

## **Noteworthy Substantive Changes Proposed** **Comments by Don Rothschild, MA, CEAP, C-SAPA** **Member of DATIA Board of Directors**

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, Sec. 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 Sec. 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.***

**Comment: "Service agent" is about right. It's all-encompassing, not to be confused with TPA, contractor, or other specifically defining terms.**

### 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 Sec. 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).***

**Comment: Collection is the weakest link in the chain of this process. Such formal training as offered by DATIA is appropriate and preferable to “self-instruction” which is currently available, and generally glossed over by the new collector. However, the requirement to “complete three consecutive error-free collections may suffice.**

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.***

**Comment: What could be worse than an incompetent trainer? There must be a standard for “sufficiently knowledgeable”. DATIA’s CPCT is one standard. Others could be hours of experience or written exam.**

#### Drug Testing Forms and Materials

The NPRM proposes (Secs. 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 (Sec. 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?).***

**Comment: The collector is the individual using the forms. The collector must understand this Part 40, written in English, as well as all other mandates pertaining to this process. If they do not read or understand English well enough to understand the regulation, why bother to use a foreign language form?**

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?***

**I'm not sufficiently knowledgeable on this subject to offer comment.**

#### 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 (Secs. 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?***

**Comment:** Failure to cooperate with the collector may be logically considered the same as refusal, even though the employee may take the stance "you can't make me drink". It is the employee's choice, as is an outright refusal.

**It has been my specific experience that with RTD (Denver Metro Transit system) drivers that their 3-hour wait is an opportunity to rest and relax, while allowing union brethren the opportunity to work in their stead.**

#### Directly Observed and Monitored Collections

In Secs. 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.***

**Comment:** If the dilute sample is the result of adulteration (diluting from bathroom plumbing or a container brought in from outside the collection site), this is the result of an incorrectly performed collection. The collector needs retraining and conditions at the collection site need to be modified to meet code. Observed collection under these conditions should never be necessary if procedure is followed.

***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.

**Comment:** It is entirely appropriate for such a sample to be rejected and to have the employee retested ASAP.

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 Sec. 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 (Sec. 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.***

### **Not qualified to comment.**

For the first time, laboratories would be required to test for nitrites, pH, creatinine and, in certain circumstances, specific gravity (Sec. 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 (Secs. 40.151 and 40.177).

**Comment: It has been my experience that adulteration is rare in programs that are properly administered, in that employees do not have an opportunity to “plan ahead”. Regardless, adulteration may, indeed be a problem that can and should be addressed. The cost of such tests should be a factor in this decision.**

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 (Secs. 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.***

**Comment: Rejected samples, in effect, negate the test, and result from errors in the procedure, not on the part of the employee providing the specimen. Therefore, having submitted the specimen in good faith, there should be no second collection of a rejected specimen.**

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?***

**Comment:** It is important that the Department stress the need for accepted standards of propriety and the elimination any conflict of interest between the separate entities involved in this process. Furthermore, the more items that are specifically enumerated, the more likely that loopholes and unstated items will arise. It is far better to simplify the content of the rule to state merely that conflicts of interest are prohibited.

The requirement should be meaningful and enforceable under the respective Codes of Ethics of the professional associations governing both the MROs and the laboratory administrators. It would be, again, within the accepted standard of practice for the laboratory to maintain a list of MROs to whom this applies without so stating in this document.

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:	Initial Testing:
1. Number of samples received for 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:	Confirmatory Testing:
2. Number confirmed positive for:	1. Number received for
A. marijuana metabolites.....	2. Number confirmed positive for:
B. cocaine metabolite.....	A. marijuana metabolites.
C. opiate metabolites.....	B. cocaine metabolite.
D. phencyclidine.....	C. opiate metabolites.
E. amphetamines.....	D. phencyclidine.
	E. amphetamines.
	F. methamphetamines.

3. Number for which test was not performed.

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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.

**Comment: All statistical information collected at the lab is of interest to the employers in confirming the accuracy of both records and in doing analyses of information for program studies.**

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

**Comment: This should be a question left to the legal profession.**

#### 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 (Sec. 40.103). Parties with fewer than 2000 DOT covered employees would no longer have to provide blind specimens (Sec. 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.

**Comment: There will always be a need for some blind sampling method to ensure confidence in the lab. However in my five years of submitting them has never shown an error. I believe the blind sample rates may be lowered for the convenience of the system, but not eliminated.**

The laboratory should have its own method of quality assurance on adulterant testing.

#### 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 (Sec. 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 (Sec. 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?***

**Comment:** I can personally see neither the appearance nor the reality of a conflict of interest in the ownership and/or administration of a collection site by an MRO. The MRO is always bound to the ethical standards of their profession.

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

**Comment:** Although the employee may sometimes not be reached except for weekends or holidays, the process is made to assure the employee of due process. Therefore, for the benefit of the process, time frames should be expressed in "business 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?***

**No comment.** This is a question applicable to the ethics of the medical profession, not me.  
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 Sec. 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 Sec. 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 (Sec. 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.***

**Comment:** Except when an employee is on an extended period of leave or vacation, 14 ranges between appropriate and too long. The general standard of practice in business is ten days. It should work in this case also.

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 (Sec. 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 Sec. 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.***

**Comment:** This appears to be a legal question regarding confronting one's accuser.

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?***

**Comment:** This requires a scientific judgment outside of my purview.

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 (Sec. 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.***

**Comment:** This would be the equivalent of a "Handicapped" parking permit, and should be entirely appropriate in order to save the time and trouble of the shy bladder drill.

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, Sec. 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 Secs. 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 (Sec. 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. Sec. 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 Sec. 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.

**Comment: This sounds like the best of all possible options, giving the employee a sense of protection without the expense and time loss in proceeding with a full test of the split.**

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.

This is outside of my purview of expertise.

***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?***

**Comment:** It should not be necessary to make such a requirement for the reasons in the Department's First Option, as stated above. The test is not confirmed to be a positive and does not need to be verified.

***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?***

**Comment:** Same as I have stated previously. The detection of adulterants needs to be part of the laboratory's quality assurance program, and administered on an ongoing basis.

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)?***

**Comment:** Too technical for me.

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" (Secs. 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?***

**Comment: Please see my previous remarks of dilute specimens.**

#### 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.***

**Comment: I concur with the current rules, at least for the small organizations served by our consortium because of the possible stigmatization of employees as drug users in cases when positive laboratory results are later downgraded.**

***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.***

**Comments: These are the kinds of questions that arise from the stand-down!**

**But if we do this, the employee may perform non-safety sensitive duties.**

**The pay status should be the same as the job they perform during the stand-down.**

**Limitation of information stimulates rumors and further stigmatization.**

**Confidentiality is not maintained for any organizations served by the consortium for small businesses.**

**Small businesses have the most to lose if drug-affected employees are still on the job during verification. The MRO should use due diligence in performing this function.**

**The stand-down is probably best used in owner-operator businesses, and should, in this case be mandated.**

We also point out that, in addition to the proposed alternative language in Secs. 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.

#### No additional comments here.

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 (Sec. 40.177(d)). ***The Department also seeks comment on whether (as proposed at Sec. 40.183(d)(4)) there should be a retest under direct observation when a split specimen is unavailable for testing.***

**Comment:** A retest is fine, but does not serve the purpose of the split specimen; that is, was the first sample shown to be a false positive. A retest will merely test the individual on a different date.

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?***

**Comment:** The purpose of the split sample is to protect the employee from the possibility of a false positive result from the laboratory. There is no reason that this protection should not be offered to those working in other OAs. The procedures should, therefore, be uniform throughout the Department, causing less errors and confusion by employers covered by multiple rules. Let's keep it simple.

#### ``Problem'' Drug Tests

The NPRM would spell out the circumstances in which an employee's actions are considered to be a refusal to test (Sec. 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 (Sec. 40.201). This portion of the proposed rule also notes the effect of a canceled test (Sec. 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 (Sec. 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)?***

**Comment: It would be more efficient if, indeed, the language required the employer to “select” the physician. It may also be assumed that the employer would be smart enough to find an appropriately qualified practitioner.**

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.***

**Comment: I’m not sure what the question was! But if this was about a physician evaluation the “insufficient breath” problem, there is always the alternative saliva test without the expense of a medical exam for shy breath.**

#### 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 (Sec. 40.213(a)(3), new requirements for test site security (Sec. 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 (Sec. 40.241) and clarifications concerning the timing of confirmation tests (Sec. 40.251). There are updated sections on “fatal flaws” and “correctable flaws,” and how to correct the latter (Sec. 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 (Sec. 40.245) adequately describe how these devices work, or whether we should modify this language.***

#### Comments:

**The QA plans for the EBTs are necessary and useful, just as blind tests are useful for the laboratories. We must always be assured that the instrument is operating effectively. The current requirements do not need to be changed in my opinion.**

**The current form is adequate, but could be simplified just as the Custody & Control Form was.**

**As far as I’m concerned, the saliva device rules seem to be working just fine.**

#### 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 (Sec. 40.281(c)). (Comment: Good) The NPRM also clarifies the role of the employer, employee, and SAP in the return-to-duty process (Secs. 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 (Secs. 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 (Secs. 40.307 and 40.309). Finally, the NPRM lists the items that must be included in SAP reports on employee evaluations (Sec. 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?***

**Comment:** I am an SAP (CEAP), having practiced assessment and referral of drug/alcohol-affected individuals for over twelve years, and haven't the faintest knowledge of any exact correlation between specific quantity of metabolites in the system and appropriate treatment venues. Nor have I seen any in the literature. This would only provide the "little knowledge" leading to dangerous conclusions.

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.***

**Comment:** My rule is four during the first six months and two the following during six. If it is truly random, the habitual offender will surely be caught. The gradual, but methodical, lengthening of the period between tests lessens cost to the employer while keeping the user ever vigilant.

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 (Sec. 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 (Sec. 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 (Sec. 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 license 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?***

**Comment:** I stand firmly behind Jeff Smith (DATIA) and his specific position that it is quite appropriate for consortium operators act as intermediaries for such reporting. We have been doing this for years, having the earned trust and personal relationship with our client members. They expect this type of service.

To resolve a dilemma that some MROs have faced, Sec. 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.***

**Comment:** For the purpose of public safety (the whole purpose this regulation) any and all employers of a drug/alcohol-affected employee should be notified, and the employee removed from any and all safety-sensitive functions until the SAP's recommendations be fulfilled and the employee tests clean. This information should be place in a universally accessible database available to all employers covered by DOT rules. This has nothing to do with personal privacy; it has to do with public safety (yours and mine).

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)?***

**Comment:** The NTSB investigation should be focused solely upon the specific incident, just as in the criminal justice system; each case is tried on its own merits. Other test data may be relevant to the individual's suitability for employment in a safety-sensitive position according to DOT regulations and organization policy statements, but this is no business of NTSB. They aren't Big Brother yet.

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?***

**Comment:** Same as the question to the MROs above. Same answer - create a universal database to report all users. Their name should be removed upon completion of SAP recommendations, presentation of a clean test and return to duty.

#### 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?***

**Comment:** There should be no conflicts of interest between those involved in the testing process, and I truly believe that the respective professional organizations to which these professionals belong should be the watchdog for the respective profession, just as AMA, MROCC AAMRO, and ABA do for the doctors and lawyers, so should DATIA, SAPAA and the professional toxicology association monitor the ethics of their members. All offenses should be reported to their Review Boards.

#### 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 Sec. 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.***

**Comment: Inasmuch as this is all new and I'm not a lawyer, I don't have much of a comment. But I believe the objective is good, and the process seems thorough.**

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