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

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## Preamble Language & Other Interpretive Guidance From Q &A's Urine Specimen Collection Guidelines & SAP Guidelines

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## For FRA and State Inspectors Formatted by 49 CFR PART 40 Sections

**Federal Railroad Administration**
**September 2006**

| PART 40<br>SUBPART A - ADMINISTRATIVE PROVISIONS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.3**<br>**Definitions** | **What do the terms used in this regulation mean?** | |
| Alcohol Use | Does not include use of an "inhaler" that contains alcohol nor the use of rubbing alcohol applied topically. | Final Rule Pg. 79482 |
| Chain of Custody | Is not intended to require the MRO to examine the internal lab chain of custody. [See 40.123 (b)(1)] | Final Rule Pg. 79483 |
| DER | An employer can designate as many DERs as it needs to carry out its program effectively. | Final Rule Pg. 79483 |
| | **Can the employer himself or herself act as a Designated Employer Representative as opposed to appointing another employee to play this role?** | |
| DER | - The employer (e.g., the owner of a small business) may act personally as the DER.<br>- The employer may also appoint an employee or employees to play this role.<br>- 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).<br>- 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.<br>- The Department will not authorize a "DER-for-hire" concept (e.g., a person under contract by several companies to serve as their DER). | ODAPC Q & A 09/01 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **If a C/TPA is hired as an "independent safety consultant" that executes all aspects of the employer's safety & drug and alcohol testing programs, can the C/TPA act as a DER?** | |
| DER | - Service agents are prohibited from acting as DERs under any circumstances.<br>- 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 & alcohol testing or safety program does not make it any less a service agent. It is still prohibited from acting as a DER. | ODAPC Q & A 09/01<br><br>See also 40.15 (d) |
| **40.5 Interpre-tations** | **Who issues authoritative interpretations of Part 40?** | |
| Web site | Interpretations issued after August 1, 2001 will be posted on the ODAPC web site (www.dot.gov/ost/dapc). They apply to the text of the rule as applied to the facts of the situation. DOT will work closely with the OAs to ensure consistency with Part 40 and the modal regulations such as Part 219. | Final Rule Pg. 79483 |
| MRO Manual | The Department will publish additional guidance pertaining to the new Part 40 in an MRO manual (the old manual is obsolete). | Final Rule Pg. 79483 |
| **40.7 Exemption** | **How can you get an exemption from a requirement in Part 40?** | |
| | An exemption is not the same thing as a waiver and only OST has the authority to grant exemptions from Part 40. In cases where DOT agency regulations impose more stringent requirements, it might be necessary to obtain an exemption from the additional DOT agency provision as well as from a Part 40 provision. | Final Rule Pg. 79483 |

| PART 40<br>SUBPART B - EMPLOYER RESPONSIBILITIES | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.13**<br>**DOT tests** | **How do DOT drug & alcohol tests relate to non-DOT tests?** | |
| (b)<br>Batches | This does NOT mean that labs must process DOT & non-DOT specimens in separate batches. | Final Rule<br>Pg. 79484 |
| (c)(d)<br>Physical Exams | Since FRA does not require physical exams, it is NOT permissible to use any remaining urine from a DOT test for a physical exam. [see 40.71 (b)(8)] | Part 219 & Lamar's E-mail |
| (e)<br>Other tests | - As with DNA testing, the result of a second urine test or a blood test obtained independently is invalid. | Final Rule<br>Pg. 79484 |
| (f)<br>Labs<br>Forms | - An employer may use the same laboratory for both DOT and non-DOT testing.<br>- Inadvertent use of non-Federal forms for a DOT test should be a correctable flaw. [see 40.47 (a)(b)] | Final Rule<br>Pg. 79484 |
| **40.15**<br>**Service agents** | **May an employer use a service agent to meet DOT drug & alcohol testing requirements?** | See also 40.3 - DER |
| (c)<br>Labs | Even though DOT relies on HHS for lab certification, labs have responsibilities independent of HHS, and must be accountable to DOT in those matters. | Final Rule<br>Pg. 79484 |
| **40.21**<br>**Stand-down** | **May an employer stand down an employee before the MRO has completed the verification process?** | |
| (c)(1)<br>Waiver request | - These are not prerequisites for a waiver to be granted. An organization doesn't have to be a particular size, have an in-house MRO, or had an accident...<br>- Petitions for waivers will be considered on a company-by-company basis. DOT agencies will not, for example, consider a petition from a trade association or C/TPA on behalf of an industry or segment of an industry. | Final Rule<br>Pg. 79485<br><br>Pg. 79465 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| (c)(1)(iii) Stand-down policy | If a waiver is granted, each employee subject to stand-down must receive an individual copy of the policy. Posting on bulletin boards or web sites is not sufficient. | Final Rule Pg. 79485 |
| (c)(2)(ii) Supervisor notification | The employee's supervisor must not be told the reason for the removal from covered service. It is sufficient that the supervisor be given a general explanation (e.g., medical qualification reasons, personnel evaluation reasons). | Final Rule Pg. 79485 |
| (c)(2)(iii) Job category | Means broad, inclusive categories of employees (e.g., a railroad granted a waiver could elect to stand-down only locomotive engineers which wouldn't include train conductors) rather than narrower subsets of employee categories that might be used for pay or personnel purposes. | Final Rule Pg. 79485 |
| (c)(2)(iv) Covered service | If the employee is scheduled to be in non-safety-sensitive service (e.g., training or personal leave), the carrier would take no action, nor notify his/her supervisor since he/she would not be performing covered service during the 5-day verification period. | Final Rule Pg. 79485 |
| | **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?** | |
| Employers | - The rule permits "employers" to apply for a stand-down waiver. It does not permit any other entity to do so.<br>- Only entities that are viewed as "employers" for purposes of DOT agency drug & 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. | ODAPC Q & A 09/01 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **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?** | |
| RS or PAT | - 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.<br>- An employer does not need a 40.21 waiver to take other actions involving the performance of safety-sensitive functions.<br>- For example, an employer could (if it is not prohibited by DOT agency regulations & 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.<br>- 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. | ODAPC Q & A 09/01 |

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| After a shy bladder | 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 MRO?<br><br>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 lab's reporting a positive, adulterated, or substituted test result to MRO.<br><br>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.<br><br>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.<br><br>The waiver request would need to meet all criteria outlined at 40.21 & 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.<br><br>The 40.21 waiver request for lab positive, adulterated, & substituted results will continue to be evaluated separately. | ODAPC Q & A 7/06 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| **40.25 Record Check** | **Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?** | |
| | **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 compliance with 40.25?** | |
| | - 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.<br>- 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.<br>- 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. | ODAPC Q & A 06/04 |
| | **When an employer is inquiring about an applicant's previous DOT drug & alcohol test results, is the employer required to send the inquiry via certified mail?** | |
| Certified Mail | - No. Certified mail is not required.<br>- The employer can make this inquiry through a variety of means, including mail (certified or not), fax, telephone, or email.<br>- However, the employer must provide the former employer the signed release or a faxed/scanned copy of the employee's release.<br>- The former employer must respond via a written response (e.g., fax, letter, email) that ensure confidentiality.<br>- The employer should document an attempt or attempts to contact & contacts with previous employers, no matter how they were made, so that it can show a good faith effort to obtain the required information. | ODAPC Q & A 09/01 |

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| | **When a previous employer receives an inquiry from a new employer for drug & alcohol testing information, does the previous employer provide information it may have received from other employers in the past?** | |
| Two years | - 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 & alcohol tests that occurred in the two years preceding the inquiry.<br>- This includes information you received about an employee from a former employer (e.g., in response to the FMCSA's pre-employment inquiry requirement).<br>- It is not a violation of Part 40 or DOT agency rules if you provide, in addition, information about the employee's DOT drug & alcohol tests obtained from former employers that dates back more than two years ago.<br>- If you are an employer regulated by the FAA, this does not impact your requirements under the Pilot Record Act. | ODAPC Q & A 09/01 |
| | **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)?** | |
| Pre-employment | - 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.<br>- This Part 40 requirement applies whether or not the pre-employment positive or refusal occurred before, on, or after August 1, 2001.<br>- 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. | ODAPC Q & A 01/02 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **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?** | |
| Leaves & returns | - No. If the information received previously is still on file with the employer, the employer need not seek to obtain the testing data again.<br>- 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. | ODAPC Q & A 01/02 |
| DOT agency can take action | The OST General Counsel's Office and ODAPC find nothing in 49 CFR Part 40 prohibiting DOT and the DOT Agencies from taking necessary actions to have employers remove employees from performance of safety sensitive duties when it is determined that the employees did not comply with the return to duty process of Subpart O after violating DOT drug & alcohol regulations. DOT and the DOT Agencies are tasked with promoting & taking actions to ensure the safety of the traveling public. Therefore, if a DOT Agency determines that an employee has not satisfied Subpart O requirements & is performing safety sensitive duties, it has an obligation to take action. Part 40, to include Subpart P [the confidentiality & release of information section], in no way precludes a DOT Agency from taking appropriate action (e.g., notifying any employer for whom the employee is performing safety-sensitive duties) to have the employee cease performance of safety sensitive duties. | ODAPC guidance issued at DOT modal meeting on 7/26/06 |

| PART 40<br>SUBPART C - URINE COLLECTION PERSONNEL | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.31 Collectors** | **Who may collect urine specimens for DOT drug testing?** | |
| (c) Supervisors | FRA does NOT allow supervisors to act as the collector for their employees. "The supervisor who makes the determination that reasonable suspicion exists may not conduct testing on that employee." [See 40.211 for alcohol] | 219.300 (b)(1) |
| Co-workers | An employee who is in a safety-sensitive position & subject to the DOT testing rules should not be a collector, 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. This is to preclude any potential appearance of collusion or impropriety. | Urine Specimen Collection Guidelines Pg. 4 |
| Self | The employee may not be the collector of his or her own urine specimen. (See Urine Specimen Collection Guidelines, Pg. 5) | |
| Relation | To avoid a potential conflict of interest, a collector should not be someone that is related to the employee (e.g., spouse, ex-spouse, relative) or a close personal friend (e.g., fiancee). | Collection Guidelines Pg. 5 |
| **40.33 Training** | **What training requirements must a collector meet?** | |
| (a) Basic information<br>(b) Qualification training | - The basic information training can be provided through classroom sessions, videos, internet courses, etc. In-person involvement of a trainer is NOT required for this part of the training process.<br>- There is no requirement that urine collectors be "certified." (See Urine Specimen Collection Guidelines, page 4) | Final Rule Pg. 79471 |
| | **What does the rule require with respect to the qualifications of persons who train collectors?** | |
| (b) Qualification training | - Part 40 does not specify any set of specific qualifications for persons who train collectors.<br>- The training must cover the items required by Part 40. | ODAPC Q & A 09/01 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **Does a person who monitors proficiency demonstrations as a part of collector qualification training have to be a qualified collector?** | |
| (c) Proficiency demonstra-tion | - Yes. It is very important for persons who monitor mock collections to have a thorough "book" & practical knowledge of relevant rules & procedures. It is also very important that, before determining whether trainees have successfully completed a proficiency demonstration, the monitor have experienced & successfully completed the same training that collectors have to undergo.<br>- Consequently, mock collection monitors have to meet collector qualification training requirements. In addition, the monitor must meet any one of three other requirements:<br>* The monitor can be a qualified collector who has regularly conducted DOT drug testing collections for at least a year before serving as a monitor; or<br>* 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<br>* 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.<br>- Monitors in the second & third categories do not need to practice actively as collectors, so long as they have met collector qualification requirements.<br>- 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 & mock collection requirements (so long as they meet any one of the three other requirements). | ODAPC Q & A 09/01 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **Is error correction training required if a drug test is cancelled due to a specimen having an insufficient amount of urine?** | |
| (f) Error-correction training | - If the laboratory finds there is an insufficient amount of urine in the primary bottle for analysis, the lab will report to the MRO that the specimen is "rejected for testing" (unless the lab can redesignate the specimens). Subsequently, the MRO must cancel the test.<br>- The MRO should seek to determine (with the assistance of the lab) if the specimen leaked in transit or if not enough urine was collected.<br>- Specimen leakage while in transit to a lab will not cause a cancellation requiring the collector to have error correction training.<br>- If the lab finds no evidence of leakage, indications would be strong that the collector failed to collect the appropriate amount of urine. If this were the case, the collector would need error correction training.<br>- If the specimen leakage is a recurrent problem for a collection site, the MRO may be wise to inquire whether or not the shipping containers used are sufficient to adequately protect the specimens or whether or not collectors are securing the bottle lids properly. | ODAPC Q & A 01/02 |
| | **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)?** | |

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| (f)<br>Error correction training | - 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. | ODAPC Q & A 09/01 |
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| | **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?** | |
| (f)<br>Error correction training<br>- 30 days | - Yes. A collector may continue to perform DOT collections during this period.<br>- 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.<br>- 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. | ODAPC Q & A 09/01 |
| | **Who is responsible for notifying a collector that error correction training is needed?** | |

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| (f)<br>Error correction training - notification | - The MRO, in canceling a drug test, will determine if the collector is at fault.<br>- 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.<br>- 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. | ODAPC Q & A 09/01 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **Must collectors, BATs, STTs, MROs, and SAPs maintain documentation of meeting training requirements on their persons?** | |
| (g) Documenta-tion | - These individuals are responsible for maintaining documentation that they currently meet all training requirements (see, for example 40.33 (g)).<br>- However, they are not required to keep this documentation on their person.<br>- They must be able to produce this documentation within a short, reasonable time of a request by a DOT representative or an employer.<br>- 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. | ODAPC Q & A 09/01 |
| | **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?** | |
| (g) Withholding of documen-tation | - 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.<br>- If a collector, BAT, STT, MRO, or SAP is not in possession of training documentation, he or she is in violation of Part 40.<br>- Therefore, Part 40 does not permit the withholding of such documentation from these service agents. | ODAPC Q & A 01/02 |
| **40.35 DERs** | **What information about the DER must employers provide to collectors?** | See also 40.345 |
| DERs | An employer can designate as many DERs as it needs to carry out its program effectively | Final Rule Pg. 79483 |

| PART 40<br>SUBPART D - COLLECTION SITES, FORMS, EQUIPMENT & SUPPLIES USED IN DOT URINE COLLECTIONS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.41**<br>**Site** | **Where does a urine collection for a DOT drug test take place?** | |
| (e)<br>Full-length privacy door | This means a door that is both opaque (can't see through) and solid. For example, a glass door, a door with a window or other means of viewing the interior of the room from outside, or a curtain is NOT adequate. Nor would it be appropriate to have a video camera or microphone monitoring the room. | Final Rule Pg. 79487 |
| (f)<br>Multi-stall | Aural (hearing) privacy is no longer a requirement. | Final Rule Pg. 79488 |
| Collector's work area | The collector's work area may be located outside the restroom. However, if there is no appropriate space available outside the restroom to serve as a secure, clean work area and the restroom is either a multi-stall facility or a single stall facility with a partial door for privacy, and is large enough to accommodate a work area, the collector may locate the work area inside the restroom as long as all procedures for a monitored collection are met. | Urine Specimen Collection Guidelines Pg. 6 |
| Mobile facility | All types of restrooms including a mobile facility (e.g., a vehicle with an enclosed toilet) are acceptable. | Collection Guidelines Pg. 5 |
| **40.43** | **What steps must operators of collection sites take to protect the security and integrity of urine collection?** | |
| Collector shift change | See 40.193 interpretation for documentation of two collectors during a shy bladder situation. | |
| Unauthorized personnel | Unauthorized personnel are any individuals that are <u>not</u> specifically authorized by the regulation, the collector, or employer to be present at the collection site. | Collection Guidelines Pg. 7 |
| Tape | 40.43 requires only that "tape" be used. This is further clarified in the DOT Urine Specimen Collection Guidelines, Section 2 as "tamper-evident" tape. Therefore, tamper-evident tape is acceptable. DOT says they would consider masking, strapping, or duct tape acceptable. | FRA's response to ADTS' questions |

| PART 40<br>SUBPART D - COLLECTION SITES, FORMS, EQUIPMENT & SUPPLIES USED IN DOT URINE COLLECTIONS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.45**<br>**Form** | **What form is used to document a DOT urine collection?** | |
| | **May the MRO's address entered on the CCF be a post-office box number only?** | |
| MRO's address | - No. The address must contain at least a number & street address.<br>- The reason for this requirement is that CCFs are often delivered by courier or messenger service who do not deliver items to post office box addresses.<br>- The post-office box can be included, but not in lieu of the number & street address.<br>NOTE: Part 40 requires a specific MRO's name and address rather than the name of the clinic or medical facility. | ODAPC Q & A 09/01<br><br>See also 40.345 |
| | **What actual address is required for "Collection Site Address" in Step 1 of the CCF, and what telephone number should the collector provide?** | |
| Collection site address/ phone | - The collection site address should reflect the location where the collection takes place. If the collection takes place at a clinic, the actual address of that clinic should be used: not a corporate or a "main office" address of the clinic/collection company.<br>- If the collection takes place on-site at the employer's place of business (e.g., a bus terminal, a rail yard), the actual address of the employer site should be used.<br>- If the collection takes place in a "mobile unit" or takes place at an accident site, the collector should enter the actual location address of the collection (or as near an approximation as possible, under the circumstances).<br>- The required collector telephone number should be the number at which it is most likely that the laboratory, MRO, or employer, if necessary, may contact the collector and the collector's supervisor.<br>- Pre-printing certain information onto the CCF is problematic if the information is subject to change. | ODAPC Q & A 01/02 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **Where can billing information be entered onto the Federal Drug Testing Custody and Control Form (CCF)?** | |
| Billing information | - 40.45 (c)(1) states that the CCF may include billing information if the information is in the area outside the border of the form.<br>- Therefore, if account codes or collection site codes are entered, they must be placed outside the border, only.<br>- CCFs with this information pre-printed inside the border (i.e., in the Step 1 box) may be used until the supply of these forms is exhausted. CCFs produced or re-ordered after February 15, 2002, must not have this information inside the border.<br>- No corrective action is needed nor will a result be impacted if the CCF contains this information inside the border. However, employers and service providers may be subject to enforcement action if this requirement is not met. | ODAPC Q & A 01/02 |
| C/TPAs | **CCF Form Errors May Lead to Violations for Employers**<br>**The Problem:** C/TPAs using their own identifying info on CCFs are not always filling out the employer-specific info in Step 1, Section A as required in 40.45(c)(2). This opens employers up to violations for non-compliance.<br>**The Fix:** Always make sure the form contains the employer's vitals: name, telephone number & fax number.<br><br>**The Problem:** Employers & C/TPAs changing labs and MROs sometimes use old CCFs with the wrong info. Urine specimens are being sent to the wrong labs, & lab results are being sent to the wrong MROs.<br>**The Fix:** Immediately update those changes to prevent testing & reporting delays & cancelled drug test results | ODAPC Dispatch-es 11/22/05 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **Can a collector mark through pre-printed employer, MRO, collection site, and/or laboratory information on the CCF if that information is not accurate for a particular collection?** | |
| Marking through pre-printed information | - Yes. When the collector has no "blank" CCFs and the CCFs on-hand contain inaccurate pre-printed employer, MRO, collection site, and/or lab information, the collector is permitted to "line through" the inaccurate information and insert legibly the proper information.<br>- The likelihood of a collection site having CCFs with inaccurate information increases with unexpected collection events (e.g., employee arrives unannounced for post-accident testing).<br>- If the specimen will be sent to a lab different than the one pre-printed on the available CCF, it becomes important for the collector to modify the CCF so that it reflects the name & address of the lab to which the specimen will actually be sent. It is also important for the collector to line through any pre-printed billing code & insert the appropriate one, if it is available.<br>- Finally, labs should honor collection site requests to provide an adequate number of "blank" CCFs for use during unexpected collection events. It is important to note that the DOT permits overprinting or pre-printing of CCFs in an effort to streamline the entire testing process, not to limit the distribution of the forms to collection sites. | ODAPC Q & A 01/02 |
| CCF shortage | **Fixes for Where Regulations Meet the Real World**<br>**The Problem:** An employee arrives at the collection site with a single Federal CCF, and you begin the collection process. The employee provides a specimen that requires an immediate second collection under direct observation. The problem is that you don't have another employer specific Federal CCF to complete the second collection because the employer provides its employees with CCFs as needed. What do you do?<br>**The Fix:** As a collection site, you probably have many Federal CCFs from different employers & labs. Find an unused Federal CCF (preferably from the same lab as the original CCF) & legibly write in the correct employer, MRO, lab name & account info, and proceed with the direct observation collection. Ship the specimens from both collections to the employer's contract-ed lab. | ODAPC Dispatch-es 5/2/7/05 |
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |

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| **40.49 DOT kit** | **What materials are used to collect urine specimens?** | |
| | Although use of a nonconforming kit is a rule violation, it is not a fatal or correctable flaw if correct collection procedures were used and no fatal flaws occurred. Labs and MROs should treat it as a "red flag." [See Appendix A] | Final Rule Pg. 79488 |
| Gloves | Single use disposable gloves are recommended for use by collectors while handling specimens. | Collection Guidelines Pg. 7 |
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.51 Shipping containers** | **What materials are used to send urine specimens to the laboratory?** | |
| (a) Box | The shipping container does not have to be a "box." [See 40.73 (a)(8)(i)] [See Appendix A] | Final Rule Pg. 79488 Pg. 79490 |

**PART 40**
**SUBPART E - URINE SPECIMEN COLLECTIONS**

| PART 40<br>SUBPART E - URINE SPECIMEN COLLECTIONS | | |
|---|---|---|
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.61**<br>**Steps** | **What are the preliminary steps in the collection process?** | |
| (a)<br>Scheduled test time | For a pre-employment test, if an employee fails to appear, fails to provide a urine specimen, or fails to remain at the collection site, this is not considered a refusal provided the employee left the testing site or did not provide a specimen before the testing process commenced (i.e., the employee was given the collection kit or cup by the collector). | Urine Specimen Collection Guidelines Pg. 11 |
| (b) (3)<br>Catherization | **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?** | |
| | - 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.<br>- No one is permitted to catheterize a conscious employee for the purpose of collecting urine for a DOT drug test.<br>- 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).<br>- In addition, an employee who normally voids through self-catheterization is required to provide a specimen in that manner.<br>- See also 40.191 regarding refusals. | ODAPC Q & A 09/01 |
| (c)<br>Identification | An employer-issued ID from an owner-operator or other self-employed person will not be acceptable because of credibility issues. | Final Rule Pg. 79489 |
| (d)<br>Collector's identification | The collector is not required to provide any certification or other documentation to the employee documenting the collector's training. (see Urine Specimen Collection Guidelines, Pg. 5) | |
| (f)<br>Boots | Employees cannot be asked to remove their boots (work boots or cowboy boots) unless the collector has a reason to suspect the employee has something in them, which may be used to adulterate or substitute a specimen. (Collection Guidelines, Pg. 13) | Final Rule Pg. 79489 |

| PART 40<br>SUBPART E - URINE SPECIMEN COLLECTIONS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| (f)<br>Hat | The regulation includes a hat as part of the removal of outer clothing. When an employee is asked to remove his or her hat or head covering, & refuses to do so based on religious practice, the collector may exempt the employee from removal of the head covering, unless the collector has an observable indicator that the employee is attempting to hide inside the head covering adulterants or other substances which may be used in an attempt to adulterate or substitute a specimen. | Urine Specimen Collection Guidelines Pg. 13 |
| (f)<br>Empty pockets<br><br>Suspect items | Whatever the employee brings into the collection site, the collector should return it to the employee at the end of the collection. Items, such as suspected urine, plastic bags with fluid in them, artificial or mechanical objects for providing substituted urine, etc., should be fully described in an attached memorandum for record, copies of which should be sent to the MRO & the employer. | Urine Specimen Collection Guidelines Pg. 13 |
| (f)<br>Safeguard belongings | To safeguard employee's belonging, procedures may be established where they are locked (at the collection site or in the bathroom) or other alternate methods may be developed. For example, if an employee comes to the collection site with his or her medications & desires that the collector secure the medication, the collector may place the medication in a locked cabinet, if available, or alternately, could seal the medication in an envelope, secure with tamper-evident tape & retain the envelope in a secure place. | Urine Specimen Collection Guidelines Pg. 12 |
| Consent form | A consent form must not be part of the paperwork for a DOT test. [See Subpart Q] | Final Rule Pg. 79489 |
| **40.63** | **What steps does the collector take in the collection process before the employee provides a urine specimen?** | |
| (b)<br>Washing hands | The employee may use soap and, if practicable, it should be a liquid or cream. A solid bar of soap gives the employee the chance to conceal soap shavings under his or her fingernails & subsequently use them to attempt to adulterate the specimen. | Collection Guidelines Pg. 14 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| (c)<br>Sealed container | Even if the collection kit is sealed, the collection container must still be sealed or individually wrapped in a plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system. | Collection Guidelines Pg. 14 |
| (d)<br>Flushing toilet | - Inadvertent flushing of the toilet does not create a "fatal flaw."<br>- Inadvertently flushing the toilet does not automatically require any corrective action by the collector or a recollection. However, to guard against this action, the collector may want to place a card with instructions not to flush by the toilet handle or tape or otherwise secure the handle with tamper-evident tape. | Final Rule Pg. 79489<br><br>Collection Guidelines Pg. 14 |
| **40.65**<br>**Collector check of specimen** | **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 & sent to the laboratory. Which requirement is correct?** | |
| Discarding first specimen | - 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.<br>- The requirement in the Urine Specimen Collection Guidelines, Version 1.0, to retain the specimen & send it to the laboratory, was inserted inadvertently.<br>- Urine Specimen Collection Guidelines, Version 1.01, contain the proper procedures as directed by 40.65. | ODAPC Q & A 09/01<br><br>Collection Guidelines Pg. 26 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| (b)(2) Temperature strip | - If the collector suspects the temperature strip was not activated, he or she should pour the urine specimen into another collection container or specimen bottle with a temperature strip and use this method to determine the temperature.<br>- Collectors should not introduce any other object, e.g., litmus paper, testing strips, etc. into the specimen.<br>- There is no requirement to take the employee's body temperature. | Urine Specimen Collection Guidelines Pg. 26 |
| (c) Adulteration or substitution | - If the employee does not provide the required amount of urine for the second collection under direct observation, the collector annotates the time the second specimen was not provided & initiates the shy bladder procedures.<br>- If unable to provide a second specimen, the collector must send the original specimen to the lab with an annotation that the specimen was suspected of being adulterated or substituted, that a second collection was attempted, but that a shy bladder prevented collection of a second specimen.<br>- If the employee refuses to provide another specimen or to provide one under direct observation, the collector discards any specimen he or she provided previously during the collection & then notifies the DER of the refusal. | Urine Specimen Collection Guidelines Pg. 27 |
| **40.67 Direct observation** | **When and how is a directly observed collection conducted?** | |
| Volunteer | An employee may not volunteer to have his or her specimen collected under direct observation. | Collection Guidelines Pg. 21 |
| Co-worker or immediate supervisor | See 40.69 | |
| (e)(1) Reason for test | The collector must mark the "reason for test" block (Step 1) the same as for the first collection (unless it is a return-to-duty or follow-up test). | Collection Guidelines Pg. 22 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| (i) Mirrors or video cameras | Use of mirrors or video cameras is not permitted. (Urine Specimen Collection Guidelines, Pg. 22) | |
| Recall of employee | See interpretations for 40.205. | |
| **40.69 Monitored** | **Can the monitor (or direct observer) of a collection be a co-worker or immediate supervisor of the employee?** | |
| (b) Co-worker or immediate supervisor | - The immediate supervisor of a particular employee may not act as the collector when that employee is tested, unless no other collector is available & the supervisor is permitted to do so under a DOT operating administration's drug & alcohol regulation.<br>NOTE: Part 219 does not allow a supervisor to act as a collector.<br>- 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.<br>- An employee who is in a safety-sensitive position & 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. | ODAPC Q & A 09/01<br><br>219.300 (b)(1)<br><br>Collection Guidelines Pg. 4 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| (b) Medical professional | Who is considered a medical professional as outlined in 40.69 (b)? Some professionals are mentioned here while others are not. Is a medical assistant, or a phlebotomist considered a medical professional? I would also like to ask for future reference why a certified technician would not be as qualified to monitor a collection as any others mentioned here? Now that training is in place could this not be changed?<br>Answer: As you mentioned, for a monitored collection, the collector must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified in practice in the jurisdiction in which the collection takes place. This includes a licensed or certified medical assistant and phlebotomist. If you are asking whether DOT will change Part 40 to allow a certified technician (collector) of the opposite gender from the employee to service as a monitor, I think this unlikely, since requiring a same-sex monitor is an employee protection. | FRA's response to ADTS' questions |
| (d) Outside stall | A monitor stands outside the stall. (Urine Specimen Collection Guidelines, Pg. 23) | |
| **40.71 Urine specimen** | **How does the collector prepare the specimen?** | |
| (b) Specimen bottles | The collector unwraps or opens the specimen bottles. The employee may be permitted to do this, however, the recommended "best practice" is for the collector to perform this procedure. | Collection Guidelines Pg. 15 |
| Visual contact | Both the collector & employee will maintain visual contact of the specimen to the greatest extent possible until the labels/seals are placed over the specimen bottle caps/lids. | |
| Wash hands | If practical, the collector may permit the employee to wash his or her hands right after the employee gives the collection container to the collector (and the collector checked the temperature), provided the employee & the collector can still maintain visual control of the specimen collection container | Collection Guidelines Pg. 15 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| (b)(7) Labels/seals | - The collector must not ask the employee to initial the labels/seals while they are still attached to the form; they must be initialed after they are placed on the bottles.<br>- If the seal is damaged or broken during this process, the collector should transfer the information to a new CCF and use the seals from the second form.<br>- If one seal in already in place on the bottle, & the second seal is broken during removal, application, or initialing, the collector should initiate a new CCF & provide an appropriate comment on the "Remarks" line in Step 5. The seals from the second CCF should be placed perpendicular to the original seals to avoid obscuring information on the original seals & must be initialed by the employee (both sets of initials should match). The collector should draw a line through the Specimen ID number & bar code on the original seals to ensure the lab does not use that number for reporting the results. The collector should not pour the specimen into new bottles.<br>- In both cases, all copies of the original, first CCF are destroyed or disposed of properly (shredded or torn into pieces).<br>- If seals are inadvertently reversed, the collector should note this in the "Remarks" line. | Collection Guidelines Pg. 16 |
| (b)(8) Physical exam | Since FRA does not require physical exams, it is NOT permissible to use any remaining urine from a DOT test for a physical exam. [see 40.13 (c)(d)] | |
| **40.73** | **How is the collection process completed?** | |
| Container seal | The requirement for a shipping container seal was removed for both the outer container and the plastic bag. | Final Rule Pg. 79490 |
| (a)(6) Excess urine | Any excess urine should be discarded. It may be used to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical exam required by a DOT operating administration's regulations (not permitted by FRA). No further testing (i.e., adulteration, DNA, drug) testing may be conducted on this excess urine & the employee has no right to demand that the excess urine be turned over to him or her. | Urine Specimen Collection Guidelines Pg. 18 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| (a)(9)<br>Fax, scan or mail<br><br><br><br><br><br><br>Service agent | - The Department views documents sent by fax as originals for purposes of 40.73. For example, the collector may fax the MRO copy of the CCF to the MRO (secure fax machine). Since the MRO now has what we regard as an original, the collector could discard the MRO copy 30 days later.<br>- The MRO copy may be scanned & the image sent to the MRO's secure computer or it may be mailed or sent by courier to the MRO (faxing is preferred for expeditious purposes)<br>- If faxed or scanned, collector or collection site should maintain the MRO copies together with the collector's copies for 30 days.<br>- Copy 4 to the DER (or service agent if authorized by the employer) | Technical Amend-ments Pg. 41945<br><br>Collection Guidelines Pg. 18 |
| | **What is the preferred method for the collector to get the MRO copy of the CCF to the MRO?** | |
| (a)(9)<br>Preferred method | - The promptness of reporting suffers when the mail is used to convey the MRO copy from the collection site.<br>- 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.<br>- If the faxed copy is not legible, the MRO must request another faxed copy or a hard copy. | ODAPC Q & A 09/01 |
| (b)<br>Security | - If the specimen will not be shipped immediately, the collector is responsible for ensuring its integrity & security. Specimens in plastic bags which have not been placed into shipping containers or which are awaiting a lab courier, must be kept in a secure location. It need not be under lock & key, however, procedures must exist that would ensure it cannot be subject to tampering.<br>- After specimens are placed into shipping containers that are subsequently sealed, they may be placed with other containers or packages awaiting pick up by a courier (reasonable security). | Urine Specimen Collection Guidelines Pg. 19 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
|---|---|---|
| **40.83 Labs** | **How do laboratories process incoming specimens?** | |
| (f) CCF | Use of expired "old" CCF will not result in cancellation or rejection of a test until November 1, 2001 (even if an appropriate correction is not made). | Technical Amend-ments Pg. 41945 |
| | **If the primary laboratory must redesignate bottle B for bottle A, can the lab test the specimen if only 15 mL of urine is present in the redesignated bottle A?** | |
| (h) Redesigna-tion of bottles | - The Department permits specimen redesignation only in limited circumstances - one such occurrence would be if the A specimen has leaked in transit, leaving only the B specimen to be tested.<br>- In such a case, the lab should test the redesignated specimen despite the fact that, under normal circumstances, a sufficient amount of specimen would not have been available for testing. | ODAPC Q & A 01/02 |

| PART 40<br>SUBPART F - DRUG TESTING LABORATORIES | | |
|---|---|---|
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.97**<br>**Lab reporting** | **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?** | |
| Incorrect reason for test | - 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 & accurate test (see 40.209).<br>- The test is not cancelled as the result of such a mistake.<br>- 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.<br>- Employers or their designated service agents should ensure that appropriate changes are documented (e.g., for MIS reporting purposes). | ODAPC Q & A 09/01 |
| | **Must a certifying scientist's signature be on Copy 1 of the CCF if the drug test result is negative?** | |
| Signature - negatives | - The certifying scientist's signature must be on Copy 1 of the CCF for non-negative results only.<br>- Therefore, the certifying scientist may simply initial (and date) the CCF when the test result is negative. | ODAPC Q & A 01/02 |
| **40.99**<br>**Retaining specimens** | - Negative tests & specimens rejected for testing (e.g., because of a fatal or uncorrected flaw), the lab should follow HHS guidance.<br>- See 40.103 interpretations for retaining blind specimens & reports. | Final Rule Pg. 79492 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
|---|---|---|
| **40.103 Blind specimens** | **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 & September, 2001 blind calculations based on new Part 40 regulations?** | |
| Rule transition | - 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. | ODAPC Q & A 09/01 |
| | **Must an employer or C/TPA who is required to submit blind specimens to the laboratories send adulterated or substituted blinds if the employer or C/TPA is not yet having specimens undergo validity testing?** | |
| Rule transition | - At the present time, validity testing remains an employer option.<br>- Therefore, if an employer or C/TPA required to submit blind specimens is not conducting validity testing during the course of its normal testing, the employer or C/TPA needs not send adulterated or substituted blind specimens to the labs used.<br>- However, if an employer or C/TPA conducts validity testing, adulterated or substituted blind specimens must be sent to the labs used.<br>- Part 40 requires that approximately 75 percent of the blinds must be blank (i.e., containing no drugs, nor adulterated or substituted); 15 percent must be positive for one or more drugs; and 10 percent must be adulterated or substituted.<br>- If the employer or C/TPA is not exercising the option to conduct validity testing, approximately 75 percent of blinds must be blank and 25 percent must be positive for one or more drugs. | ODAPC Q & A 01/02 |
| (a) Who submits blinds? | In general, the employer determines who will conduct this regulatory requirement. It may be the employer itself, the collection site, MRO, or the C/TPA. | Collection Guidelines Pg. 27 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| (d)(2) Employee & employer copies | - Copies 4 & 5 of the CCF may be discarded by the collector, unless the employer or service agent requires the employer copy (in this case, the collector must ensure the employer copy has the same "blind quality control" annotation as the MRO copy. | Collection Guidelines Pg. 27 |
| | **What are the retention requirements for blind specimens & records of blind specimen tests?** | |
| Retention requirement | - Laboratories, employers & other parties required to retain specimens & records of tests should retain blind specimens & records of blind specimen tests in exactly the same way & for the same periods of time as they do actual employee specimens & test records.<br>- For example, an employer would keep a record of a blind positive test for five years & a blind negative test for two years.<br>- Laboratories would keep blind specimens for negatives in accordance with their SOPs and non-negatives for one year. | ODAPC Q & A 09/01 |
| **40.107 Inspection** | **Who may inspect laboratories?** | |
| Employer inspection | Employers who may inspect labs are those who use or are negotiating to use its services for DOT-regulated testing. | Final Rule Pg. 79492 |
| Lab contract | After August 1, 2001, there is no longer any requirement for railroads to have an "unannounced inspection clause" in their contract [previous requirement of 219.701 (b)]. | |
| **40.111 Summaries** | **When and how must a laboratory disclose statistical summaries and other information it maintains?** | |
| (b) Non-reports | "Non-reports" are not required for smallest employers, labs, and C/TPAs unless specifically requested as part of a DOT audit. | Final Rule Pg. 79493 |

| PART 40<br>SUBPART G - MEDICAL REVIEW OFFICERS<br>AND THE VERIFICATION PROCESS | | |
|---|---|---|
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.121**<br>**MROs** | **Who is qualified to act as an MRO?** | |
| (a)<br>All jurisdictions | Any attempt by a state medical regulatory organization to limit the geographic scope of an MRO's work is pre-empted under the pre-emption provisions of DOT agency rules. | Final Rule<br>Pg. 79493 |
| (c)(2)<br>Qualification training | "Certification" is not required. However, people who take the MRO courses typically get a "certificate" from the program. | Final Rule<br>Pg. 79493 |
| (e)<br>Documenta-tion | See 40.33 (g) interpretations regarding employers or training entities providing service agents their training records. | |
| **40.127**<br>**Negatives** | **What are the MRO's functions in reviewing negative test results?** | |
| (g)<br>MRO staff review of negatives | MROs need not share the same physical space with all of their staff members at all times. Direct personal supervision need not be physically face-to-face on an all-day, every day basis. Supervision can also take place through using a variety of electronic communications. However, the direct personal supervision must be meaningful. It involves personal oversight of staff members' work; personal involvement in evaluation, hiring, and firing; line authority over the staff for decisions, direction & control; & regular contact & oversight concerning drug testing program matters. It also means that the MRO's supervision & control of the staff members cannot be superseded by or delegated to anyone else with respect to test result review & other functions staff members perform for the MRO. See also 40.353 (c) | Final Rule<br>Pg. 79494<br>Pg. 79512 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
|---|---|---|
| | **How should the MRO's review of negative results processed by the MRO's staff take place?** | |
| MRO's review of negatives | - The MRO's personal review of the MRO's staff work (to include the CCFs, lab results documentation, corrective documents, & results reports to employers) should be spread throughout the quarter.<br>- Even if the MRO has reviewed the required 500 per quarter, the MRO must still review all those that needed corrective actions.<br>- The MRO need not review a sampling from all employers or transportation industries he or she serves.<br>- 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 & review documents generated from an FAA-sanctioned test).<br>Part 40 is a One-DOT effort. | ODAPC Q & A 09/01 |
| **40.131 Employee notification** | **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?** | |
| 24-hour period | - 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.<br>- 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. | ODAPC Q & A 09/01 |
| | **Is it appropriate for the MRO to attempt to contact the employee after normal office hours?** | |
| After hours contact | - Yes. Copy 2 of the CCF contains spaces for the employee's daytime and evening telephone numbers. We expect MROs or their staffs to attempt to contact the employee at the evening phone number if the employee is not available at the daytime number. | ODAPC Q & A 01/02 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| **40.137 Drugs** | **On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, or PCP?** | |
| (e) Foreign country | - Use of substances which-if obtained in the U.S.-would not form the basis of a legitimate medical explanation (e.g., hemp products, coca leaf teas) cannot form the basis of a legitimate medical explanation when obtained abroad.<br>- Did the employee have a genuine medical need for using the substance (e.g., an acute condition that arose while the employee was in a foreign country)?<br>- Employee should provide travel documentation.<br>- Discussions with a foreign physician or pharmacist are relevant (for prescriptions).<br>- Review documentation of purchase<br>- Take special note of use after returning to the U.S.<br>- Did employee consult with a U.S. physician before using a foreign medication in the U.S.? [See preamble language] | Final Rule Pg. 79496 |
| **40.139 Opiates** | **On what basis does the MRO verify test results involving opiates?** | |
| (a) No 6-AM in split | When primary specimen is positive for opiates & 6-AM, MRO verifies as a positive. However, if split reconfirms the presence of opiates but not 6-AM, the test would not be cancelled. MRO would take additional verification steps. | Final Rule Pg. 79497 |
| (c)(4) Canadian over-the-counter medication | Codeine medications are legally available in Canada, & might produce test levels in excess of 15,000 ng/mL. In such a case, the employee would have the burden of proof with respect to a legitimate medical explanation, which the employee could meet through showing that he/she had used a legal over-the-counter medication. | Final Rule Pg. 79497 |
| **40.141** | **How does the MRO obtain information for the verification decision?** | |
| Internet prescriptions | Question: Is a MRO permitted to accept an employee's prescription for medication obtained over the Internet?<br>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. | ODAPC Q & A 7/06 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | The following four elements generally serve as an indication that a legitimate doctor-patient relationship has been established:<br>- A patient has a medical complaint;<br>- A medical history has been taken;<br>- A physical exam has been performed; and<br>- Some logical connection exists between the complaint, the medical history, the physical exam, & the drug prescribed.<br>Standing alone, the completion of an online questionnaire reviewed later by a pharmacy-employed doctor fails to establish a proper doctor-patient relationship.<br>The MRO should, at a minimum, consider the following items when verifying the test result:<br>- The name, physical location, & state(s) of licensure of the prescribing practitioner;<br>- Whether the employee was professionally evaluated for the current medical complaint by the prescribing practitioner, & the last time the employee was in direct contact with the prescribing practitioner;<br>- Whether the employee initiated the request to the pharmacy for a particular medication; and<br>- Whether a proper doctor-patient relationship existed.<br>It is the employee's responsibility to provide sufficient information to address MRO inquiries as to whether there was a legitimate doctor-patient relationship. | |
| **40.145** Adulterated or substituted | **On what basis does the MRO verify test results involving adulteration or substitution?** | |
| (g)(5) ODAPC notification | ODAPC would not, in such a case, act as a "court of appeals" that would overturn the results of the MRO review process. | Final Rule Pg. 79497 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| Admission of adulteration or substitution | If an employee admits to the MRO of having placed water from the toilet into his urine specimen, this constitutes a refusal to test even though there is no test result indicating adulteration or substitution. This was based upon the CCF which indicated a discolored first specimen & an employee admission to the collector that he tampered with his specimen. | 10/25/04 Jim Swart ODAPC/OGC written position |
| **40.149 MRO determination** | **Can arbitrators change or overturn the MRO's determination about the verification of a test result?** | |
| Arbitrators | - 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.<br>- 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.<br>- 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).<br>- 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. | ODAPC Q & A 09/01 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **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?** | |
| Arbitrator's decision | - 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.<br>- 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).<br>- 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.<br>- 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). | ODAPC Q & A 09/01 |
| **40.151 (d)** | Claims of accidental or innocent ingestion may not be considered by the MRO. | 8/5/03 FRA letter to William Euker, Arbitrator |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
|---|---|---|
| **40.153 Split** | **How does the MRO notify employees of their right to a test of the split specimen?** | |
| (a) Removal from service | Employers must remove employees from covered service as soon as they are notified of a verified positive, adulterated, or substituted test result. In addition, employers are free to take personnel action once they receive the verified result, although the Department believes it would be wise to avoid taking final action (e.g., termination) until the 72 hours are up or, when the employee requests a test of the split, until the MRO reports the second lab's split test result to the employer. Nothing requires the employee to be in paid status during this period. | Final Rule Pg. 79498 |
| (d) 72-hour period<br><br>Written request | - Nothing precludes the MRO from authorizing test of splits after the 72-hour period. However, the employee cannot insist on having the split tested after that time, and the employer is not obligated, financially or otherwise, to make the test happen.<br>- The request for a test of the split does NOT have to be in writing. [See 40.171 (a)] | Final Rule Pg. 79499 |
| **40.159 Invalid test result** | **What does the MRO do when a drug test result is invalid?** | |
| (a) Invalid | This section uses the term "invalid" (contains an unexplained interfering substance) rather than "unsuitable for testing." When an adulterant has not been identified by name, there is no conclusive evidence that the employee tampered with the specimen. There could be medical reasons for an invalid test. | Final Rule Pg. 79499 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| **40.163 Reporting drug test results** | **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?** | |
| Multiple-result report | - The Department recommends that MROs use Copy 2 of the CCF as the means of reporting all drug test results to employers.<br>- 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. | ODAPC Q & A 09/01 |
| | **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?** | |
| Written reports | - The MRO must sign all reports of non-negative results (i.e., positives, refusals, tests canceled, and invalids).<br>- The MRO or an MRO's staff member may rubber stamp and initial negative results. The rubber stamp should identify the MRO.<br>- Each written report should be dated and indicate the address of the MRO. | ODAPC Q & A 09/01 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **May the MRO report an "interim" or "preliminary" test result to the employer (or C/TPA) while awaiting receipt of the MRO copy and/or the laboratory result?** | |
| Reporting | - No. An MRO must not report test results until and unless he or she has received all required information from the collection site and lab.<br>- This means the MRO must have Copy 2 or a legible copy of Copy 2 (or any legible copy of a CCF page signed by the employee) and must have the drug test result (sent in the appropriate manners for negatives and non-negatives) from the lab.<br>- An MRO sending "in-progress" negative or non-negative results will be considered to be in violation of Part 40. | ODAPC Q & A 01/02 |

| PART 40<br>SUBPART H - SPLIT SPECIMEN TESTS | | |
|---|---|---|
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.171** | **How does an employee request a test of a split specimen?** | |
| | **Can someone other than the employee direct that an MRO have the employee's split specimen tested?** | |
| (a)<br>Request by employee only | - No. Because the split specimen exists to provide the employee with "due process" in the event that he or she desires to challenge the primary specimen's results, only the employee can request that the split specimen be tested.<br>- In addition, an employer or a union (or other labor representative) may <u>not</u> act on the behalf of the employee in requesting that the split specimen be tested.<br>- The employee must make the request directly to the MRO. | ODAPC Q & A 01/02 |
| | **Can the MRO require an employee's split specimen request to be in writing rather than verbal?** | |
| Request format | - 40.171(a) states that the employee's request may be verbal or in writing. Therefore, the MRO <u>must</u> accept a verbal request.<br>- The MRO may ask the employee for written documentation, but must immediately honor the verbal request.<br>- An MRO should always document whether or not an employee requested to have the split tested.<br>- The MRO must document the date and time of the employee's request. | ODAPC Q & A 01/02 |
| | **Can a split specimen be sent to a second laboratory that is under the same corporate title as the primary laboratory?** | |
| (c)<br>Second laboratory | - Yes. The rule requires the split to be tested at a different or second HHS-certified lab. For example, if the primary specimen was tested at XYZ Laboratory in Dallas, TX, the split specimen may be sent to XYZ Laboratory in Chicago, IL.<br>- HHS certifies each lab separately and on its own merits. Labs on the HHS listing of certified labs, even those under the same corporate title, are individually certified and are considered separate & unique from one another. | ODAPC Q & A 01/02 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| **40.175** | **What steps does the first laboratory take with a split specimen?** | |
| (f)<br>Choice of second lab | A question was posed as to who gets to choose the lab that tests the split specimen. DOT answered that this is an issue on which the Department does not have a position. It is satisfied as long as the parties use an HHS-certified lab. | Final Rule Pg. 79500 |
| **40.187** | **What must an MRO do when he or she determines that there is no split laboratory capable of testing the <u>adulterant</u> identified by the primary lab after the employee has asked for the split to be tested?** | |
| | - The Department views this situation as closely paralleling the MRO reporting requirement, at 40.187(d), when the split 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.<br>- The MRO must report to the employer that the specimen, "Failed to Reconfirm: Split Laboratory not Available for Testing."<br>- The MRO must also report to the DER and the employee that the test result must be cancelled and the reason for the cancellation.<br>- The MRO must direct the DER to ensure the <u>immediate collection</u> of another specimen from the employee <u>under direct observation</u>, with no notice given to the employee of this collection requirement until immediately before the collection.<br>- Finally, the MRO must notify ODAPC of the failure to reconfirm.<br>- The result of the collection under direct observation will be the result of record for this testing event. | ODAPC Q & A 06/04 |

| PART 40<br>SUBPART I - PROBLEMS IN DRUG TESTS | | |
|---|---|---|
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.191**<br>**Refusals** | **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)?** | |
| Signing CCF | - 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.<br>- The collector would then provide his or her name and signature in Step 4 of the CCF.<br>- The employee's name and phone number should be included on the MRO copy.<br>- The collector would then transmit the CCF copies to the appropriate parties (e.g., employer, MRO). | ODAPC Q & A 09/01 |
| Catheteriza-tion | - If an employee needs medical attention, treatment takes priority & should not be delayed to collect a specimen.<br>- If an employee is catheterized as part of a medical procedure (following an accident), once the employee's medical condition is stabilized & the employee can understand that a DOT collection is required & can sign the CCF, a urine specimen should be obtained.<br>- A urine specimen must not be collected, by catheterization or other means, from an unconscious employee.<br>- Catherization to obtain a urine specimen is also not authorized.<br>- An employee who normally voids through intermittent or self-catheterization is required to provide a specimen (may provide directly from the catheter into the collection container in the privacy of a restroom). If this employee declined to do so, this would constitute a refusal to test. | Urine Specimen Collection Guidelines Pg. 24 |

| PART 40<br>SUBPART I - PROBLEMS IN DRUG TESTS | | |
|---|---|---|
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| External urine bag | - Should be a freshly voided specimen.<br>- With indwelling catheter may urinate directly into a collection container.<br>- With external bag, should be asked to empty his or her bag in the privacy of a bathroom, show the empty bag to the collector, & then drink fluids to provide 45 mL of urine, which can be subsequently poured by the employee from the bag into a collection container in the privacy of a bathroom.<br>- The temperature would not be a critical factor.<br>- Conduct with appropriate decorum.<br>- Does not have to be done in a medical environment/health clinic or by a collector of the same gender, although employee may be accommodated if it does not significantly delay the process.<br>- Subject to same testing requirements, i.e., pre-employment, random & to the shy bladder protocol or constitutes a refusal. | Urine Specimen Collection Guidelines Pg. 24 |

| PART 40<br>SUBPART I - PROBLEMS IN DRUG TESTS | | |
|---|---|---|
| Refusals & handling | Question: What are some examples of an employee's failure to cooperate with the testing process that would cause a refusal to test & how should the collector handle them?<br><br>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:<br><br>- The employee fails to wash his or her hands after being directed to do so by the collector.<br>- The employee admits to the collector that he or she adulterated or substituted the specimen; and<br>- 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.<br><br>When the issue is a problem with refusing to follow 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; & if practical, seek assistance from the DER or supervisor to ensure that the employee understands the ramifications.<br><br>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.<br><br>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 <u>thoroughly</u> documenting the circumstances surrounding the event in the remarks section of the CCF.<br><br>Any specimen that had been collected before the refusal should be discarded. | ODAPC Q & A 7/06 |

| **40.193**<br>**Shy bladder** | **What happens when an employee does not provide a sufficient amount of urine for a drug test?** | |
|---|---|---|
| (a)<br>Attempt | - If an employee tells the collector, upon arrival at the collection site, that he or she cannot provide a specimen, the collector must still begin the collection procedure regardless of the reason given. The collector should tell the employee that most individuals can provide 45 mL of urine, even when they think they cannot urinate, & direct the employee to make the attempt to provide the specimen.<br>- The employee demonstrates his or her inability to provide a valid specimen when the employee comes out of the rest room with an insufficient quantity of specimen or an empty collection container.<br>- This is the time when the "shy bladder" collection process starts.<br>- If there was actually no specimen provided on an attempt, the same collection container may be used & the employee may keep possession of the container during the waiting period. | Urine Specimen Collection Guidelines Pg. 19 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
|---|---|---|
| (b) (2) Waiting period | - Collectors should be sensitive to how frequently they should ask the employee to provide a specimen. For example, asking the employee to provide a specimen every half hour may not produce sufficient specimen... In this case, the collector needs to determine if a longer time is needed...<br>- Under no circumstances can a collector "combine" urine collected from separate voids to creat one specimen of sufficient volume.<br>- The collector should maintain a record in the "Remarks" line of the CCF of the time of each attempt, whether there was any specimen provided or the quantity of specimen provided, & the amount of fluids the employee was given to drink.<br>- During the waiting time, the employee must be monitored by the collector (the one conducting the collection or another collector at the site) or by another responsible collection staff member or a company representative... | Urine Specimen Collection Guidelines<br>Pg. 20<br><br>Pg. 21 |
| (c) Stand-down | During the 5 days that may elapse between the shy bladder and the determination of whether there is a refusal to test, the employee should not be stood-down. | Final Rule Pg. 79501 |
| | **Do the five days within which an employee is given to obtain a medical evaluation after providing an insufficient amount of urine or breath include holidays & weekends, or does this refer to five business days?** | |
| (c) Five days | - The five-day limit for obtaining an examination by a licensed physician refers to business days.<br>- Therefore, holidays & weekend days should not be included in the 5-day time frame. | ODAPC Q & A 01/02 |
| (c) Referral physician | The referral physician could be a specialist (e.g., urologist), but need not be. | Final Rule Pg. 79501 |
| (e) Psycholog-ical condition | In order to be regarded as a pre-existing psychological disorder, it is not necessary that the condition be diagnosed before the time of the test, but the symptoms have to have been medically documented before the time of the test. | Final Rule Pg. 79501 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **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 & second collection attempts). How should this be handled?** | |
| Collector shift change | - In this situation, it is permissible for one collector to turn the process over to another collector to complete the collection.<br>- The first collector would document the start time for the 3-hour period. The second would provide his or her name & 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 & the start time for the shy bladder procedure). | ODAPC Q & A 09/01 |
| **40.195 Long-term medical condition** | **What happens when an individual is unable to provide a sufficient amount of urine for a pre-employment or return-to-duty test because of a permanent or long-term medical condition?** | |
| (a) Random | This procedure does NOT apply to random drug testing and an individual covered by this section should not be taken out of the random testing pool. If the individual cannot provide a specimen within 3 hours, the shy bladder medical evaluation is conducted. If it reveals the person has a medical reason, the test is cancelled. | Final Rule Pg. 79502 |
| (a) Alcohol RTD or follow-up | In the rare situation in which an employee is required to have a negative alcohol test in a return-to-duty or follow-up test situation, & could not produce sufficient breath because of a permanent, long-term disability, the Department would apply the reasoning of this section to that situation. | Final Rule Pg. 79502 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| **40.197 Dilute specimen** | **May an employer have a policy of declining to hire applicants who have a negative dilute test result on a pre-employment drug test?** | |
| Pre-employment | - The Department's rules do not require an employer to hire anyone. That decision is an employer's.<br>- 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.<br>- 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.<br>- 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. | ODAPC Q & A 09/01 |
| **40.209 Correction not required** | - See 40.97 interpretation for situation in which the CCF listed the wrong reason for the test.<br>- See 40.149 interpretation for arbitrator's decision claiming to overturn the result of a DOT drug or alcohol test. | |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| **40.203 Cancelled unless corrected** | **If a collector makes an error on a CCF & 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?** | |
| Signing corrective statement | - 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.<br>- If the missing information is the printed name & signature of the collector, neither the collector nor the supervisor may supply the missing information. This is a fatal, uncorrectable flaw.<br>- 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 collector performed the collection, but did not sign his or her name.<br>- If the employee's signature is omitted & 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. | ODAPC Q & A 09/01 |
| **40.205 Correction** | **How are drug test problems corrected?** | |
| (a)(1) Recall employee | - A collector may conduct another collection as part of this effort. However, the collector must not recall an employee for another collection once the employee has left the collection site. There is one exception: when the collector learns that a directly observed collection should have been conducted, but was not, the collector must notify the employer to direct the employee to return for an immediate recollection under direct observation. | Urine Specimen Collection Guidelines Pg. 28 |

| PART 40<br>SUBPART J - ALCOHOL TESTING PERSONNEL | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.211 Alcohol** | **Who conducts DOT alcohol tests?** | |
| (c) Supervisor | FRA does NOT allow supervisors to act as the collector for their employees. "The supervisor who makes the determination that reasonable suspicion exists may not conduct testing on that employee." [See 40.31 (c) for drug testing] | 219.300 (b)(1) |
| **40.213 Training** | **What training requirements must STTs and BATs meet?** | Final Rule Pg. 79503 |
| (a) Academic | For the academic portion of the training, a variety of training media<br>is permitted (e.g., classroom instruction, internet, video, CD-ROM) [same as for urine collectors] | Final Rule Pg. 79503 |
| (b)(4) Certification on one instrument | In retraining of BATS it is required that someone who meets the criteria in the regs must retrain a BAT at least every 5 years. If someone is certified as a BAT instructor on one instrument would they be qualified to observe the required mock scenarios on an instrument that they are not certified on? In most cases, the BAT knows his/her instrument & how to operate it. The instructor is aware of all the criter that must (be) met. Would this be sufficient?<br>Answer: The regs state that the same criteria for qualification training applies to 5-year refresher training. 40.213 (b)(4) states that the instructor must be either an individual who has demonstrated necessary knowledge, skills, & abilities by regularly conducting DOT alcohol tests as an STT or BAT, as applicable, for a period of at least a year; who has conducted STT or BAT training, as applicable, under Part 40 for a year; or who has successfully completed a "train the trainer" course. The regs are silent as to whether an instructor must be certified on the specific instrument upon which they are conducting refresher training. | FRA's response to ADTS' questions |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| | **Is error correction training required if an alcohol test is cancelled due to equipment failure?** | |
| (f) Error-correction training | - Normally, equipment will not require the BAT to have error correction training.<br>- However, if it is determined that the equipment failure was related to the BAT's failure to properly maintain equipment (e.g., the EBT), error correction training would be in order.<br>- In addition, error correction training would be required if the BAT does not attempt to accomplish the test following equipment failure using another device – provided that another device was reasonably available. | ODAPC Q & A 01/02 |
| (g) Documenta-tion | See 40.33 (g) interpretations for employers or training entities providing service agents their training records. | |

| PART 40<br>SUBPART K - TESTING SITES, FORMS, EQUIPMENT & SUPPLIES<br>USED IN ALCOHOL TESTING | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **Pre-Employment Alcohol** | **Can an employer wishing to conduct pre-employment alcohol testing, do so?** | |
| | - A DOT-regulated employer (except under USCG & RSPA rules) wishing to conduct pre-employment alcohol testing under DOT authority may do so if certain conditions are met.<br>- The testing must be accomplished for all applicants (i.e., the employer cannot select for testing some applicants and not others) & 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).<br>- In addition, the testing and its consequences must comply with requirements of Part 40. | ODAPC Q & A 09/01 |
| **40.225 Form** | **What form is used for an alcohol test?** | |
| (a)<br>Step 4 | Use of the new ATF is authorized now, and mandatory on February 1, 2002. To maintain consistency, employees should be asked to sign Step 4 only if their test result is 0.02 or higher. | Technical Amend-ments Pg. 41949 |
| **40.231 EBTs** | **What devices are used to conduct alcohol confirmation tests?** | |
| (b)(2)<br>Sequential number | The Final Rule removed the word “sequential” from the requirements that an EBT print a unique number on each copy of the result. | Final Rule Pg. 79504 |

| PART 40<br>SUBPART L - ALCOHOL SCREENING TESTS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.241 Alcohol** | **What are the first steps in any alcohol screening test?** | |
| (c) Identification | An employer-issued ID from an owner-operator or other self-employed person will not be acceptable because of credibility issues. | Final Rule Pg. 79489 |
| **40.243 Screening test** | **Is it acceptable to affix printed alcohol test results on the back of the Alcohol Testing Form (ATF) rather than on the front?** | |
| Affixing test result | - 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.<br>- The designated space on the ATF is on the front of the form. That is where BATs and STTs should affix the printouts.<br>- 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. | ODAPC Q & A 09/01 |
| **40.245 Saliva ASD** | **What is the procedure for an alcohol screening test using a saliva ASD?** | |
| (f)(3) New form | The same form may be used for two separate devices. However, there is no mandate to use the same form. If one form is getting too cluttered, the STT can use a new form for the part of the process involving the second device. | Final Rule Pg. 79505 |
| **40.247 Screening test** | **What procedures does the BAT or STT follow after a screening test result?** | |
| (a)(2) C/TPAs | The final rule permits transmission of negative alcohol test results from BATs to employers via C/TPAs. [See Appendix F] | Final Rule Pg. 79505 |

| PART 40<br>SUBPART M - ALCOHOL CONFIRMATION | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.251 Confirma-tion tests** | **Is an employer considered to be in compliance with Part 40 if EBTs are not available within 30 minutes of an alcohol screening test location?** | |
| (a)<br>30 minutes | - An employer is <u>not</u> considered to be in compliance if an EBT is not available for use within 30 minutes to confirm the screening test.<br>- However, there may exist unusual circumstances (e.g., post-accident testing) in which an EBT is not available within the appropriate time frame. In such a case, the employer would not be considered out of compliance with the regulation if documentation exists showing a "good faith" effort to get an EBT. [It is important to note that most operating administrations give employers up to 8 hours to administer the appropriate alcohol test following a qualifying accident.] | ODAPC Q & A 01/02<br><br>See 219.302 (b) |
| **40.253 Confirma-tion tests** | See 40.243 for interpretation on affixing printed alcohol test results on the back or front of the ATF. | |
| **Printing through a laptop computer** | We think the printing of an alcohol test result through a laptop would be acceptable under 40.253(f) if the result can be printed contemporaneously to the collection (and not sometime later) and the EBT is designed to print through a laptop as an option. We would see this as the same as if any printer broke down during the collection and it was immediately replaced. However, if the printing of the test result through the laptop can only be done later, the test should be cancelled in accordance with 40.267(c)(4). | 11/22/06 email from George Ellis, ODAPC |

| PART 40<br>SUBPART N - PROBLEMS IN ALCOHOL TESTING | | |
|---|---|---|
| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.265**<br>**Shy lung** | **What happens when an employee is unable to provide a sufficient amount of breath for an alcohol test.** | |
| | **Do the five days within which an employee is given to obtain a medical evaluation after providing an insufficient amount of urine or breath include holidays & weekends, or does this refer to five business days?** | |
| (c)<br>Five days | - The five-day limit for obtaining an examination by a licensed physician refers to business days.<br>- Therefore, holidays & weekend days should not be included in the 5-day time frame. | ODAPC Q & A 01/02 |
| (c)(1)(iv) (C) | The evaluating physician could be a specialist, but need not be. | Final Rule Pg. 79506 |

| PART 40<br>SUBPART O - SUBSTANCE ABUSE PROFESSIONALS & THE RETURN-TO-DUTY PROCESS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |

| PART 40<br>SUBPART O - SUBSTANCE ABUSE PROFESSIONALS & THE RETURN-TO-DUTY PROCESS | | |
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| DOT Agency Removal-From-Duty Actions | An employee tests positive on a DOT drug test for Employer A. The DOT Agency learns about it, and they also know that the employee also works for Employer B. The DOT Agency wants to be able to tell Employer B about the test for Employer A, since it is contrary to regulations & the Omnibus Transportation Employees Testing Act of 1991 for an employee to perform safety-sensitive functions for anyone after testing positive, until & unless the return-to-duty process is completed. Obviously, there is a safety & program credibility issue here: [For example, if FMCSA knows that a truck driver who has tested positive is driving a school bus & says nothing, & the driver uses drugs & drives a bus off the road & kills a number of children, the FMCSA has failed in its safety function & is roundly-and rightly-criticized for its fatal failure.]<br><br>According to the DOT Privacy Act Counsel, because information about specific employee drug & alcohol testing regulation violations are not routinely collected by the DOT or the DOT Agencies, finding out about them through program inspections, audits, & reviews or by third-party reporting (e.g., phone calls from concerned citizens, family members, employers, & service agents) is not covered under the Privacy Act.<br><br>…Apart from the FAA, the following policy statement will apply across DOT:<br><br>"The OST General Counsel's Office & ODAPC find nothing in 49 CFR Part 40 or the Privacy Act prohibiting DOT & the DOT Agencies form taking necessary actions to have employers remove employees from performance of safety sensitive duties when it is determined that the employees did not comply with the return to duty process of Subpart O after violating DOT drug & alcohol regulations. DOT & the DOT Agencies are tasked with promoting & taking actions to ensure the safety of the traveling public. Therefore, if a DOT Agency determines that an employee has not satisfied Subpart O requirements & is performing safety sensitive duties, it has an obligation to take action. Part 40, to include Subpart P [the confidentiality & release of information section], in no way precludes a DOT Agency from taking appropriate action (e.g., notifying any employer for whom the employee is performing safety-sensitive duties) to have the employee cease performance of safety sensitive duties." | 11/13/06 ODAPC policy statement for internal use only |

| PART 40<br>SUBPART O - SUBSTANCE ABUSE PROFESSIONALS & THE RETURN-TO-DUTY PROCESS | | |
|---|---|---|
| **40.281 SAP** | **Who is qualified to act as a SAP?** | |
| (c)(2) Exam | - SAP qualification training includes a requirement for an examination; The preamble to the Final Rule (Pg. 79507) said that the exam did not need to be a formally designed and validated examination. However, the Department's policy is now that a nationally-recognized SAP training organization that constructs an exam should have the exam validated by an outside test evaluation organization or by an effective peer review.<br>- DOT requires these training or professional organizations to have their SAP examination validated by a test evaluation organization. | Technical Amend-ments Pg. 41949<br><br>SAP Guidelines Pg. 2 |
| Accepted credentials | DOT recently included state-licensed or certified marriage & family therapists to the list of credentialed professionals eligible to serve as a SAP. | FR Vol. 71<br>No. 163<br>8/23/06 |
| Training resources | A list of some of the SAP training resources appears on DOT's website at www.dot.gov/ost/dapc/sap.html | ODAPC Dispatch-es 5/27/05 |
| (e) Documenta-tion | See 40.33 (g) interpretations for employers or training entities providing service agents their training records. | |
| **40.285 Evaluation** | **When is a SAP evaluation required?** | |
| (b) DUI | A SAP evaluation would NOT be needed for an employee who has a DUI/DWI charge against him or her in a private automobile. | Final Rule Pg. 79507 |
| **40.287 List** | If an applicant fails a pre-employment test, the employer must provide this information even if the employer intends not to hire the applicant. | Final Rule Pg. 79507 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
|---|---|---|
| **40.289 Treatment** | **Are employers required to provide SAP and treatment services to employees?** | |
| (c) Insurance | Imposing coverage requirements on health care providers or insurers is outside the Department's jurisdiction. | Final Rule Pg. 79507 |
| **40.291 Role or 40.293 Initial evaluation** | **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, & simply sends the employee back to the employer for a return-to-duty (RTD) test. What is the employer to do?** | |
| Fails to recommend education or treatment | - The employer should not administer an RTD test under these circumstances.<br>- The employer should refer the employee back to the SAP with direction to prescribe education and/or treatment & conduct a re-evaluation of the employee to determine whether the employee has successfully complied with the SAP's instructions.<br>- If the employer has compounded the problem by having conducted the RTD test & 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."<br>- 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. | ODAPC Q & A 09/01 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
|---|---|---|
| **40.299 Conflict of interest** | **What is the SAP's role & what are the limits on a SAP's discretion in referring employees for education & treatment?** | |
| (a) Referral | - When a variety of appropriate treatment programs are available within the employee's geographical area, the SAP may permit the employee to select the facility or practice from a SAP-approved provider list. | SAP Guidelines Pg. 7 |
| (b) Spouse | Referral to a spouse is NOT allowed because of the prohibition on referrals to people with whom the SAP shares a financial interest. | Final Rule Pg. 79508 |
| (c)(4) Travel | If an employee had to make an overnight trip to get to another source of services, the Department would NOT consider it reasonably available. | Final Rule Pg. 79508 |
| **40.305 Return-to-duty** | **How does the return-to-duty process conclude?** | |
| (c) | FRA does NOT require a "fitness for duty" determination so the SAP or MRO must not make such a determination. | |
| **40.307 Follow-up** | **What is the SAP's function in prescribing the employee's follow-up tests?** | |
| (a) Follow-up random pool | - Employees should not be placed into a follow-up random testing pool & selected for follow-up testing on a random basis.<br>- It should be individualized & designed to ensure the employee receives the requisite number of tests. | SAP Guidelines Pg. 19 |
| (c) No. of tests | For locomotive engineers, follow-up tests shall include not fewer than 6 alcohol tests and 6 drug tests during the first 12 months following return to service. | 240.119 (d)(2) |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
|---|---|---|
| | **May an employer conduct follow-up testing under company authority that goes beyond the follow-up testing which the SAP determines necessary?** | |
| (d)(4) Company follow-up tests<br><br>Discussion with SAP | - No. The regulation (at 40.307 (d)(4)) and SAP guidelines state that employers must not impose additional testing requirements that go beyond the SAP's follow-up testing plan. This includes additional testing requirements under company authority.<br>- In addition to follow-up testing and random testing, an employer has other means available to ascertain an employee's alcohol- and drug-free performance and functions.<br>– The employer can choose to monitor the employee's compliance with the SAP's recommendations for continuing treatment and/or education as part of a return-to-duty agreement with the employee.<br>– The employer can conduct reasonable suspicion testing if the employee exhibits signs & symptoms of drug or alcohol use.<br>– The employer can meet regularly with the employee to discuss the employee's continuing sobriety & drug-free status.<br>- The Department is not opposed to an employer discussing his or her desires for having more than the minimum rule requirement (i.e., 6 tests in the first year) for follow-up testing with SAPs they intend to utilize. | ODAPC Q & A 01/02 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| **40.311 Reports** | **What is meant by "SAP's own letterhead?"** | |
| | - By "SAP's own letterhead" we mean the letterhead the SAP uses in his or her daily counseling practice.<br>- If the SAP is in private practice, the SAP should use the letterhead of his or her practice.<br>- If the SAP works as an EAP for an organization, the SAP should use the EAP's letterhead.<br>- If the SAP works for a community mental health service, the SAP should use the community mental health service's letterhead.<br>- The Department wants to avoid a SAP network provider requiring the SAP to use the provider's letterhead rather than that of the SAP.<br>- 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.<br>- 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.<br>- 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.<br>- The SAP must generate & complete all information on the SAP report. | ODAPC Q & A 09/01<br><br>SAP Guidelines Pg. 18 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| Where to send? | **Substance Abuse Professional (SAP) Reports**<br>**The Problem:** During the initial substance abuse evaluation, the SAP learns the employee is no longer employed, & as expected, the SAP completes the evaluation along with the appropriate recommendations. So, the problem is what does the SAP do with the evaluation report? After all, there is no company to send the report to.<br>**The Fix:** The written report can be provided directly to the employee if the employee does not have a current employer. The SAP may also provide the report to the future transportation employer.<br><br>But what about the employee who then completes the initial report's recommendations & has a follow-up evaluation? Can the SAP provide the employee with the follow-up evaluation report?<br><br>Yes, the SAP can provide the written report directly to the employee but only if the SAP redacts the follow-up testing info. Once the employee is hired for a safety-sensitive position, the SAP can then release the report to the new transportation employer that includes the follow-up testing info. | ODAPC Dispatch-es 6/24/05 |

| PART 40<br>SUBPART P - CONFIDENTIALITY & RELEASE OF INFORMATION | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.327 Medical information** | **When must the MRO report medical information gathered in the verification process?** | |
| (a) | A prudent MRO may choose to provide the medical information in writing, but it is NOT required in writing. | Final Rule Pg. 79510 |
| | **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 FMCSA 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?** | |
| Physical qualifications | - Under 40.327 (a), an MRO must report drug test results & medical information to third parties without the employee's consent, under certain circumstances spelled out in the rule.<br>- 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.<br>- 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. | ODAPC Q & A 09/01 |
| (b) Reporting to multiple employers | This is a discussion of MROs sharing test results with other employers. Among other things, it says, "Many employers, MROs, unions and other parties opposed allowing MROs to do so because it would breach employee confidentiality." It went on to say that, "Other MROs and employers favored giving MROs this discretion, in order to enhance safety and help MROs who find themselves in this dilemma [knowing the employee works for another company, too.]" In the DOT response to the issue, it said, "The Department has decided to drop the proposal to permit or require MROs to | Final Rule pg 79475 |

| PART 40<br>SUBPART P - CONFIDENTIALITY & RELEASE OF INFORMATION | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| | pass on to third party employers information about the results of tests the employer took at the direction of another employer." It goes on to say, "Consequently, as under the current (old) rule, MROs will be prohibited from passing such information on to third party employers without the employee's consent." See also 40.135 (d)(3). | |
| DOT Agencies | See interpretations for 40.25 regarding DOT Agencies taking action to remove a covered employee who has not satisfied Subpart O requirements. | |

| PART 40<br>SUBPART P - CONFIDENTIALITY & RELEASE OF INFORMATION | | |
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| Written authorization to release test results<br>(HIPAA) | Question: Are employers & their service agents in the DOT drug & alcohol testing program required to obtain employee written authorizations in order to disclose drug & alcohol testing information?<br><br>Answer: In the DOT drug & alcohol testing programs, employers & service agents are not required to obtain written employee authorization to disclose drug & alcohol testing information where disclosing the information is required by Part 40 & other DOT Agency & USCG drug & alcohol testing regulations. Part 40 and USCG regulations provide for confidentiality of individual test-related information in a variety of other circumstances.<br><br>Even if drug & alcohol testing information is viewed as protected under the Health Insurance Portability & 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 Part 40 or the DOT Agency & USCG drug & alcohol testing information.<br><br>Unless otherwise stipulated by Part 40 or DOT Agency & USCG regulations, use or disclosure of the DOT drug & alcohol testing information without a consent or authorization from the employee is required by the Omnibus Transportation Employees Testing Act of 1991, Part 40, & DOT Agency & USCG drug & alcohol regulations.<br><br>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:<br><br>- Employers need no written authorizations from employees to conduct DOT tests.<br><br>- Collectors need no written authorizations from employees to perform DOT urine collections, to distribute Federal Drug Testing Custody & Control Forms, or to send specimens to labs.<br><br>- Screening Test Technicians & 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.<br><br>- Labs need no written authorizations from employees to perform DOT drug & validity testing, or to report test results to MROs.<br><br>- MROs need no written authorizations from employees to verify drug tests results, to discuss alternative medical explanations with prescribing physicians & issuing | ODAPC Q & As 7/06 |

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| | pharmacists, to report results to employers, to confer with SAPs & evaluating physicians, or to report other medical information (see 40.327).<br>- SAPs need no written authorizations from employees to conduct SAP evaluations, to confer with employers, to confer with MROs, to confer with appropriate education & treatment providers, or to provide SAP reports to employers.<br>- C/TPAs need no written authorizations from employees to bill employers for service agent functions that they perform for employers or contract on behalf of employers.<br>- Evaluating physicians need no written authorizations from employees to report evaluation information & results to MROs or to employers, as appropriate.<br>- 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. | |
| **40.329 Release to employees** | **What information must labs, MROs, & other service agents release to employees?** | |
| | **If an employee requests his/her records from the MRO, do these records include the MRO's notes and comments or only copies of the CCF and laboratory result?** | |
| (a) MRO notes & comments | - In general, the MRO should provide all records that are available related to that employee, to include written notes, checklists, or comments. All of this information was obtained from the employee or from appropriate individuals or organizations (with the employee's authorization) or from documentation provided by the employee.<br>- Consistent with appropriate medical record constraints, the MRO may need to withhold or interpret sensitive medical, psychiatric, and mental health record information. | ODAPC Q & A 01/02 |
| (b) Data pkg. | A "data package" is sometimes referred to as a "litigation package."<br>It is also not necessary to list the contents of a litigation package. | Final Rule Pg. 79510 |

| PART 40<br>SUBPART P - CONFIDENTIALITY & RELEASE OF INFORMATION | | |
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| (b)<br>Witnesses | Labs are NOT required to produce witnesses for appearances at legal proceedings. | Final Rule<br>Pg. 79510 |
| (b)<br>Results of lab reviews | Labs are NOT required to provide employees with results of relevant HHS certification reviews. | Final Rule<br>Pg. 79510 |
| **40.331**<br>**Release of information** | **To what additional parties must employers & service agents release information?** | |
| (b)(c)<br>Canada | Canadian law is not relevant in this case because the release of information is part of the DOT oversight process, not on release to third parties. | Final Rule<br>Pg. 79510 |
| **40.333**<br>**Records** | **What records must employers keep?** | |
| (d)<br>Service agts | Part 219 does NOT specify a "time" required for production of records maintained by service agents. However, 40.349 (e) requires 2 days. | Part 219<br>40.349 (e) |
| Blind specimens & reports | See 40.103 interpretation for retention of blind specimens and reports. | |
| | **When records are stored and transferred electronically, how should they be made available to DOT representatives?** | |
| Electronic | - The obligations of employers & service agents to make records available expeditiously to DOT representatives apply regardless of how the records are maintained.<br>- All records must be easily & quickly accessible, legible, & formatted & stored in a well-organized & orderly way.<br>- If electronic records do not meet these criteria, then the employer or service agent must convert them to printed documentation in a rapid & readily auditable way. | ODAPC<br>Q & A<br>09/01 |

| PART 40<br>SUBPART Q - ROLES & RESPONSIBILITIES OF SERVICE AGENTS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.343**<br>**Service agts** | **What tasks may a service agent perform for an employer?** | |
| Non-DOT provisions | Service agents can recommend provisions not covered by DOT rules, but they cannot make adoption of these recommendations a condition of approving employers' plans for DOT compliance purposes. See also 40.355 (m) | Final Rule Pg. 79511 |
| **40.345**<br>**C/TPA** | **How should the employer's decision to have a C/TPA act as intermediary in the handling of drug test results be documented?** | |
| Documenta-tion | - 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.<br>- We advise the MRO to obtain some documentation of the employer's decision prior to sending results through the C/TPA.<br>- Documentation could be in the form of a letter, an email, or record of a telephone conversation with the employer.<br>- DOT also recommends that MROs maintain listings of the names, addresses, & phone numbers of C/TPA points of contact. | ODAPC Q & A 09/01 |
| **40.353**<br>**MROs** | **What principles govern the interaction between MROs & other service agents?** | |
| (c) Supervision | "Day-to-day supervision and control of an MRO" does not require MROs to exercise full-time, in-person, over-the-shoulder supervision of their staffs. As long as MROs really supervise their staff, this supervision need not always take place at the same site. The rule is intended to prohibit C/TPA staff, working on their own or under C/TPA rather than MRO supervision, from performing MRO staff functions. See also 40.127 (g) | Final Rule Pg. 79512 Pg. 79494 |

| PART 40<br>SUBPART R - PUBLIC INTEREST EXCLUSIONS (PIEs) | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| **40.365**<br>**Policy** | **What is the Department's policy concerning starting a PIE proceeding?** | |
| Non-retroactive | A PIE proceeding would NOT be initiated on the basis of conduct that occurred before the PIE provisions took effect (January 18, 2001). | Final Rule Pg. 79513 |
| Egregious misconduct | PIEs were intended to be used in cases of "egregious" misconduct and noncompliance. | Final Rule Pg. 79465 Pg. 79468 |
| Labs | As a policy matter, the Department would not start a PIE action if HHS had already taken a certification action against a lab on the same matter. | Final Rule Pg. 79468 |
| **40.367**<br>**Initiation** | **Who initiates a PIE proceeding?** | |
| (a) (c) Designee | Individual inspectors and subordinate staff members, while they may provide information to initiating officials, are not themselves authorized to initiate PIE proceedings. | Final Rule Pg. 79513 |
| **40.395**<br>**Settling a PIE** | **Can you settle a PIE proceeding?** | |
| | A settlement of a PIE proceeding (prior to the Director's decision) could include for example, provisions to ensure compliance or a period of voluntary exclusion during which the service agent agrees not to provide certain services to DOT-regulated employers while it fixes noncompliance problems. | Final Rule Pg. 79514 |
| **40.401**<br>**Notification** | **How does the Department notify employers and the public about a PIE?** | |
| | The Department anticipates informing employer and testing industry groups about a PIE, so that they can inform their members. | Final Rule Pg. 79514 |

| SECTION | INTERPRETIVE GUIDANCE | SOURCE |
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| **40.413 Notices** | **How are notices sent to service agents?** | |
| Follow up | As a policy matter, the initiating official will make reasonable efforts to follow up with the service agent to ensure that the service agent has received & understood the notice. | Final Rule Pg. 79514 |

| APPENDIX A TO PART 40<br>DOT STANDARDS FOR URINE COLLECTION KITS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| Collection container<br><br>Plastic specimen bottles<br><br>Tamper-evident mechanism | The collection container needs to be securely wrapped separately from the specimen bottles and the bottles must be either shrink wrapped, sealed in plastic bags, or may be secured with other methodology provided that the tamper-evident mechanism is effective & easily discernable to the employee. For example, the use of a tiny filament between the bottle and the cap which breaks when the bottle is first opened may be effective in determining if the bottle was opened, but only if the employee has this pointed out to him or her. Another example would be a bottle that has a paper label. | Final Rule Pg. 79515 |
| Leak-resistant plastic bag | The sealing methodology must be tamper-evident. Hence, zip-lock bags are NOT allowed. | Final Rule Pg. 79515 |
| Shipping container | - Could be a box or padded mailer<br>- Could have a number of specimens (each wrapped in a plastic bag) placed into one large shipping container or box, or even in a larger plastic envelope (if the plastic bottles are constructed of stronger plastic).<br>- Some couriers do not accept styrofoam boxes, plastic bags, & paper envelopes as outer packaging.<br>- There is no requirement for a seal on the outer shipping container. | Final Rule Pg. 79515 |

| APPENDIX B TO PART 40<br>DOT DRUG TESTING SEMI-ANNUAL LABORATORY REPORT | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| | - The lab report is a good place to see how many negative-dilutes the railroad has had. If they've had quite a few, you may want to recommend they develop a policy to perform a recollection (non-observed) following negative-dilutes on some types of Federal tests (e.g., random, follow-up, etc.) as long as they treat all covered employees the same.<br>- Note that the lab report is not going to be totally consistent with the number of Federal tests reported on a railroad's MIS report because the lab report includes blind/quality control specimens.<br>- Also look at the number of cancelled drug tests due to collector errors. | |

| APPENDIX D TO PART 40<br>REPORT FORMAT; SPLIT SPECIMEN FAILURE TO RECONFIRM | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| | - No standard report, although DOT has a form developed to assist MROs (see DOT web site)<br>- The purpose of this report is to determine if there was an administrative or collection error (e.g., the primary bottle and the split bottle were not the same urine) or if the failure to reconfirm was one of a technical nature, requiring review by HHS.<br>- MRO also has to report cancelled tests such as when a split fails to indicate the adulterant or the substitution is not supported by the test of the split or the MRO cancels the test based on medical evidence.<br>- The same format can be used for reporting cancellation of a positive as well as for adulteration & substitution. | |

| APPENDIX E TO PART 40<br>SAP EQUIVALENCY REQUIREMENTS FOR CERTIFICATION ORGANIZATIONS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
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| APPENDIX F TO PART 40<br>DRUG & ALCOHOL TESTING INFORMATION THAT C/TPAs MAY TRANSMIT TO EMPLOYERS | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
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| APPENDIX G TO PART 40<br>ALCOHOL TESTING FORM | | |
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| **SECTION** | **INTERPRETIVE GUIDANCE** | **SOURCE** |
| | Use of the form was authorized beginning January 18, 2001, and required after August 1, 2001. | |