, as a result of the follow-up evaluation, the employee has not demonstrated successful compliance with your initial recommendation, you must postpone the follow-up evaluation pending the employee's further compliance with the education and/or treatment plan.

§ 40.303 What happens if the SAP believes the employee needs additional treatment, aftercare, or support group services even after the employee returns to safety-sensitive duties?

(a) As a SAP who believes that on-going services are needed to assist an employee to maintain sobriety or abstinence from drug use upon returning to safety-sensitive duties, you must clearly state what services are needed as part of the follow-up evaluation report sent directly to the DER (see § 40.311(e)(10)).

(b) As an employer receiving this determination from the SAP, you must, as part of a return-to-work agreement with the employee, require the employee to continue to participate in recommended on-going services after returning to safety-sensitive duties.

(c) As an employer, you must monitor and document the employee's participation in on-going services after returning to safety-sensitive duties.

§ 40.305 Must an employer return an employee to safety-sensitive functions following a SAP determination that the employee demonstrated successful compliance with the SAP's recommendation?

(a) As an employer, you are not obligated under DOT regulations to return the employee to safety-sensitive duties.

(b) The employee's demonstrating successful compliance with prescribed education and/or treatment as determined by the SAP and subsequently testing negative on the return-to-duty drug and/or alcohol test are not guarantees of continued employment or of return to work in a safety-sensitive position. They are merely preconditions the employee must meet in order to be considered for reinstatement into safety-sensitive duties.

(c) As a SAP, you are not to make a ''fitness for duty'' determination as part of this re-evaluation unless required to do so under an applicable DOT agency regulation. It is the employer, rather than you, who must decide whether to put the employee back to work in a safety-sensitive position.

§ 40.307 What is the SAP's function in prescribing the employee's follow-up tests?

(a) As the SAP, when you have made a ''successful compliance'' determination regarding the employee during the follow-up evaluation, you must then determine what manner of follow-up testing (as specified in paragraph (c) of this section) is needed when the employee returns to safety-sensitive duties, and present a plan for follow-up testing directly to the DER (see § 40.311(e)(9)).

(b) Under specific DOT agency regulations, you must determine what manner of follow-up testing (as specified in paragraph (c) of this section) is needed following an initial evaluation when you have concluded that the employee needs no assistance and present a plan for follow-up testing directly to the DER (see § 40.311(d)(6)).

(c) You are the sole determiner of the number and frequency of follow-up tests and whether these tests will be for drugs, alcohol, or both, unless otherwise directed by the appropriate DOT agency regulation. For example, if the employee had a positive drug test, but your evaluation or the treatment program professionals determined that the employee had an alcohol problem as well, you could require that the employee have follow-up tests for both drugs and alcohol.

(d) However, you must, at a minimum, direct that the employee be subject to six unannounced follow-up tests in the first 12 months following the employee's return to safety-sensitive duties.

(1) You may require a greater number of tests during the first 12-month period (e.g., you may require one test a month during the 12-month period; you may require two tests per month during the first 6-month period and one test per month during the final 6-month period).

(2) You may also require follow-up tests during the 48 months following this first 12-month period.

(3) You are not to establish the actual dates for the follow-up tests you prescribe. The decision on specific dates to test is up to the employer.

(e) You may modify the determinations you have made concerning follow-up tests. For example, even if you recommended follow-up testing beyond the first 12-months, you can terminate the testing requirement at any time after the first year of testing.

§ 40.309 What are the employer's responsibilities with respect to the SAP's directions for follow-up tests?

(a) As the employer, you must carry out the SAP's follow-up testing requirements. You may not allow the employee to continue to perform safety-sensitive functions unless follow-up testing is conducted as directed by the SAP.

(b) You should schedule follow-up tests on dates of your own choosing, but you must ensure that the tests are unannounced with no discernable pattern as to their timing, and that the employee is given no advance notice.

(c) You cannot substitute any other tests (e.g., those carried out under the random testing program) conducted on the employee for this follow-up testing requirement.

(d) You cannot count a follow-up test that has been canceled as a completed test. A canceled follow-up test must be recollected.

§ 40.311 Are there any special instructions regarding SAP reports to employers and SAP records?

(a) As the SAP conducting the required evaluations, you must send your written reports in writing directly to the DER and not to a third party or entity for forwarding to the DER.

(b) As an employer, you must ensure that you receive SAP written reports directly from SAPs performing the evaluation and that no third party or entity forwarded those reports to you or changed the SAP's report in any way.

(c) The SAP's written report, following an initial evaluation that determines that *assistance is needed* to address the employee's drug and/or alcohol problems, must be on the SAP's letterhead, signed by the SAP, and must contain the following delineated items:

(1) Employee's name and SSN;

(2) Employer's name and address;

(3) Reason for the assessment;

(4) Date of the assessment;

(5) SAP's education and/or treatment recommendation; and

(6) SAP's telephone number.

(d) The SAP's written report, following an initial evaluation that determines that *no assistance is needed* to address the employee's drug and/or alcohol problems, must be on the SAP's letterhead, signed by the SAP, and must contain the following delineated items:

(1) Employee's name and SSN;

(2) Employer's name and address;

(3) Reason for the assessment;

(4) Date of the assessment;

(5) SAP's reasons for determining that no assistance is needed;

(6) Follow-up testing plan (if required or authorized by the appropriate DOT agency regulation); and

(7) SAP's telephone number.

(e) The SAP's written report concerning the follow-up evaluation that determines the employee has demonstrated *successful compliance,* must be on the SAP's letterhead, signed by the SAP, and must contain the following delineated items:

(1) Employee's name and SSN;

(2) Employer's name and address;

(3) Reason for the initial assessment;

(4) Date of the initial assessment and synopsis of the treatment plan;

(5) Name of practice(s) or service(s) providing the recommended education and/or treatment;

(6) Inclusive dates of employee's program participation;

(7) Clinical characterization of employee's program participation;

(8) SAP's clinical determination as to whether the employee has demonstrated successful compliance;

(9) Follow-up testing plan;

(10) Employee's continuing care needs with specific treatment, aftercare, and/or support group services recommendations; and

(11) SAP's telephone number.

(f) As a SAP, you must provide these written reports directly to the employee if the employee has no current employer and to the gaining DOT regulated employer in the event the employee obtains another transportation industry safety-sensitive position.

(g) As a SAP, you are to maintain copies of your reports to employers for 5 years, and your employee clinical records in accordance with Federal, state, and local laws regarding record maintenance, confidentiality, and release of information.

(h) As an employer, you must maintain your reports from SAPs for 5 years.

§ 40.313 Where is other information on SAP functions found in this regulation?

You can find other information on the role and functions of SAPs in the following sections of this part:

§ 40.1—application to SAPs of regulation coverage.
§ 40.3—definition.
§ 40.347—service agent assistance with SAP-required follow-up testing.
§ 40.353—transmission of SAP reports.

Subpart P—Confidentiality and Release of Information

§ 40.321 What is the general confidentiality rule for drug and alcohol test information?

Except as otherwise provided in this subpart, as a service agent or employer participating in the DOT drug or alcohol testing process, you are prohibited from releasing individual test results or medical information about an employee to third parties without the employee's specific written consent.

(a) A ''third party'' is any person or organization to whom other subparts of this regulation do not explicitly authorize or require the transmission of information in the course of the drug or alcohol testing process.

(b) ''Specific written consent'' means a statement signed by the employee that he or she agrees to the release of a particular piece of information to a particular, explicitly identified, person or organization at a particular time. ''Blanket releases,'' in which an employee agrees to a release of a category of information (e.g., all test results) or to release information to a category of parties (e.g., other employers who are members of a consortium, companies to which the employee may apply for employment) are not permitted under this part.

§ 40.323 Can program participants release drug or alcohol test information in connection with legal proceedings?

(a) As an employer, you may release information pertaining to an employee's drug or alcohol test without the employee's consent in certain legal proceedings.

(1) These proceedings include a lawsuit (*e.g.,* a wrongful discharge action), grievance (*e.g.,* an arbitration concerning disciplinary action taken by the employer), or administrative proceeding (*e.g.,* an unemployment compensation hearing) brought by, or on behalf of, an employee and resulting from a positive DOT drug or alcohol test.

(2) In such a proceeding, you may release the information to the decisionmaker in the proceeding (e.g., the court in a lawsuit, the arbitrator in a grievance). You may release the information only with a binding stipulation that the party to whom it is released will not release it to additional parties.

(b) If you are a service agent, you may release information pertaining to an employee's drug or alcohol test without the employee's consent to the employer who directed that the test occur so that the employer can introduce it in such a proceeding or directly to the decision maker in the proceeding.

§ 40.325 May service agents transfer drug or alcohol test information to one another?

(a) As a service agent authorized to maintain drug and/or alcohol test results and you are no longer providing services with respect to an employer, you may transfer that employer's records to your successor without obtaining each employee's consent. For example, if Employer X is replacing Dr. A with Dr. B as its MRO, Dr. A may transfer drug testing records of Employer X's employees to Dr. B without getting the employees' consent.

(b) The service agent must use the provisions of § 40.335 in determining which records to transfer and the time period that must be covered.

(c) Records that are not transferred must be maintained for the employer in accordance with the provisions of section § 40.335.

§ 40.327 When may the MRO release medical information gathered in the verification process?

(a) As the MRO, you must warn an employee who has a confirmed positive test that you may provide medical information the employee gives you in the verification process to other persons specified in this section, without the employee's consent.

(1) You must give this warning to the employee before obtaining any medical information as part of the verification process.

(2) For purposes of this section, medical information includes information on medications or other substances the employee reports using or medical conditions the employee reports having.

(3) The only other persons to whom you may provide such information are the employer, a physician responsible for determining the medical qualifications of the employee under an applicable DOT agency safety regulation, a DOT agency, the National Transportation Safety Board in the course of an accident investigation, or another employer who would receive a positive test result under § 40.329.

(b) As the MRO, you may provide medical information to third parties without the employee's consent only if you determine, in your reasonable medical judgment, that:

(1) The information is likely to result in the employee being determined to be medically unqualified under an applicable DOT agency regulation; or

(2) The information indicates that continued performance by the employee of his or her safety-sensitive function is likely to pose a significant safety risk.

(c) As the MRO, before informing any third party about any medication the employee is using pursuant to a prescription legally valid under the Controlled Substances Act, you should, if the employee consents, contact the prescribing physician to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk.

§ 40.329 May an MRO provide information about a positive drug test result to another employer?

(a) Except as otherwise provided in this section, as an MRO you must provide the results of a verified drug positive test result only to the employer who required that particular test to be conducted.

(b) If you have personal knowledge that an employee whose drug test result you have verified positive is also employed or is seeking employment in

a safety-sensitive position for another employer subject to a DOT agency's drug testing regulations, you must notify the other employer of the positive drug test result if you meet all of the following conditions:

(1) You also personally are the current MRO, perform DOT-required physical examinations, function as the Aviation Medical Examiner, or function as the Medical Examiner conducting medical qualification physicals in the transportation industry for the other employer;

(2) Your knowledge that the employee works for the other employer was obtained in one of these capacities or through your review of the result of a drug test mandated by a DOT agency regulation;

(3) You have affirmed that the employee is currently employed by the other employer in a safety-sensitive position subject to drug testing under a DOT agency regulation; and

(4) You have informed the employee at the beginning of the verification process that a verified positive test result may be shared with other employers for whom the employee is performing, or is seeking employment to perform, safety-sensitive functions subject to drug testing under a DOT agency regulation.

(c) The only party to whom you are authorized to convey this information is the other employer itself. You must not convey the information to or through a service agent who performs drug testing services for the other employer.

(d) In notifying the other employer, you must follow the same procedures as you follow in notifying any employer of a drug test result. In doing so, you must notify the other employer to immediately remove the employee from performing safety-sensitive functions. You must also inform the other employer if the employee requests a test of a split specimen, cautioning the other employer not to take irrevocable personnel action until the result of the test of the split specimen is known. You must also provide to the other employer the results of the test of the split specimen.

Example to § 40.329: Employer 1 sends in Employee X for a random drug test. You verify the result positive. You also act as the MRO for Employer 2, which is subject to DOT drug testing regulations. In that capacity, you have learned that Employee X also performs DOT safety sensitive functions for Employer 2. You must inform Employer 2 about the positive test result. You do not need to obtain the employee's consent to do so. Employer 2 has the same obligation as Employer 1 after receiving this information. That is, both employers must remove Employee X from the performance of safety-sensitive functions.

§ 40.331 What information must laboratories and other service agents release to employees?

(a) As a service agent you must provide, within 10 business days of receiving a written request from an employee, copies of any records pertaining to the employee's use of alcohol and/or drugs, including records of the employee's DOT-mandated drug and/or alcohol tests. You may charge no more than the cost of preparation and reproduction for copies of these records.

(b) As a laboratory, you must also provide, within 10 business days of receiving a written request from an employee, and made through the MRO, the records relating to the results of any relevant HHS certification, review, or revocation-of-certification (*i.e.,* **Federal Register** Notice listing current laboratories). You may charge no more than the cost of preparation and reproduction for copies of these records.

(c) As a laboratory, you must also provide, within 10 business days of receiving a written request from an employee, and made through the MRO, the records relating to the results of the employee's drug test (*i.e.,* laboratory report and data package). You may charge no more than the cost of preparation and reproduction for copies of these records.

§ 40.333 To what additional parties must employers and service agents release information?

As an employer or service agent you must release information under the following circumstances:

(a) If you receive a specific, written consent from an employee authorizing the release of information about that employee's drug or alcohol tests to an identified person, you must provide the information to the identified person. For example, as an employer, when you receive a written request from someone who worked for you to provide information to a subsequent employer, you must do so. In providing the information, you must comply with the terms of the employee's consent.

(b) Upon request and as required by DOT agency regulations, employers must provide to DOT agencies the following:

(1) Access to your facilities used for this part and DOT agency drug and alcohol program functions.

(2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations.

(c) Upon request and as required by DOT agency regulations, service agents must provide to DOT agencies the following:

(1) Access to your facilities used for this part and DOT agency drug and alcohol program functions.

(2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents/documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations.

(d) When requested by the National Transportation Safety Board as part of an accident investigation, you must provide information concerning post-accident tests administered after the accident.

(e) As a laboratory you must not release or provide a specimen or an aliquot of a specimen to a requesting party, without first obtaining written consent from a DOT agency. You are permitted to release a specimen or an aliquot of a specimen if you are presented with a court order to do so from a court with proper and legal jurisdiction.

§ 40.335 What records must employers keep?

(a) As an employer, you must keep the following records for the following periods of time:

(1) You must keep the following records for five years:

(i) Records of employee alcohol test results indicating an alcohol concentration of 0.02 or greater;

(ii) Records of employee verified positive drug test results;

(iii) Documentation of refusals to take required alcohol and/or drug tests;

(iv) SAP reports;

(v) Calibration documentation for EBTs;

(vi) Records related to the administration of the alcohol and drug testing programs; and

(vii) All follow-up tests and schedules for follow-up tests.

(2) You must keep records related to the alcohol and drug testing process, records of the inspection and maintenance (but not calibration) of EBTs, for two years.

(3) You must keep records of negative and canceled drug test results and alcohol test results with a concentration of less than 0.02 for one year.

(4) You must keep records related to the education and training of applicable

service agents, supervisors, and employees as long as the individual performs the functions which require the training and for two years after he or she ceases to perform those functions.

(5) You must keep signed statements of any agreements with service agents as long as the organization or individual performs functions under the DOT drug and alcohol testing program and for two years after it ceases doing so.

(b) You do not have to keep records related to a program requirement that does not apply to you (*e.g.*, a maritime employer who does not have a DOT-mandated alcohol testing program need not maintain alcohol testing records).

(c) You must maintain the records in a secure location with controlled access.

(d) A service agent may maintain these records for you. However, you must ensure that you can produce these records, at your principal place of business, in the time required by the DOT agency. For example, as a motor carrier, when an FMCSA inspector requests your records, you must make sure that you can provide them within two working days.

Subpart Q—Roles And Responsibilities of Service Agents

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

(a) Yes. As an employer, you may use a service agent to perform the tasks needed to comply with DOT agency drug and alcohol testing regulations.

(b) As an employer, you are responsible for ensuring that the service agent you use performs these tasks in accordance with DOT agency regulations.

(c) If a consortium, third-party administrator, or other service agent fails to comply with DOT agency regulations, you as the employer are responsible for the noncompliance. A DOT agency can subject you to sanctions for the noncompliance of a consortium, third-party administrator, or any other service agent who works for you.

§ 40.343 May service agents impose requirements on employers that DOT agency regulations do not authorize?

As a service agent, you must not impose conditions or requirements on employers that DOT regulations do not authorize. For example, as a consortium or third-party administrator serving employers in the pipeline industry, you may not require employers to have provisions in their plans that RSPA regulations do not require.

§ 40.345 If, as a service agent, you fail to comply with DOT regulations, can employers use your services?

(a) As a service agent, employers are not permitted to use your services if, in providing these services, you fail to comply with DOT drug and alcohol testing requirements.

(b) If you do not comply, you are subject to proceedings under Subpart R of this part that can result in a directive to employers not to use your services.

§ 40.347 What functions can service agents perform with respect to selection for testing?

As a service agent, you may perform the following functions for employers concerning random selection and other selections for testing.

(a) You may operate random testing programs for employers and may assist (*e.g.*, contracting with labs or collectors, conducting collections) employers with other types of testing (*e.g.*, pre-employment, post-accident, reasonable suspicion, return-to-duty, and follow-up).

(b) You may combine employees from more than one employer or one transportation industry in a random pool if permitted by individual DOT agency regulations.

(1) If you combine employees from more than one transportation industry, you must ensure that the random testing rate is at least equal to the highest rate required by each DOT agency.

(2) Employees not covered by DOT agency regulations may not be part of the same random pool with DOT covered employees.

(c) You may assist employers in ensuring that follow-up testing is conducted in accordance with the schedule established by the SAP or MRO. However, you may not randomly select employees from a ''follow-up pool'' for follow-up testing.

§ 40.349 What requirements must a service agent implement concerning the use and confidentiality of information?

As a service agent, the following requirements apply to you with respect to the use and confidentiality of information.

(a) You may receive confidential information about employees (*e.g.*, individual test results) from an employer without the employees' written consent. You must follow the same confidentiality regulations as the employer with respect to the use and release of this information.

(b) You may receive and maintain all records concerning DOT drug and alcohol testing programs, including individual test results, both positive and negative, as well as SAP follow-up summary reports to employers.

(c) Where DOT agency regulations require employers to keep certain information in their own files (*e.g.*, for purposes of review during inspections), employers must do so, but you may also maintain copies of these records at the employer's direction.

(d) You may maintain information needed for operating a drug/alcohol program (*e.g.,* names of employees in random pools, random selection lists, copies of notices to employers of selected employees) on behalf of an employer.

(e) If you are either conducting or arranging for drug testing, the employer's copy of the CCF may pass through you to provide notice so that you know the employee's specimen has been collected. You must ensure that the document is forwarded immediately to the actual employer.

(f) You must follow all confidentiality and records retention requirements applicable to employers.

(g) You may not provide individual test results or other confidential information to another employer without a specific, written consent from the employee. For example, suppose you are a consortium that has employers X and Y as members. Employee Jones works for X, and has a drug or alcohol test result maintained for X by you. Jones wants to change jobs and work for Y. You may not inform Y of the result of a test conducted for X without obtaining specific, written consent from Jones. Likewise, you may not provide this information to Z, who is not a consortium member, without this consent.

(h) You may not use blanket consent forms authorizing the release of employee testing information.

(i) You must establish adequate confidentiality and security measures to ensure that confidential employee records are not available to unauthorized persons. This includes protecting the physical security of records, access controls, and computer security measures to safeguard confidential data in electronic data bases.

(j) You must permit DOT agency access to all facilities, files, records, and documents used in complying with DOT agency drug and alcohol testing regulations.

§ 40.351 What principles govern the interaction between MROs and other service agents?

As a service agent, the following principles govern your interaction with MROs:

(a) As a service agent you may provide MRO services to employers, directly or through contract, if you ensure that the provisions of §§ 40.101(a) and 40.125(a) are met.

(b) If you employ or contract for an MRO, the MRO must perform duties independently and confidentially. When you have a relationship with an MRO, you must structure the relationship in writing (e.g., through a contract) to ensure that this independence and confidentiality are not compromised. Specific means (including both physical and operational measures, as appropriate) to separate MRO functions and other service agent functions are essential.

(c) Only your staff who are actually under the day-to-day supervision and control of an MRO with respect to MRO functions may perform these functions. This does not mean that those staff may not perform other functions at other times. However, the designation of your staff to perform MRO functions under MRO supervision must be limited and not used as a subterfuge to circumvent confidentiality and other requirements of this part and DOT agency regulations. You must ensure that MRO staff operate under controls sufficient to ensure that the independence and confidentiality of the MRO process are not compromised.

(d) You may not act as an intermediary in the transmission of individual drug test results from the laboratory to the MRO. That is, the laboratory may not send results to you, with you in turn sending them to the MRO. For example, a practice in which results are transmitted from a laboratory to your computer system, and then assigned to an available MRO, is not permitted.

(e) You may not act as an intermediary in the transmission of negative and verified positive test results from the MRO to the actual employer. That is, the MRO may not send these results to you, with you in turn sending them to the actual employer. However, you may maintain individual test results after they are sent to the DER, and the MRO may transmit such results to you simultaneously with sending them to the DER.

(f) In exception to paragraph (e) of this section, you may receive positive results directly from the MRO, if you are authorized by a DOT agency's regulation to do so.

(g) Like other MROs, an MRO whom your service agent employs or contracts with must personally conduct verification interviews with employees who have tested positive and must personally make the decision concerning whether to verify a test as positive or negative. Your staff cannot perform these functions.

§ 40.353 What other limitations apply to the activities of service agents?

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

(a) You may not act as an intermediary in the transmission of individual positive alcohol test results from the BAT to the actual employer. That is, the BAT may not send such results to you, with you in turn sending them to the actual employer. However, you may maintain individual test results after they are sent to the DER, and the BAT may transmit such results to you simultaneously with sending them to the DER.

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

(c) You cannot make decisions to test an employee based upon reasonable suspicion, post-accident, return-to-duty, and follow-up determination criteria. These are non-delegable duties of the actual employer. You may, however, provide advice and information to employers regarding these testing issues and schedule required testing.

(d) You cannot make a determination that an employee has refused a drug or alcohol test. This is a non-delegable duty of the actual employer. You may, however, provide advice and information to employers regarding refusal-to-test issues.

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

(1) You are authorized by a DOT agency's regulation to do so; and

(2) You schedule a required test for an owner-operator and subsequently find out that he or she failed to show for the test.

(f) It is not your responsibility, but the actual employer's, to make sure that an employee who has tested positive for alcohol or drugs, or otherwise violated the DOT agency regulations, is removed from performance of safety-sensitive duties.

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

(h) You may not act as ''program manager'' in FAA and RSPA programs, which call for the employer itself to designate an individual within the company to manage the drug and alcohol testing program for the employer.

(i) You must continue to transmit laboratory statistical summaries to each actual employer.

(j) The limitations on SAP referrals (see § 40.299(b)) for education and/or treatment apply where SAPs are part of your organization or its services.

(k) Even if your organization is operated by or affiliated with a laboratory, you must ensure that laboratories receive only the appropriate CCFs. (This is because, under this part, it is not appropriate for laboratories to receive an individual's CCF and the BATF packaged or attached (*e.g.,* stapled) together, since this is inconsistent with the privacy and confidentiality of personally-identified test records.) You can comply with this requirement by, for example, establishing separate addresses for the receipt of CCFs and BATFs, respectively, or establishing procedures to separate alcohol and drug forms that arrive together.

Subpart R—Public Interest Exclusions

§ 40.361 What is the purpose of a public interest exclusion?

(a) The purpose of a public interest exclusion (PIE) is to protect employers from noncompliance with DOT drug and alcohol regulations resulting from the use of a service agent who fails or refuses to provide drug and alcohol testing-related services to DOT-regulated employers consistent with the requirements of this part. A PIE is also intended to protect employees from the consequences of services that do not meet DOT requirements. A PIE is a serious action used only in the public interest and not for the purposes of punishment.

(b) Nothing in this subpart precludes a DOT agency from taking other action authorized by its regulations with respect to service agents or employers that violate its regulations.

§ 40.363 In what circumstances does the Department issue a public interest exclusion concerning a service agent?

(a) The Department may issue a PIE concerning a service agent if the

Department determines that the service agent has failed or refused to provide drug or alcohol testing services to one or more DOT-regulated employers consistent with the requirements of this part.

(b) The Department also may issue a PIE concerning a service agent who has failed to cooperate with DOT agency representatives concerning inspections, complaint investigations, interviews, compliance and enforcement reviews, or requests for documents and other information.

§ 40.365 Who issues public interest exclusions on behalf of the Department?

The person responsible for issuing PIEs is the ODAPC Director, or her or his designee.

§ 40.367 Who initiates the public interest exclusion process?

(a) If a DOT agency official, an ODAPC official (other than the Director), or an official of the Office of Inspector General learns that a service agent may be failing or refusing to provide drug and alcohol testing-related services to DOT-regulated employers consistent with the requirements of this part, this official (the ''initiating official'') may investigate the matter.

(b) Initiating officials have broad discretion in deciding whether to take action on the basis of information concerning the conduct of a service agent. In exercising their discretion, initiating officials may take into account such factors as the seriousness of the alleged conduct of the service agent and the availability of agency resources to pursue the matter.

§ 40.369 Does a service agent have the opportunity to correct a problem before becoming subject to a public interest exclusion?

(a) If the initiating official determines that there is a reasonable basis for believing that the service agent is failing or refusing to provide drug and alcohol testing-related services to DOT-regulated employers consistent with the requirements of this part, the official issues a written correction notice to the service agent. This notice tells the service agent what changes it must make to ensure that its services to DOT-regulated employers are provided consistent with the requirements of this part.

(b) If the service agent makes and documents the changes set forth in the correction notice to the satisfaction of the initiating official within 60 days of the date the notice is received, the Department will not begin the process leading to a PIE. In this case, the Department sends a notice to the service agent that the matter is concluded.

(c) If the initiating official learns, in a matter concluded through a notice under paragraph (b) of this section, that the service agent has failed to implement satisfactory corrections, the initiating official may begin the process set forth in § 40.371. The initiating official does not issue a second correction notice in this case.

§ 40.371 How does the process leading to a public interest exclusion begin?

(a) If a service agent who receives a correction notice does not make and document the corrections set forth in the notice in a manner satisfactory to the initiating official within 60 days of receiving the notice, the initiating official sends a written notice to the service agent.

(b) The notice will include the following information:

(1) That the Department is considering issuing a PIE concerning the service agent;

(2) The reasons for believing that the service agent is not providing drug and/or alcohol testing services to DOT-regulated employers consistent with the requirements of this part;

(3) The consequences of the PIE that the Department is considering issuing and a proposed interval between the issuance of an exclusion and the first date on which the service agent may apply to end it; and

(4) That the service agent will have the opportunity to contest the issuance of a PIE, as provided in § 40.373.

§ 40.373 How does a service agent contest the issuance of a public interest exclusion?

(a) If, as a service agent, you receive a notice that the Department is considering issuing a PIE concerning you, you have the right to contest the issuance of the exclusion.

(b) Within 30 days of receiving the notice, you may submit a written response containing information and arguments contesting the issuance of a PIE. You submit this material to the Director. If you do not submit a written response contesting the issuance of the PIE within this time, the matter will proceed as an uncontested case.

(c) Within this same 30-day period, you may also request, in writing, an opportunity to meet with the Director or her or his designee, stating what material facts, if any, you believe are in dispute. If you do not submit such a written notice within this time, the matter will proceed as a case in which there are no material facts in dispute. The Director will grant your request for a meeting if she or he determines that there are any material facts in dispute. The meeting may be in person or a teleconference, at the option of the service agent.

(d) This opportunity to meet with the Director is informal. During the meeting, you may appear with a representative, submit documentary evidence, present witnesses, and confront any witnesses the initiating official presents.

(e) A transcribed record of the meeting will be made available to the service agent, at cost, upon the service agent's request.

§ 40.375 How does the Department make decisions in public interest exclusion matters?

(a) The initiating official acts as the proponent of issuing a PIE. The Director acts as a neutral decisionmaker.

(b) The initiating official bears the burden of proof, which is to demonstrate by a preponderance of the evidence that the service agent has failed or refused to perform drug and/or alcohol testing services as required by this part.

(c) In an uncontested case or a case in which there are no material facts in dispute, the Director makes her or his decision on the basis of all the information in the administrative record, including any submission by the service agent.

(d) In a case in which there are material facts in dispute, the Director makes written findings of fact. The Director makes her or his decision on the basis of the facts as found, together with any information and argument submitted by the service agent, and any other information in the administrative record (including any meeting between the Director and the service agent).

(e) The initiating official and the service agent, with the concurrence of the Director or her or his designee, may settle a PIE matter at any time before the issuance of the Director's decision.

(f) For purposes of judicial review under the Administrative Procedure Act, the Director's decision is a final administrative action of the Department.

§ 40.377 How does the Department notify service agents and employers about decisions on public interest exclusions?

(a) The Director provides a notice to the service agent concerning her or his decision on whether to issue a PIE. The notice includes the following elements:

(1) A reference to the notice that initiated the process (see § 40.371);

(2) A statement of the reasons for the decision; and

(3) When the Director issues a PIE, a statement of the first date on which the service agent may apply to end the exclusion.

(b) When the Director issues a PIE, she or he also issues a **Federal Register** notice, the text of which is posted on the Department's Web site. This notice includes the name of the service agent and other persons to which the exclusion applies (see § 40.379), the reason for the PIE, and the first date on which the service agent may apply to end the exclusion. This issuance constitutes notice to DOT-regulated employers that they may not use the service agent's drug or alcohol testing-related services. ODAPC also publishes a list in the **Federal Register** on a quarterly basis of those service agents who are currently the subject of PIEs.

(c) The Director notifies the DOT agencies of her or his decision.

§ 40.379 To whom does a public interest exclusion apply?

(a) A PIE applies to all the divisions and organizational elements of, and types of services provided by, the service agent, unless the Director limits the scope of the exclusion to one or more of those divisions, organizational elements, or types of services.

(b) A PIE may apply to any affiliate of the service agent, if the affiliate is specifically notified and given the opportunity to respond as provided by this subpart.

(c) A PIE applies to individuals who are officers, employees, directors, shareholders, partners, or other individuals associated with the service agent in the following circumstances:

(1) Conduct forming any part of the basis of PIE occurred in connection with the individual's performance of duties by or on behalf of the service agent; or

(2) The individual knew, had reason to know of, approved, or acquiesced in such conduct. The individual's acceptance of benefits derived from such conduct is evidence of such knowledge, acquiescence, or approval.

§ 40.381 What is the effect of a public interest exclusion?

(a) As an employer, you must not use a service agent that is covered by a PIE that the Director has issued under this subpart. If you do so, you are in violation of the Department's regulations.

(b) As an employer, you must stop using the services of a service agent concerning whom the Director has issued a PIE no later than 90 days after the Department has published the decision in the **Federal Register** and posted it on its Web site.

(c) This prohibition on using a service agent concerning whom the Director has issued a PIE applies to employers in all industries subject to DOT drug and alcohol testing regulations. For example, if the initiating office is the FAA, and the conduct forming the basis of the PIE pertains to the aviation industry, as an employer in another regulated industry (e.g., trucking, railroads, transit), you are also prohibited from using the service agent involved.

(d) The issuance of a PIE does not affect the validity of drug or alcohol tests conducted using the service agent involved before the issuance of the Director's decision or up to 90 days following its publication in the **Federal Register** and posting on the Department's Web site. For example, if the Department published a decision issuing a PIE concerning a service agent on September 1, all tests conducted using the service agent's services before September 1, and through November 30, would be valid for all purposes under DOT drug and alcohol testing regulations, assuming they met all other regulatory requirements.

(e) If you are a service agent concerning whom the Director has issued a PIE, you must, on the request of any employer covered by DOT drug and alcohol testing regulations, immediately transfer all records pertaining to that employer and its employees to the employer or to any service agent the employer designates.

§ 40.383 How long does a public interest exclusion stay in effect?

(a) A PIE remains in effect until the Director ends it.

(b) In each decision issuing a PIE, the Director designates the first date on which a service agent may apply to end its exclusion. This date shall be at least nine months but no more than five years from the date on which the Department publishes the exclusion in the **Federal Register** and posts it on its Web site.

(c) As a service agent concerning whom the Department has issued a PIE, you may apply to the Director at any time after this date, in writing, to end the exclusion. You must include documentation that supports a determination that the reasons for the issuance for the exclusion have been eliminated and all drug or alcohol testing-related services provided to DOT-regulated employers will be consistent with the requirements of this part.

(d) If the Director determines that the reasons for the issuance for the exclusion have been eliminated and all drug or alcohol testing-related services provided to DOT-regulated employers will be consistent with the requirements of this part, the Director issues a notice ending the exclusion.

(e) The Department will publish a notice ending an exclusion in the **Federal Register** and post it on the Department's Web site.

§ 40.385 What is the role of the Inspector General's office?

(a) An official of the DOT Office of Inspector General may act as the initiating official in a PIE proceeding.

(b) Any person may bring concerns about waste, fraud, or abuse on the part of a service agent to the attention of Office of Inspector General.

(c) In appropriate cases, the Office of Inspector General may pursue criminal or civil remedies against a service agent.

(d) The Office of Inspector General may provide factual information to other DOT officials for use in a PIE proceeding.

Appendix A to Part 40—DOT Standards for Urine Collection Kits

The Collection Kit Contents

1. Single-Use Plastic Collection Container

a. Must be large enough to easily catch and hold at least 55 mL urine voided from the body.

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

c. Must have a temperature strip providing graduated temperature readings 90°–100° F or 32°–38° C, that is affixed or can be affixed at a proper level on the collection container.

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

2. Plastic Specimen Bottles

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

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

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

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

e. Must be wrapped (with caps) together in a sealed plastic sack or shrink wrapping; or must be wrapped (with cap) individually in sealed plastic sacks or shrink wrapping; or must have peelable, sealed lid or other easily-visible tamper-evident system.

f. Must be leach-resistant.

3. Leak-resistant Plastic Bag

Must have two sealable compartments or pouches; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.

4. Plastic Bag Seal

a. Must be tamper-evident.

b. Must have pre-printed space for the collector's initials and the date of the collection.

5. Shipping Container

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

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

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

Appendix B to Part 40—DOT Drug Testing Semi-annual Laboratory Report

The following items are required on each report:
Reporting Period: (inclusive dates)
Laboratory Identification:
Employer Identification:
C/TPA Identification: (where applicable)

1. Number of specimen results reported: (total number) By test type:
(a) Pre-employment testing: (number)
(b) Post-accident testing: (number)
(c) Random testing: (number)
(d) Reasonable suspicion/cause testing: (number)
(e) Return-to-duty testing: (number)
(f) Follow-up testing: (number)
(g) Type not noted on CCF: (number)

2. Number of specimens reported as Negative: (total number)

3. Number of specimens reported as Test Not Performed: (total number) By reason:
(a) Fatal Flaw/Uncorrected Flaw: (number)
(b) Specimen Unsuitable: (number)
(c) Specimen Rejected for Testing: (number)
(d) Specimen Adulterated: (number)
(e) Specimen Substituted: (number)

4. Number of specimens reported as Positive: (total number) By drug:
(a) Marijuana Metabolite: (number)
(b) Cocaine Metabolite: (number)
(c) Opiates:
(1) Codeine: (number)
(2) Morphine: (number)
(3) 6–AM (number)
(d) Phencyclidine: (number)
(e) Amphetamines: (number)

Appendix C to Part 40—CCF Copies Needed for the MRO Review

I. Negative Laboratory Results

a. To initiate and complete the MRO's administrative review and report the test result to the employer, the MRO needs:

1. The original or a legible facsimile of the original MRO copy of the CCF, or if not available, a legible copy of any copy of the CCF signed by the employee; *and*

2. A legible facsimile of the original laboratory copy of the CCF, or the original laboratory copy of the CCF, or the electronically-transmitted laboratory report.

b. Laboratories sending an electronically-transmitted report must also follow-up by sending a legible facsimile of the original laboratory copy or the original laboratory copy of the CCF. Upon receiving this laboratory copy of the CCF, MROs must match it with the MRO copy.

II. All Other Laboratory Results

a. To initiate the MRO review, the MRO needs:

1. The original or a legible facsimile of the original MRO copy of the CCF; or if not available, a legible copy of any copy of the CCF signed by the employee; *and*

2. A legible facsimile of the original laboratory copy of the CCF, the original laboratory copy of the CCF, or the electronically-transmitted laboratory report.

b. To complete the MRO review and report the result to the employer, the MRO needs:

1. The original or a legible facsimile of the original MRO copy of the CCF; or if not available, a legible copy of any copy of the CCF signed by the employee; *and*

2. A legible facsimile of the original laboratory copy or the original laboratory copy of the CCF.

III. Employee Inability to Provide Requisite Amount of Urine at the Collection Site

To report the result (i.e., refusal to test or canceled test) to the employer, the MRO needs:

1. The original or a legible facsimile of the original MRO copy of the CCF; *and*

2. The examining physician's report documenting whether the employee had a legitimate medical (i.e., physiological or psychological) reason for the inability to provide a complete urine specimen.

IV. Employee Refusals to Test at the Collection Site

To advise the employer, the MRO needs the original or a legible facsimile of the original MRO copy of the CCF that documents the on-site refusal (e.g., employee leaves collection site prior to providing specimen) to test.

Appendix D to Part 40—DOT Drug Testing MRO Reporting Summary

A. Bottle A Lab Report:

	MRO Reporting Action
1. Negative	The MRO reports the negative result to the employer.
2. Negative Dilute	The MRO reports the negative result to the employer and informs the employer that the next time the employee is selected for a drug test the employer may require the specimen to be collected under direct observation.
3. Positive	a. If the MRO verifies the test as positive, the MRO reports the positive result to the employer. b. If the MRO ''downgrades'' the test, the MRO reports the negative result to the employer.
4. Positive Dilute	a. If the MRO verifies the test as positive, the MRO reports the positive result to the employer and informs the employer that the next time the employee is selected for a drug test the employer may require the specimen to be collected under direct observation. b. If the MRO ''downgrades'' the test, the MRO reports the negative result to the employer and informs the employer that the next time the employee is selected for a drug test the employer may require the specimen to be collected under direct observation.
5. Test Not Performed—Fatal Flaw or Uncorrected Flaw.	The MRO reports the result to the employer as canceled and the reason for cancellation. Certain tests—pre-employment, return-to-duty, and follow-up tests—requiring a negative result, must be recollected.
6. Test Not Performed—Specimen Unsuitable.	a. If the employee provides an acceptable explanation and/or a prescription, the MRO reports to the employer that the test is canceled and the reason for cancellation. Certain tests—pre-employment, return-to-duty, and follow-up tests—requiring a negative result, must be recollected. b. If the employee is unable to provide an acceptable explanation and/or a prescription, but denies having adulterated the specimen, the MRO reports to the employer that the test is canceled and the reason for cancellation. The MRO shall also inform the employer that an immediate collection under direct observation of another specimen is required of the employee and that no advanced notice is to be given the employee.[1]

	MRO Reporting Action
7. Test Not Performed—Specimen Rejected for Testing.	a. If the MRO determines that the specimen is rejected for testing due to collector error, the MRO reports the result to the employer as canceled and the reason for cancellation. The MRO shall also inform the employer that an immediate collection of another specimen is required of the employee and that no advanced notice is to be given the employee. This collection is not to be collected under direct observation. b. If the MRO determines that collector error is not the cause of the specimen being rejected for testing, the MRO reports to the employer that the test is canceled and the reason for cancellation. The MRO shall also inform the employer that an immediate collection under direct observation of another specimen is required of the employee and that no advanced notice is to be given the employee.
8. Test Not Performed—Specimen Adulterated/Substituted.	The MRO reports to the employer that the test was either adulterated or substituted and is, therefore, a ''refusal to test.'' [2]
B. Bottle B Lab Report:	
1. Reconfirmed	The MRO reports the reconfirmation to the employer and to the employee.
2. Failure to Reconfirm—Drug/Drug Metabolite Not Detected.	The MRO reports to the employer and to the employee that both tests must be canceled. The MRO also reports the failure to reconfirm to the ODAPC.
3. Failure to Reconfirm—Specimen Adulterated/Substituted.	The MRO reports to the employer and to the employee that the specimen was adulterated or substituted and that this constitutes a ''refusal to test.'' The ''refusal to test'' becomes the final, single result for both tests.
4. Test Not Performed	The MRO reports to the employer and the employee that both tests must be canceled and the reason for cancellation. The MRO shall also inform the employer that an immediate collection under direct observation of another specimen is required of the employee and that no advanced notice is to be given the employee.

[1] For a ''test not performed specimen unsuitable'' lab result, if the employee admits to adulterating or substituting a specimen, the result will be a ''refusal to test.''

[2] The employee cannot have the ''split'' specimen tested following an adulterated or substituted test result.

Appendix E to Part 40—Report Format for Split Specimen Failure to Reconfirm

Fax or mail to: Department of Transportation, Office of Drug and Alcohol Policy and Compliance 400 7th Street, SW., Washington, DC 20590, (fax) 202 366–3897.

1. MRO name, address, phone number, and fax number.
2. Collector name, address, and phone number.
3. Date of collection.
4. Specimen I.D. number.
5. Laboratory accession number.
6. Primary specimen laboratory name, address, and phone number.
7. Date specimen received.
8. Split specimen laboratory name, address, and phone number.
9. Date split specimen received.
10. Drug present in primary specimen.
11. Reason for failure to reconfirm as reported by the laboratory (e.g., drug not present, specimen unsuitable for testing, split not collected, insufficient volume).
12. Action taken by MRO.

Appendix F to Part 40—SAP Equivalency Requirements for Certification Organizations

1. Experience: Minimum requirements are for three years' full-time supervised experience or 6,000 hours of supervised experience as an alcoholism and/or drug abuse counselor. The supervision must be provided by a licensed or certified practitioner. Supervised experience is important if the individual is to be considered a professional in the field of alcohol and drug abuse evaluation and counseling.

2. Education: There exists a requirement of 270 contact hours of education and training in alcoholism and/or drug abuse or related training. These hours can take the form of formal education, in-service training, and professional development courses. Part of any professional counselor's development is participation in formal and non-formal education opportunities within the field.

3. Continuing Education: The certified counselor must receive at least 40—60 hours of continuing education units (CEU) during each two year period. These CEUs are important to the counselor's keeping abreast of changes and improvements in the field.

4. Testing: A passing score on a national test is a requirement. The test must accurately measure the application of the knowledge, skills, and abilities possessed by the counselor. The test establishes a national standard that must be met to practice.

5. Testing Validity: The certification examination must be reviewed by an independent authority for validity (examination reliability and relationship to the knowledge, skills, and abilities required by the counseling field). The reliability of the exam is paramount if counselor attributes are to be accurately measured. The examination passing score point must be placed at an appropriate minimal level score as gauged by statistically reliable methodology.

6. Measurable Knowledge Base: The certification process must be based upon measurable knowledge possessed by the applicant and verified through collateral data and testing. That level of knowledge must be of sufficient quantity to ensure a high quality of SAP evaluation and referral services.

7. Measurable Skills Base: The certification process must be based upon measurable skills possessed by the applicant and verified through collateral data and testing. That level of skills must be of sufficient quality to ensure a high quality of SAP evaluation and referral services.

8. Quality Assurance Plan: The certification agency must ensure that a means exists to determine that applicant records are verified as being true by the certification staff. This is an important check to ensure that true information is being accepted by the certifying agency.

9. Code of Ethics: Certified counselors must be pledged to adhering to an ethical standard for practice. It must be understood that code violations could result in de-certification. These standards are vital in maintaining the integrity of practitioners. High ethical standards are required to ensure quality of client care and confidentiality of client information as well as to guard against inappropriate referral practices.

10. Re-certification Program: Certification is not just a one time event. It is a continuing privilege with continuing requirements. Among these are continuing education, continuing state certification, and concomitant adherence to the code of ethics. Re-certification serves as a protector of client interests by removing poor performers from the certified practice.

11. Fifty State Coverage: Certification must be available to qualified counselors in all 50 states and, therefore, the test must be available to qualified applicants in all 50 states. Because many companies are multi-state operators, consistency in SAP evaluation quality and opportunities is paramount. The test need not be given in all 50 states but should be accessible to candidates from all states.

12. National Commission for Certifying Agencies (NCCA) Accreditation: Having NCCA accreditation is a means of demonstrating to the Department of Transportation that your certification has been reviewed by a panel of impartial experts that have determined that your examination(s) has met stringent and appropriate testing standards.

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