PART 40 QUESTIONS AND ANSWERS

§40.159 [Medical Review Officer – pH Issue] 07/08

QUESTION:

During periods of hot weather, how may Medical Review Officers (MROs) handle laboratory results reported as invalid because of pH greater than or equal to 9.0 but less than or equal to 9.5?

ANSWER:

• Part 40 requires an MRO to provide an employee the opportunity to present a medical explanation for an invalid test result, to include any related to pH.

-- If the employee provides an acceptable medical explanation, the MRO is authorized to cancel the test and take no further action.

-- If there is no acceptable medical explanation, the MRO will cancel the test and will notify the employer or Designated Employer Representative (DER) to direct another collection under direct observation.

• The Department is aware of current research and studies offering evidence that, over time, heat may cause the pH to rise, typically into the range of 9.0 through 9.3, but not higher than 9.5. [See, for example, "Urine pH: the Effects of Time and Temperature after Collection," Journal of Analytical Toxicology, Vol. 31, October 2007.]

• Consequently, when an employee has no other medical explanation for the pH in the 9.0 - 9.5 range, MROs should consider whether there is evidence of elapsed time and increased temperature that could account for the pH value.

• In doing so, MROs are authorized to consider the following:

-- The temperature conditions that were likely to have existed between the time of collection and transportation of the specimen to the laboratory; and

-- The length of time between the specimen collection and arrival at the laboratory.

• MROs may talk with the collection sites to discuss time and temperature issues, including any pertinent information regarding specimen storage.

• If the MRO determines that time and temperature account for the pH value, the MRO is authorized to cancel the test and take no further action.

• If the MRO determines that time and temperature fail to account for the pH value, the MRO is authorized cancel the test and direct another collection under direct observation.

§40.193 **07/08**

QUESTION:

Are there any circumstances for which an employee should be given more than 3 hours and 40 ounces of fluids to provide a sufficient amount of urine during a collection?

ANSWER:

• No. The Department sees no situations for which an employee should be given more than 3 hours and offered more than 40 ounces of fluids to provide a sufficient amount of urine after the "first unsuccessful attempt" to do so [see §40.193(b)(4)].

• The Department regards the "first unsuccessful attempt" to be very first time the employee comes out of the urination area with less than 45 mL of urine.

• This is true about the "first unsuccessful attempt" even if a subsequent attempt during the three-hour period requires an immediate collection under direct observation because the specimen is outside the appropriate temperature range or shows signs of tampering [see §40.65(b)&(c)].

• For example: An employee presents an insufficient amount of urine at noon and is urged by the collector to drink up to 40 ounces of fluid distributed through a period of up to 3 hours (3 o'clock, in this example).

-- At 2 o'clock, the employee indicates that he or she can now provide the specimen, enters the collection area, but returns with a specimen outside the acceptable temperature range.

-- The collector immediately conducts an observed collection, but the employee – for the second time during this collection event, which began at noon – provides less than 45 mL of urine.

-- The employee has up to 3 o'clock and any remaining fluids to provide an adequate amount of urine under direct observation: The employee is <u>not</u> given an additional three hours and is <u>not</u> offered an additional 40 ounces of fluids.

-- If the employee ultimately fails to provide a sufficient amount of urine during the remaining time, the collector discontinues the collection, discards any specimen the employee previously provided, appropriately documents the CCF, and immediately notifies the DER and the MRO – following the requirements at **§**40.193(b)(4) and (b)(5).

§40.193 **07/08**

QUESTION:

Must a test result be cancelled by the MRO when it is discovered the employee did not have a full three hours to provide a sufficient amount of urine?

ANSWER:

• Not affording the employee a full three hours to provide a specimen is not automatically a basis for the MRO to cancel a test.

• The three hour time period is a maximum rather a minimum. But, to avoid potential issues about the fairness of the collection, collectors are advised to provide the full three hours.

• In each of the following examples, the collector could stop the collection process, thoroughly document the details and times on Copy 2 of the CCF, and inform the DER of the employee's inability to provide a sufficient amount of urine:

-- After 2 hours and 50 minutes, the employee informs the collector there is no reason to try again because he or she will not be able to provide a specimen. The collector terminates the collection.

-- After 2 hours and 50 minutes, the employee requests to try again but provides another insufficient amount of urine. The collector terminates the collection because there is no practical possibility that the employee will provide the requisite amount in the next 10 minutes.

• In each of these two examples, the employee has had a fair opportunity to provide 45 mL of urine, and the test should not be cancelled because the full three-hour period was not used.

• The medical evaluation should be conducted to determine if there is a legitimate physiological condition or psychological disorder explanation for the employee's inability to provide the requisite amount of urine.

• In situations where it appears the employee was <u>not</u> provided a fair opportunity to provide the requisite amount of urine, the MRO could cancel the test.

-- For example, the collector terminates a collection after two hours because the collection site is closing and all collectors are leaving.

• Please note that it remains a refusal to test if the employee leaves the collection site without permission.

§40.225 **07/08**

QUESTION:

In addition to information needed for billing purposes, does DOT authorize other information to be included outside the boundaries of the Alcohol Testing Form (ATF)?

ANSWER:

• Yes. For record storage, tracking, and retrieval purposes, the DOT will permit other information, such as barcodes and tracking numbers, to be affixed or printed on the ATF.

General Issue Update **07/06**

QUESTION:

Are employers and their service agents in the Department of Transportation (DOT) drug and alcohol testing program required to obtain employee written authorizations in order to disclose drug and alcohol testing information?

ANSWER: HIPAA Statement

• In the DOT drug and alcohol testing program, employers and service agents are not required to obtain written employee authorization to disclose drug and alcohol testing information where disclosing the information is required by 49 CFR Part 40 and other DOT Agency & U.S. Coast Guard (USCG) drug and alcohol testing regulations. 49 CFR Part 40 and DOT Agency & USCG regulations provide for confidentiality of individual test-related information in a variety of other circumstances.

• Even if drug and alcohol testing information is viewed as protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules, it is not necessary to obtain employee written authorization where DOT requires the use or disclosure of otherwise protected health information under 49 CFR Part 40 or the other DOT Agency & USCG drug and alcohol testing regulations.

• Unless otherwise stipulated by 49 CFR Part 40 or DOT Agency & USCG regulations, use or disclosure of the DOT drug and alcohol testing information without a consent or authorization from the employee is required by the Omnibus Transportation Employees Testing Act of 1991, 49 CFR Part 40, and DOT Agency & USCG drug and alcohol testing regulations.

• Consequently, an employer or service agent in the DOT program may disclose the information without the written authorization from the employee under many circumstances. For example:

-- Employers need no written authorizations from employees to conduct DOT tests.

-- Collectors need no written authorizations from employees to perform DOT urine collections, to distribute Federal Drug Testing Custody and Control Forms, or to send specimens to laboratories.

-- Screening Test Technicians and Breath Alcohol Technicians need no written authorizations from employees to perform DOT saliva or breath alcohol tests (as appropriate), or to report alcohol test results to employers.

-- Laboratories need no written authorizations from employees to perform DOT drug and validity testing, or to report test results to Medical Review Officers (MROs).

-- MROs need no written authorizations from employees to verify drug test results, to discuss alternative medical explanations with prescribing physicians and issuing pharmacists, to report results to employers, to confer with Substance Abuse Professionals (SAPs) and evaluating physicians, or to report other medical information (see §40.327).

-- SAPs need no written authorizations from employees to conduct SAP evaluations, to confer with employers, to confer with MROs, to confer with appropriate education and treatment providers, or to provide SAP reports to employers.

-- Consortia/Third Party Administrators need no written authorizations from employees to bill employers for service agent functions that they perform for employers or contract on behalf of employers.

-- Evaluating physicians need no written authorizations from employees to report evaluation information and results to MROs or to employers, as appropriate.

-- Employers and service agents need no written authorizations from employees to release information to requesting Federal, state, or local safety agencies with regulatory authority over them or employees.

§40.21 **07/06**

QUESTION:

If an employee fails to provide a sufficient amount of urine during an observed collection, can an employer remove the employee from performing safety-sensitive functions pending receipt of the verified result from the Medical Review Officer (MRO)?

ANSWER:

• The Department believes an employee's failing to provide a sufficient amount of urine during a directly observed collection is very similar to a laboratory's reporting a positive, adulterated, or substituted test result to MRO.

• While we do not believe it is appropriate for an employer to remove the employee from safety-sensitive duties until receiving the MRO's verified result, we think stand-down waiver provisions could be relevant.

• Therefore, employers can apply for a stand-down waiver that would permit the employee to be removed from safety-sensitive duties when he or she does not provide an adequate amount of urine during an observed collection.

• The waiver request would need to meet all criteria outlined at 40.21 and should reference the fact that it is for standing an employee down who fails to provide an adequate amount of urine during an observed collection.

• The 40.21 waiver request for laboratory positive, adulterated, and substituted results will continue to be evaluated separately.

40.141 **07/06**

QUESTION:

Is a Medical Review Officer (MRO) permitted to accept an employee's prescription for medication obtained over the Internet?

ANSWER:

• An MRO is authorized to accept an employee's prescription for medication obtained over the Internet only if there is proof that a legitimate doctor-patient relationship had been established.

• The following four elements generally serve as an indication that a legitimate doctor-patient relationship has been established:

-- A patient has a medical complaint;

-- A medical history has been taken;

-- A physical examination has been performed; and

-- Some logical connection exists between the complaint, the medical history, the physical examination, and the drug prescribed.

• Standing alone, the completion of an online questionnaire reviewed later by a pharmacy-employed doctor fails to establish a proper doctor-patient relationship.

• The MRO should, at a minimum, consider the following items when verifying the test result:

-- The name, physical location, and state(s) of licensure of the prescribing practitioner;

-- Whether the employee was professionally evaluated for the current medical complaint by the prescribing practitioner, and the last time the employee was in direct contact with the prescribing practitioner;

-- Whether the employee initiated the request to the pharmacy for a particular medication; and

-- Whether a proper doctor-patient relationship existed.

• It is the employee's responsibility to provide sufficient documentation to address MRO inquiries as to whether there was a legitimate doctor-patient relationship.

40.191 **07/06**

QUESTION:

What are some examples of an employee's failure to cooperate with the testing process that would cause a refusal to test and how should the collector handle them?

ANSWER:

• Part 40 highlights two examples of failure to cooperate – the employee refuses to empty pockets when instructed to do so; and the employee behaves in a confrontational way that disrupts the testing process.

• Among others are:

-- The employee fails to wash his or her hands after being directed to do so by the collector.

-- The employee admits to the collector that he or she adulterated or substituted the specimen; and

-- The employee is found to have a device – such as a prosthetic appliance – the purpose of which is to interfere with providing an actual urine specimen.

• When the issue is a problem with refusing to following instructions – for example, refusing to empty pockets or refusing to wash hands – or if there is a confrontation, the collector should warn the employee of potential consequences of a failure to cooperate; and if practical, seek assistance from the DER or supervisor to ensure that the employee understands the ramifications.

• When the issue is admission of adulteration or substitution or when a device is found, there is no need for the collector to warn the employee or to seek assistance from the DER or supervisor.

• In every case, the collector must carefully follow the procedures at 40.191(d) by terminating the collection process, immediately notifying the DER of the refusal, and thoroughly documenting the circumstances surrounding the event in the remarks section of the CCF.

• Any specimen that had been collected before the refusal should be discarded.

§40. 25 **06/04**

QUESTION:

Will FMCSA- and FAA-regulated employers complying with the drug and alcohol information records check requirements contained in the Federal Motor Carrier Safety Administration (FMCSA) regulation 49 CFR Part 391 and the Federal Aviation Administration (FAA) Pilot Record Improvement Act be considered compliant with 40.25?

ANSWER:

• Yes. Employers who are required by and who comply with the FMCSA's three-year requirement for obtaining and providing employee drug and alcohol testing information are considered to have satisfied the two-year requirement contained in 40.25.

• Likewise, employers who are required by and who comply with the FAA's five-year requirement for obtaining and providing employee drug and alcohol testing information are considered to have satisfied the two-year requirement contained in 40.25.

• These employers do not need to seek separately the 40.25 information if the employer adheres to the FMCSA and FAA regulations, as appropriate, for obtaining an employee's prior drug and alcohol testing information.

§40.187 **06/04**

QUESTION:

What must an MRO do when he or she determines that there is no split laboratory capable of testing the adulterant identified by the primary laboratory after the employee has asked for the split to be tested?

ANSWER:

• The Department views this situation as closely paralleling the MRO reporting requirement, at 40.187(d), when the split specimen is not available for testing after the

request to test the split is made by the employee. Therefore, the MRO needs to follow similar steps.

* The MRO must report to the employer that the specimen, "Failed to Reconfirm: Split Laboratory not Available for Testing."

* The MRO must also report to the DER and the employee that the test result must be cancelled and the reason for the cancellation.

* The MRO must direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice give to the employee of this collection requirement until immediately before the collection.

* Finally, the MRO must notify ODAPC of the failure to reconfirm.

• The result of the collection under direct observation will be the result of record for this testing event.

11//03

§40.25
QUESTION:

May the previous employer delay sending an employee's drug and alcohol testing information to the gaining employer pending payment for the cost of the information?

Answer:
• No. Part 40 specifically requires that previous employers immediately provide the gaining employer with the appropriate drug and alcohol testing information.

• No one (i.e., previous employer, service agent [to include C/TPA], employer information / data broker) may withhold this information from the requesting employer pending payment for it.

11/03

§40.159

QUESTION:

What does an MRO do when a drug test result is invalid due to "color discrepancy?"

ANSWER:

• If "Invalid – Color difference" is the only result reported to you, you must follow the guidance of §40.159 by contacting the laboratory to obtain more specific information about the color difference between the specimens, and contacting the donor to obtain a legitimate explanation for the color difference. While there is no legitimate medical reason for anyone being able to provide a specimen that separates into two different

colors when placed in two different bottles, the interview is necessary to determine appropriate follow-on action.

• You must determine whether the donor has provided you with a legitimate explanation for the color difference (e.g., the collector used two separate voids for the collection), or not (e.g., no clue as to how the colors changed by the time the specimens reached the laboratory).

• You must follow §40.159 for canceling the result, reporting the result to the employer, determining whether a recollection is necessary and, if so, should it be under direct observation.

• If the laboratory has also reported to you that the specimen is positive, adulterated, or substituted, then you must process the results in accordance with §40.129-131. If you determine (i.e., verify) the final result to be positive, adulterated, or substituted, then no additional action is required by you due to the color difference. You must not direct the employee to take another test.

• Notify the employer that the collector must receive "error correction training" as required by §40.33(f). The area of Part 40 in which the collector needs to be retrained is §40.65(a).

§40.25 **01/02**

QUESTION:

If an applicant admits to testing positive on or refusing to take a pre-employment test within the past two years, must the applicant be held out of safety-sensitive duties if he or she did not complete the return-to-duty process (i.e., the SAP process)?

ANSWER:

• If the applicant admits that he or she had a positive or a refusal to test result on a pre-employment test, the employer is not permitted to use the applicant to perform safety-sensitive duties until and unless the applicant documents successful completion of the return-to-duty process.

• This Part 40 requirement applies whether or not the pre-employment positive or refusal occurred before, on, or after August 1, 2001.

• Should no proof exist that the return-to-duty process was successfully complied with by the applicant, a current return-to-duty process must occur before the individual can again perform safety-sensitive functions.

§40.25 **01/02**

QUESTION:

When an employee leaves an employer for a period of time (but not exceeding two years) and returns to that same employer, must the employer once again seek to obtain information it may have received previously from other employers?

ANSWER:

- No. If the information received previously is still on file with the employer, the employer need not seek to obtain the testing data again.

- However, the employer must seek information from all other employers for whom the employee performed safety-sensitive duties since the employee last worked for the employer.

§§40.33; 40.121; 40.213; 40.281 **01/02**

QUESTION:

Because Part 40 requires collectors, MROs, BATs and STTs, and SAPs to maintain their own training records, can employers or training entities refuse to provide these service agents their training records?

ANSWER:

- No. Employers and trainers who provide training for these service agents must not withhold training documentation from them when they have successfully completed the training requirements.

- If a collector, BAT, STT, MRO, or SAP is not in possession of training documentation, he or she is in violation of Part 40.

- Therefore, Part 40 does not permit the withholding of such documentation from these service agents.

Pre-Employment Alcohol Testing **09/01**
Revised 03/10

QUESTION:

Can an employer wishing to conduct pre-employment alcohol testing, do so?

ANSWER:

- A DOT-regulated employer (except under USCG rules) wishing to conduct pre-employment alcohol testing under DOT authority may do so if certain conditions are met.

• The testing must be accomplished for all applicants (i.e., the employer cannot select for testing some applicants and not others) and the testing must be conducted as a post-offer requirement (i.e., the employer needs to inform the applicant that he or she has the job if he or she passes a DOT alcohol test).

• In addition, the testing and its consequences must comply with requirements of Part 40.

§40.3 **09/01**

QUESTION:

Can the employer himself or herself act as a Designated Employer Representative (DER), as opposed to appointing another employee to play this role?

ANSWER:

• The employer (e.g., the owner of a small business) may act personally as the DER.

• The employer may also appoint an employee or employees to play this role.

• The DER must exercise his or her authority to remove an employee from safety sensitive functions either directly or by causing the employee to be removed from performing these functions (e.g., by having the employee's supervisor effect the actual removal).

• The employer may not delegate the DER role to a service agent. Only the employer or an actual employee of the employer may perform this function.

• The Department will not authorize a "DER-for-hire" concept (e.g., a person under contract by several companies to serve as their DER), either.

§40.3; §40.15(d) **09/01**

QUESTION:

If a C/TPA is hired as an "independent safety consultant" that executes all aspects of the employer's safety and drug and alcohol testing programs, can the C/TPA act as a DER?

ANSWER:

• Service agents are prohibited from acting as DERs under any circumstances.

• The fact that an organization that is called an "independent safety consultant" acts as a consultant to an employer for purposes of executing a drug and alcohol testing or safety program does not make it any less a service agent. It is still prohibited from acting as a DER.

§40.21 **09/01**

QUESTION:

Can union hiring halls, driver-leasing companies, and other entities have a stand-down policy, or is the ability to obtain a waiver for this purpose limited to actual employers?

ANSWER:

• The rule permits "employers" to apply for a stand-down waiver. It does not permit any other entity to do so.

• Only entities that are viewed as "employers" for purposes of DOT agency drug and alcohol testing regulations can apply for stand-down waivers. If a DOT agency rule provides that hiring halls, leasing agencies, etc. are treated as employers, such organizations could apply for a stand-down waiver.

§40.21 **09/01**

QUESTION:

Does an employer need a stand-down waiver in order to implement a policy that requires employees to cease performing safety-sensitive functions following a reasonable suspicion or post-accident test?

ANSWER:

- §40.21 requires an employer to obtain a waiver to do one very specific thing: remove employees from performance of safety-sensitive functions on the basis of the report of confirmed laboratory test results that have not yet been verified by the MRO.

- An employer does not need a §40.21 waiver to take other actions involving the performance of safety-sensitive functions.

- For example, an employer could (if it is not prohibited by DOT agency regulations and it is consistent with applicable labor-management agreements) have a company policy saying that, on the basis of an event (e.g., the occurrence of an accident that requires a DOT post-accident test, the finding of reasonable suspicion that leads to a DOT reasonable suspicion test), the employee would immediately stop performing safety-sensitive functions. Such a policy, which is not triggered by the MRO's receipt of a confirmed laboratory test result, would not require a §40.21 waiver.

- It would not be appropriate for an employer to remove employees from performance of safety-sensitive functions pending the result of a random or follow-up test, since there is no triggering event to which the action could rationally be tied.

§40.25 **09/01**

QUESTION:

When an employer is inquiring about an applicant's previous DOT drug and alcohol test results, is the employer required to send the inquiry via certified mail?

ANSWER:

- No. Certified mail is not required.

- The employer can make this inquiry through a variety of means, including mail (certified or not), fax, telephone, or email.

- However, the employer must provide the former employer the signed release or a faxed or scanned copy of the employee's signed release.

• The former employer must respond via a written response (e.g., fax, letter, email) that ensures confidentiality.

• The employer should document an attempt or attempts to contact and contacts with previous employers, no matter how they were made, so that it can show a good faith effort to obtain the required information.

§40.25 **09/01**

QUESTION:

When a previous employer receives an inquiry from a new employer for drug and alcohol testing information, does the previous employer provide information it may have received from other employers in the past?

ANSWER:

• As an employer, when you receive an inquiry about a former employee, you must provide all the information in your possession concerning the employee's DOT drug and alcohol tests that occurred in the two years preceding the inquiry.

• This includes information you received about an employee from a former employer (e.g., in response to the Federal Motor Carrier Safety Administration's pre-employment inquiry requirement).

• It is not a violation of Part 40 or DOT agency rules if you provide, in addition, information about the employee's DOT drug and alcohol tests obtained from former employers that dates back more than two years ago.

• If you are an employer regulated by the FAA, this does not impact your requirements under the Pilot Record Act.

§40.33 **09/01**

QUESTION:

If a collector makes a mistake resulting in a cancellation of a test before he or she has obtained qualification training (e.g., in the period before January 31, 2003), does he or she have to obtain error correction training under §40.33(f)?

ANSWER:

- Yes. If a collector makes a mistake that causes a test to be cancelled, the collector must undergo error correction training (even if the collector has yet to undergo qualification training). There are no exceptions to this requirement.

§40.33 **09/01**

QUESTION:

A collector who is notified that he or she made a mistake has 30 days in which to obtain error correction training. Can the collector continue to perform DOT collections during this 30-day period?

ANSWER:

- Yes. A collector may continue to perform DOT collections during this period.

- After 30 days have elapsed following the notification to the collector of the need to obtain error correction training, the collector is no longer qualified to conduct DOT collections until and unless he or she has successfully completed error correction training.

- As provided in §40.209(b)(3), collection of a specimen by a collector who has not met training requirements does not result in the cancellation of the test, assuming the collection is otherwise proper. However, use of an unqualified collector can result in enforcement action.

§40.33 **09/01**

QUESTION:

Who is responsible for notifying a collector that error correction training is needed?

ANSWER:

- The MRO, in canceling a drug test, will determine if the collector is at fault.

• When the MRO reports the cancelled test to the employer, the MRO will note the reason for the cancellation and that, if appropriate, it was the result of collector error.

• The employer or service agent (e.g., MRO, C/TPA) designated by the employer is responsible for notifying the collection site of the error and the retraining requirement; and for ensuring that the training takes place.

§40.33 **09/01**

QUESTION:

Must collectors, BATs, STTs, MROs, and SAPs maintain documentation of meeting training requirements on their persons?

ANSWER:

• These individuals are responsible for maintaining documentation that they currently meet all training requirements (see, for example, §40.33(g)).

• However, they are not required to keep this documentation on their person.

• They must be able to produce this documentation within a short, reasonable time of a request by a DOT representative or an employer.

• Nothing precludes an organization (e.g., a collection site) from also maintaining a file of the training records of its personnel, if it wishes to do so.

§40.33 **09/01**

QUESTION:

What does the rule require with respect to the qualifications of persons who train collectors?

ANSWER:

• Part 40 does not specify any set of specific qualifications for persons who train collectors.

• The training must cover the items required by Part 40.

§40.33 **09/01**

QUESTION:

Does a person who monitors proficiency demonstrations as a part of collector qualification training have to be a qualified collector?

ANSWER:

• Yes. It is very important for persons who monitor mock collections to have a thorough "book" and practical knowledge of relevant DOT rules and procedures. It is also very important that, before determining whether trainees have successfully completed a proficiency demonstration, the monitor have experienced and successfully completed the same training that collectors have to undergo.

• Consequently, mock collection monitors have to meet collector qualification training requirements. In addition, the monitor must meet any one of three other requirements:

* The monitor can be a qualified collector who has regularly conducted DOT drug testing collections for a least a year before serving as a monitor; or

* The monitor can be a qualified collector who has had a "train-the-trainer" course. Such a course could include the mandatory elements of collector qualification training as well as instruction on how to conduct training effectively; or

* The monitor can be a qualified collector who has conducted collector training under Part 40 for at least a year before serving as a monitor.

• Monitors in the second and third categories do not need to practice actively as collectors, so long as they have met collector qualification requirements.

• Individuals acting as collectors prior to August 1, 2001, have until January 31, 2003, to meet qualification training requirements. In the meantime, such collectors can serve as monitors even though they may not have met the qualification and mock collection requirements (so long as they meet any one of the three other requirements).

§40.35; 40.45; 40.345 **09/01**

QUESTION:

How should the employer's decision to have a C/TPA act as intermediary in the handling of drug test results be documented?

ANSWER:

- When an employer chooses to use the C/TPA as the intermediary in the transmission of the MRO's verified drug test results, this decision should be communicated from the employer to the MRO and the C/TPA.

- We advise the MRO to obtain some documentation of the employer's decision prior to sending results through the C/TPA.

- Documentation could be in the form of a letter, an email, or record of a telephone conversation with the employer.

- DOT also recommends that MROs maintain listings of the names, addresses, and phone numbers of C/TPA points of contact.

§40.45 **09/01**

QUESTION:

May the MRO's address entered on the CCF be a post-office box number only?

ANSWER:

- No. The address must contain at least a number and street address.

- The reason for this requirement is that CCFs are often delivered by courier or messenger services who do not deliver items to post office box addresses.

- The post-office box can be included, but not in lieu of the number and street address.

§40.61 **09/01**

QUESTION:

May a DOT urine specimen be obtained via catheterization from a patient who is catheterized as part of a medical procedure or who is unconscious?

ANSWER:

- No one is ever permitted to obtain a urine specimen for DOT testing purposes from an unconscious individual, whether by catheterization or any other means.

- No one is permitted to catheterize a conscious employee for the purpose of collecting urine for a DOT drug test.

- However, if a person has been catheterized for medical purposes (e.g., a conscious, hospitalized patient in a post-accident test situation), it is permissible to use urine collected by this means for DOT testing purposes. All necessary documentation for a DOT collection must be provided (e.g., the CCF).

- In addition, an employee who normally voids through self-catheterization is required to provide a specimen in that manner.

§40.65 **09/01**

QUESTION:

Part 40 directs the collector to discard the first specimen if the temperature was out of range or the specimen showed signs of tampering and the employee refused to provide a second specimen under direct observation. The Urine Specimen Collection Guidelines [at Section 8, Directly Observed Collection, Number 7] indicate that, in such a situation, the first specimen should be retained and sent to the laboratory. Which requirement is correct?

ANSWER:

- When a specimen is out of temperature range or shows signs of tampering and the employee refuses to provide a second specimen under direct observation, it is considered a refusal to test. The collector does not retain the first specimen, but discards it.

- The requirement in the Urine Specimen Collection Guidelines, Version 1.0, to retain the specimen and send it to the laboratory, was inserted inadvertently.

- Urine Specimen Collection Guidelines, Version 1.01, contain the proper procedures as directed by 40.65.

§40.67; §40.69 **09/01**

QUESTION:

Can the monitor (or direct observer) of a collection be a co-worker or immediate supervisor of the employee?

ANSWER:

- The immediate supervisor of a particular employee may not act as the collector when that employee is tested, unless no other collector is available and the supervisor is permitted to do so under a DOT operating administration's drug and alcohol regulation.

- The immediate supervisor may act as a monitor or observer (if same gender) if there is no alternate method at the collection site to conduct a monitored or observed collection.

- An employee who is in a safety-sensitive position and subject to the DOT drug testing rules should not be a collector, an observer, or a monitor for co-workers who are in the same testing pool or who work together with that employee on a daily basis.

§40.73; §40.193 **09/01**

QUESTION:

What is the preferred method for the collector to get the MRO copy of the CCF to the MRO?

ANSWER:

- The promptness of reporting suffers when the mail is used to convey the MRO copy from the collection site.

- Even though we permit other means (e.g., overnight courier service) of transmitting MRO copies from the collection site to the MRO, collectors should fax the MRO copies when possible.

- If the faxed copy is not legible, the MRO must request another faxed copy or a hard copy.

§40.97; §40.209 **09/01**

QUESTION:

After the laboratory reports a test result, someone (e.g., the employer, a service agent) discovers that the CCF listed the wrong reason for the test (e.g., the CCF says the test was a pre-employment test when it was actually a random test). How is this corrected and by whom?

ANSWER:

- This is another example of an error that does not have a significant adverse effect on the right of an employee to have a fair and accurate test (see §40.209).

- The test is not cancelled as the result of such a mistake.

- While concerned parties may wish to correct the faulty description of the reason for the test, Part 40 does not require a correction to be made.

- Employers or their designated service agents should ensure that appropriate changes are documented (e.g., for MIS reporting purposes).

§40.103 **09/01**

QUESTION:

Requirements for submitting quarterly blind specimens to the laboratory went into effect mid-quarter, August 1, 2001. How are the new requirements for blind sample submission to be calculated? Are the blinds for July, 2001 to be calculated on the old Part 40 regulations and August and September, 2001 blind calculations based on new Part 40 regulations?

ANSWER:

- It is acceptable to send in blind specimens for July 2001, based on the requirements of the old Part 40 and for August-September based on the new Part 40 that went into effect August 1, 2001.

§40.103; §40.99; §40.333 **09/01**

QUESTION:

What are the retention requirements for blind specimens and records of blind specimen tests?

ANSWER:

- Laboratories, employers and other parties required to retain specimens and records of tests should retain blind specimens and records of blind specimen tests in exactly the

same way and for the same periods of time as they do actual employee specimens and test records.

• For example, an employer would keep a record of a blind positive test for five years and a blind negative test for two years.

• Laboratories would keep blind specimens for negatives in accordance with their SOPs and non-negatives for one year.

§40.127 **09/01**

QUESTION:

How should the MRO's review of negative results processed by the MRO's staff take place?

ANSWER:

• The MRO's personal review of the MRO's staff work (to include the CCFs, lab results documentation, corrective documents, and results reports to employers) should be spread throughout the quarter.

• Even if the MRO has reviewed the required 500 per quarter, the MRO must still review all those that needed corrective actions.

• The MRO need not review a sampling from all employers or transportation industries he or she serves.

• The MRO must provide documentation of the CCF quality assurance review to DOT agency representatives regardless of their DOT agency affiliation (e.g., an FRA inspector can obtain and review documents generated from an FAA-sanctioned test). Part 40 is a One-DOT effort.

§40.131 **09/01**

QUESTION:

Must an MRO use the full 24-hour period to contact the donor if the MRO is sure that the donor is not and will not be available at the phone numbers provided by the donor?

ANSWER:

• 40.131(a)(1) states that if the phone numbers provided by the donor are wrong, an MRO may contact the DER to inform the donor to contact the MRO without waiting the full 24 hours.

• If the MRO discovers that phone numbers provided by the donor will not permit the MRO to contact the donor within the 24-hour period, the MRO may contact the DER immediately. For example, the MRO may discover that the employee is not expected to be available for another five days at the number provided.

§40.149 **09/01**

QUESTION:

Can arbitrators change or overturn the MRO's determination about the verification of a test result?

ANSWER:

• No. The MRO is the only person authorized to change a verified test result (see §40.149(c)). The MRO can do so with respect to a verification decision he or she has made, in the circumstances described in §40.149.

• An arbitrator is someone who derives his authority from the employer, or from a labor-management agreement. The arbitrator cannot exercise authority that the employer could not exercise on its own. The arbitrator could not overturn a decision of the MRO concerning a test verification any more than the employer could on its own.

• This prohibition applies to substantive decisions the MRO makes about the merits of a test (e.g., with respect to whether there is a legitimate medical explanation for a positive, adulterated, or substituted test result or whether a medical condition precluded an individual from providing a sufficient specimen).

• An arbitrator could determine that a test result should be cancelled because of a defect in the drug testing process involving the MRO (e.g., that the MRO failed to afford the employee the opportunity for a verification interview). But an arbitrator could not overturn the substantive judgment of the MRO about whether, for example, the information submitted by the employee constituted a legitimate medical explanation.

General Issue Update **07/06**

QUESTION:

Are employers and their service agents in the Department of Transportation (DOT) drug and alcohol testing program required to obtain employee written authorizations in order to disclose drug and alcohol testing information?

ANSWER:

• In the DOT drug and alcohol testing program, employers and service agents are not required to obtain written employee authorization to disclose drug and alcohol testing information where disclosing the information is required by 49 CFR Part 40 and other DOT Agency & U.S. Coast Guard (USCG) drug and alcohol testing regulations. 49 CFR Part 40 and DOT Agency & USCG regulations provide for confidentiality of individual test-related information in a variety of other circumstances.

• Even if drug and alcohol testing information is viewed as protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules, it is not necessary to obtain employee written authorization where DOT requires the use or disclosure of otherwise protected health information under 49 CFR Part 40 or the other DOT Agency & USCG drug and alcohol testing regulations.

• Unless otherwise stipulated by 49 CFR Part 40 or DOT Agency & USCG regulations, use or disclosure of the DOT drug and alcohol testing information without a consent or authorization from the employee is required by the Omnibus Transportation Employees Testing Act of 1991, 49 CFR Part 40, and DOT Agency & USCG drug and alcohol testing regulations.

• Consequently, an employer or service agent in the DOT program may disclose the information without the written authorization from the employee under many circumstances. For example:

-- Employers need no written authorizations from employees to conduct DOT tests.

-- Collectors need no written authorizations from employees to perform DOT urine collections, to distribute Federal Drug Testing Custody and Control Forms, or to send specimens to laboratories.

-- Screening Test Technicians and Breath Alcohol Technicians need no written authorizations from employees to perform DOT saliva or breath alcohol tests (as appropriate), or to report alcohol test results to employers.

-- Laboratories need no written authorizations from employees to perform DOT drug and validity testing, or to report test results to Medical Review Officers (MROs).

-- MROs need no written authorizations from employees to verify drug test results, to discuss alternative medical explanations with prescribing physicians and issuing pharmacists, to report results to employers, to confer with Substance Abuse Professionals (SAPs) and evaluating physicians, or to report other medical information (see §40.327).

-- SAPs need no written authorizations from employees to conduct SAP evaluations, to confer with employers, to confer with MROs, to confer with

appropriate education and treatment providers, or to provide SAP reports to employers.

-- Consortia/Third Party Administrators need no written authorizations from employees to bill employers for service agent functions that they perform for employers or contract on behalf of employers.

-- Evaluating physicians need no written authorizations from employees to report evaluation information and results to MROs or to employers, as appropriate.

-- Employers and service agents need no written authorizations from employees to release information to requesting Federal, state, or local safety agencies with regulatory authority over them or employees.

§40.149; §40.209 **09/01**

What is an employer to do if an arbitrator's decision claims to overturn the result of a DOT drug or alcohol test on grounds contrary to DOT regulations?

ANSWER:

• There could be instances in which an arbitrator makes a decision that purports to cancel a DOT test for reasons that the DOT regulation does not recognize as valid.

• For example, the arbitrator might make a decision based on disagreement with an MRO's judgment about a legitimate medical explanation (see §40.149) or on the basis of a procedural error that is not sufficient to cancel a test (see §40.209).

• Such a test result remains valid under DOT regulations, notwithstanding the arbitrator's decision. Consequently, as a matter of Federal safety regulation, the employer must not return the employee to the performance of safety-sensitive functions until the employee has completed the return to duty process.

• The employer may still be bound to implement the personnel policy outcome of the arbitrator's decision in such a case. This can result in hardship for the employer (e.g., being required to pay an individual at the same time as the Department's rules prevent the individual from performing the duties of his job).

§40.163 **09/01**

QUESTION:

Is it acceptable for an MRO to transmit a number of reports of drug test results per page to the employer, rather than one per page?

ANSWER:

• The Department recommends that MROs use Copy 2 of the CCF as the means of reporting all drug test results to employers.

• However, if you use a written report (all results) or an electronic report (negative results) meeting all the requirements of §40.163, rather than using Copy 2 of the CCF for this purpose, you must put only one such report on each page. This will help to prevent inadvertent breaches of confidentiality by the employer resulting from photocopying a multiple-result report and putting a copy in the file of each employee involved.

§40.163 **09/01**

QUESTION:

If the MRO uses a written report instead of a copy of the CCF to report results to employers, how should those reports be signed?

ANSWER:

- The MRO must sign all reports of non-negative results (i.e., positives, refusals, tests canceled, and invalids).

- The MRO or an MRO's staff member may rubber stamp and initial negative results. The rubber stamp should identify the MRO.

- Each written report should be dated and indicate the address of the MRO.

§40.191; §40.193 **09/01**

QUESTION:

Do collectors sign the CCF in situations in which a urine specimen is not provided during a collection (i.e., a refusal to provide a specimen; a shy bladder situation)?

ANSWER:

- In any such case, the collector would check the box in Step 2 of the CCF indicating that no specimen was provided and enter an explanatory remark.

- The collector would then provide his or her name and signature in Step 4 of the CCF.

- The employee's name and phone number should be included on the MRO copy.

- The collector would then transmit the CCF copies to the appropriate parties (e.g., employer, MRO).

§40.193; §40.43 **09/01**

QUESTION:

Generally, only one collector is supposed to supervise a collection for an employee. However, given the time span involved, it is possible that two collectors could be involved in a shy bladder collection (e.g., because of a shift change during the three-hour period between the first and second collection attempts). How should this be handled?

ANSWER:

• In this situation, it is permissible for one collector to turn the process over to another collector to complete the collection.

• The first collector would document the start time for the 3-hour period. The second would provide his or her name and signature after the second collection, as the collector of record. The Remarks line (Step 2 of the CCF) would be used to document the transition (including the first collector's name and the start time for the shy bladder procedure).

§40.197 **09/01**

QUESTION:

May an employer have a policy of declining to hire applicants who have a negative dilute test result on a pre-employment drug test?

ANSWER:

• The Department's rules do not require an employer to hire anyone. That decision is an employer's.

• While §40.197(b) authorizes an employer to obtain one additional test following a negative dilute result (in pre-employment or other testing situations), a negative dilute test result is a valid negative test for DOT's purposes.

• Because a negative dilute test result is a negative test for DOT program purposes, the employer is authorized to have the applicant begin performing safety-sensitive functions.

• If the employer declines to hire the applicant in this situation, the employer's decision is based solely on its own policy. The employer cannot claim that its action is required or authorized by DOT rules.

§40.203 **09/01**

QUESTION:

If a collector makes an error on a CCF and the collector is not available to sign a corrective statement (e.g., collector on vacation, no longer with the company), can the collector's supervisor sign the corrective statement for the collector?

ANSWER:

• If the error was the use of a non-DOT form (to include use of the old Federal CCF), the collector or the collector's supervisor may sign the corrective statement explaining the circumstances of why a non-DOT form was used.

• If the missing information is the printed name and signature of the collector, neither the collector nor the supervisor may supply the missing information. This is a fatal, uncorrectable flaw.

• If the CCF contains the printed name of the collector, but the signature is missing, the collector or the collector's supervisor may attest that that collector performed the collection, but did not sign his or her name.

• If the employee's signature is omitted and there is no notation in the "Remarks" line, only the collector can provide the corrective statement. The collector's supervisor cannot sign the corrective statement.

§40.243; §40.253; §40.275; Appendix G **09/01**

QUESTION:

Is it acceptable to affix printed alcohol test results on the back of the Alcohol Testing Form (ATF) rather than on the front?

ANSWER:

• §40.243(f) and §40.253(g) instruct the BAT to affix the printout of the information from the alcohol testing device to the designated space on the ATF.

• The designated space on the ATF is on the front of the form. That is where BATs and STTs should affix the printouts.

• However, because the instructions on the ATF also permit the printout to be affixed to the back of the ATF, the Department has no objections to having the printouts on the back of the ATF.

§40.291; §40.293 **09/01**

QUESTION:

Suppose the SAP fails to make the required recommendation for education and/or treatment of an employee who has violated a DOT agency drug or alcohol testing rule, and simply sends the employee back to the employer for a return-do-duty (RTD) test. What is the employer to do?

ANSWER:

- The employer should not administer an RTD test under these circumstances.

- The employer should refer the employee back to the SAP with direction to prescribe education and/or treatment and conduct a re-evaluation of the employee to determine whether the employee has successfully complied with the SAP's instructions.

- If the employer has compounded the problem by having conducted the RTD test and returned the employee to safety-sensitive duties (i.e., only realizes that a mistake has been made some time after the fact), the employer should work with the SAP to "go back and do it right."

- This means that the employee should be removed from performance of safety-sensitive functions, referred back to the SAP for an education and/or treatment prescription, and re-evaluated by the SAP for successful compliance. Following the receipt of a successful compliance report from the SAP, the employer would conduct another RTD test before returning the employee to performance of safety-sensitive functions.

§40.311 **09/01**

QUESTION:

What is meant by "SAP's own letterhead?"

ANSWER:

- By "SAP's own letterhead" we mean the letterhead the SAP uses in his or her daily counseling practice.

- If the SAP is in private practice, the SAP should use the letterhead of his or her practice.

- If the SAP works as an employee assistance professional for an organization, the SAP should use the employee assistance program's letterhead.

• If the SAP works for a community mental health service, the SAP should use the community mental health service's letterhead.

• The Department wants to avoid a SAP network provider requiring the SAP to use the provider's letterhead rather than that of the SAP.

• The Department wants to avoid another service agent contracting the SAP's services to require the contracted SAP to use the service agent's letterhead.

• The Department wants to avoid any appearance that anyone changed the SAP's recommendations or that the SAP's report failed to go directly from the SAP to the employer.

• The Department does not want the SAP to use a "fill-in-the-blanks" / "check-the-appropriate-boxes" type of pre-printed form, including any that are issued to the SAP by a SAP network provider, to which the network or SAP would affix the SAP's letterhead information.

• The SAP must generate and complete all information on the SAP report.

§40.327 **09/01**

QUESTION:

If an MRO knows the identity of a physician responsible for determining whether a DOT-regulated employee is physically qualified to perform safety-sensitive duties (e.g., under Federal Motor Carrier Safety Administration regulations for physical qualifications of motor carrier drivers) for another company, can the MRO report drug test result as well as medical information to that physician?

ANSWER:

• Under §40.327(a), an MRO must report drug test results and medical information to third parties without the employee's consent, under certain circumstances spelled out in the rule.

• Under §40.327(b), a physician responsible for determining the medical qualifications of an employee under an applicable DOT agency safety regulation is a party to whom the MRO is instructed to provide this information.

• Consequently, if an MRO knows the identity of such a physician – even if the physician performs this function for a different employer – the MRO would provide the information. The MRO is not required to affirmatively seek out such physicians, however.

§40.333 **09/01**

QUESTION:

When records are stored and transferred electronically, how should they be made available to DOT representatives?

ANSWER:

- The obligations of employers and service agents to make records available expeditiously to DOT representatives apply regardless of how the records are maintained.

- All records must be easily and quickly accessible, legible, and formatted and stored in a well-organized and orderly way.

- If electronic records do not meet these criteria, then the employer or service agent must convert them to printed documentation in a rapid and readily auditable way.