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DRUG TESTING
URINE SPECIMEN COLLECTION

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GCMA INTRODUCTION

Drug testing for safety-sensitive positions throughout the transportation industry has become a common, every-day, routine practice not only for mariners but also for airplane pilots, truck drivers, bus drivers, and train crews. It has become so common, in fact, that our mariners may forget that a single "positive" drug test can damage your career and a second "positive" can end it permanently.

Drug and alcohol testing is now "the law of the land." If you disagree with the law, you have the right to work to change it. However, if you "do" drugs you are in the position of fighting the law as well as dealing with an addiction. If you need help with the addiction, seek professional help before it destroys your career. If you do not and continue, be sure you are prepared to accept the punishment. The purpose of this report is NOT to show you how to "beat" the law; rather it is to explain some of the regulations that carry out the law. If you are a mariner, you need to understand these (and other) regulations to protect your career.

Every time you take a drug test, you hand your career in a pair of small bottles to persons you may have never met before to be processed with hundreds of samples in a laboratory far removed from your home or your job. One problem area involves the actual collection of the sample. If you are not alert during every step of the procedure, you are open to a number of errors that CANNOT be corrected at some future date. Knowing the rules BEFORE YOU TAKE YOUR NEXT TEST can prevent an error that could devastate your career. That is one purpose of this report.

What you will read are U.S. Department of Transportation (DOT) regulations you may not be familiar with although you may have taken many drug tests. You will see that some of these rules were revised as late as 2000. We have not changed any of the words, but we did add **GCMA Comments** to help explain what you read.

GCMA's position is that you must obey the laws promulgated by Congress and the regulations enforced by the Department of Transportation and the Coast Guard. We want to help you obey these rules by showing you what they are and how they are applied.

URINE COLLECTION PERSONNEL

49 CFR §40.31 Who May Collect Urine Specimens For DOT Drug Testing?

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

(b) A collector must meet training requirements of §40.33.[1]

(c) As the immediate supervisor of an employee being tested, you may not act as the collector when that employee is tested, unless no other collector is available and you are permitted to do so under DOT agency[2] drug and alcohol regulations.

(d) You must not act as the collector for the employee being tested if you work for a HHS-certified laboratory (e.g., as a technician or accessioner) and could link the employee with a urine specimen, drug testing result, or laboratory report.

[65 FR 79462, Dec. 19, 2000. ***GCMA Comment:*** *This notation explains that this regulation was first published in Volume 65 of the Federal Register on Dec. 19, 2000.*

[[1]***GCMA Comment:*** *Each collector must have been trained to perform the job correctly. Your license and livelihood may depend upon how carefully the collector does his or her job!*

[2]***GCMA Comment:*** *"DOT Agency" regulations in this case refers to the U.S. Coast Guard regulations in 46 CFR Part 16.]*

49 CFR §40.33 What Training Requirements Must A Collector Meet?

To be permitted to act as a collector in the DOT drug testing program, you[1] must meet each of the requirements of this section:

(a) **Basic information**. You must be knowledgeable about this part, the current "DOT Urine Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers for whom you perform collections, and you must keep current on any changes to these materials. The DOT Urine Specimen Collection Procedures Guidelines document is available from ODAPC (Department of Transportation, 400 7th Street, S.W., Room 10403, Washington DC, 20590, 202-366-3784, or on the

ODAPC web site (http://www.dot.gov/ost/dapc). *[(1)**GCMA Comment:** "You" refers to a specimen collector. However, mariners also need to be alert to these qualifications.]*

(b) **Qualification training**. You must receive qualification training meeting the requirements of this paragraph. Qualification training must provide instruction on the following subjects:

(b)(1) All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;(1)

(b)(2) "Problem" collections (e.g., situations like "shy bladder" and attempts to tamper with a specimen);

(b)(3) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(b)(4) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate;(1) *[(1)**GCMA Comment:** CCF is the abbreviation for the Custody and Control Form, the paperwork that accompanies your sample and accounts for its custody throughout the process.]*

(c) **Initial Proficiency Demonstration**. Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections.

(c)(1) The five mock collections must include two uneventful collection scenarios, one insufficient quantity of urine scenario, one temperature out of range scenario, and one scenario in which the employee refuses to sign the CCF and initial the specimen bottle tamper-evident seal.

(c)(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are "error-free." This person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities byð

(c)(2)(i) Regularly conducting DOT drug test collections for a period of at least a year;

(c)(2)(ii) Conducting collector training under this part for a year; or

(c)(2)(iii) Successfully completing a "train the trainer" course.

(d) **Schedule for qualification training and initial proficiency demonstration**. The following is the schedule for qualification training and the initial proficiency demonstration you must meet:

(d)(1) If you became a collector before August 1, 2001, and you have already met the requirements of paragraphs (b) and (c) of this section, you do not have to meet them again.

(d)(2) If you became a collector before August 1, 2001, and have yet to meet the requirements of paragraphs (b) and (c) of this section, you must do so no later than January 31, 2003.

(d)(3) If you become a collector on or after August 1, 2001, you must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

(e) **Refresher training**. No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section.

(f) **Error Correction Training**. If you make a mistake in the collection process that causes a test to be cancelled (i.e., a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining.

(f)(1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (c)(2) of this section.

(f)(2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(f)(3) As part of the error correction training, you must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections. The mock collections must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were "error-free."

(g) **Documentation**. You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs(1) who are using or negotiating to use your services.

*[54 FR 49866, Dec. 1, 1989, as amended at 59 FR 7356, Feb. 15, 1994; 61 FR 37699, July 19, 1996; 65 FR 79462, Dec. 19, 2000; 66 FR 3884, Jan. 17, 2001; 66 FR 41944, Aug. 9, 2001. (1)**GCMA Comment:** C/TPA is the abbreviation for a Consortium/ Third-Party Administrator. This is a service agent that provides drug and alcohol testing services. The term "consortium" refers to a group of employers, unions, etc. who join together to provide testing services for their employees or members.]*

49 CFR §40.35 What Information About The DER(1) Must Employers Provide To Collectors? *[(1)**GCMA Comment:** A Designated Employer Representative (DER) is an employee that is authorized by the employer to immediately remove an employee from safety-sensitive duties. He is authorized to make decisions about testing and evaluations. He is authorized to receive test results and other correspondence on behalf of the employer.]*

As an employer, you must provide to collectors the name and telephone number of the appropriate DER (and C/TPA, where applicable) to contact about any problems or issues that may arise during the testing process.

[65 FR 79462, Dec. 19, 2000]

49 CFR §40.37 Where Is Other Information On The Role Of Collectors Found In This Regulation?

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

§40.3ð Definition.

§40.43ð Steps to prepare and secure collection sites.

§§40.45-40.47ð Use of CCF.

§§40.49-40.51ð Use of collection kit and shipping materials.

§§40.61-40.63ð Preliminary steps in collections.

§40.65ð Role in checking specimens.
§40.67ð Role in directly observed collections.
§40.69ð Role in monitored collections.
§40.71ð Role in split specimen collections.
§40.73ð Chain of custody completion and finishing the collection process.
§40.103ð Processing blind specimens.
§40.191ð Action in case of refusals to take test.
§40.193ð Action in "shy bladder" situations.
§§40.199-40.205ð Collector errors in tests, effects, and means of correction.
[65 FR 79462, Dec. 19, 2000]

49 CFR PART 40, SUBPART D COLLECTION SITES, FORMS, EQUIPMENT AND SUPPLIES USED IN DOT URINE COLLECTIONS

49 CFR §40.41 Where Does A Urine Collection For A DOT Drug Test Take Place?

(a) A urine collection for a DOT drug test must take place in a collection site meeting the requirements of this section.[1] *[(1)**GCMA Comment:** Be alert to these provisions. Point out any deficiencies to the collector at once to avoid the chance of an error on your test. However, do NOT refuse to take the test! File specific protests of violations with the collector immediately to accompany your specimen.]*

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

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

(d) Your collection site must include a facility for urination described in either paragraph (e) or paragraph (f) of this section.

(e) The first, and preferred, type of facility for urination that a collection site may include is a single-toilet room, having a full-length privacy door, within which urination can occur.

(e)(1) No one but the employee may be present in the room during the collection, except for the observer in the event of a directly observed collection.

(e)(2) You must have a source of water for washing hands, that, if practicable, should be external to the closed room where urination occurs. If an external source is not available, you may meet this requirement by securing all sources of water and other substances that could be used for adulteration and substitution (e.g., water faucets, soap dispensers) and providing moist towelettes outside the closed room.

(f) The second type of facility for urination that a collection site may include is a multistall restroom.

(f)(1) Such a site must provide substantial visual privacy (e.g., a toilet stall with a partial-length door) and meet all other applicable requirements of this section.

(f)(2) If you use a multi-stall restroom, you must eitherð

(f)(2)(i) Secure all sources of water and other substances that could be used for adulteration and substitution (e.g., water faucets, soap dispensers) and place bluing agent in all toilets or secure the toilets to prevent access; or

(f)(2)(ii) Conduct all collections in the facility as monitored collections (see §40.69 for procedures). This is the only circumstance in which you may conduct a monitored collection.

(f)(3) No one but the employee may be present in the multistall restroom during the collection, except for the monitor in the event of a monitored collection or the observer in the event of a directly observed collection.

(g) A collection site may be in a medical facility, a mobile facility (e.g., a van), a dedicated collection facility, or any other location meeting the requirements of this section.
[65 FR 79462, Dec. 19, 2000]

49 CFR §40.43 What Steps Must Operators Of Collection Sites Take To Protect The Security And Integrity Of Urine Collections?

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

(b) As a collector, you must do the following before each collection to deter tampering with specimens:

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

(b)(2) Ensure that the water in the toilet is blue;

(b)(3) Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants[1] are present;

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

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

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

(b)(7) Secure areas and items (e.g., ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants;[1] and

(b)(8) Recheck items in paragraphs (b)(1) through (7) of this section following each collection to ensure the site's continued integrity. *[(1)**GCMA Comment: Vocabulary: Adulterant** or **contaminants** are substances that could affect, change or destroy the sample before it is tested. These can be easily detected and reported.]*

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

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

(c)(2) The facility is secured against access during the procedure to ensure privacy to the employee and prevent distraction[1] of the collector. Limited-access signs must be posted. *[(1)**GCMA Comment**: The collector must pay complete attention to the collection of each sample to prevent substitution, switching, or adulteration. Trying to handle too many people at one time can lead to errors that can destroy lives and careers. Never consider <u>any</u> collection to be "routine." Give every step your undivided attention.]*

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

(d)(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only

one employee at a time. However, during the time one employee is in the period for drinking fluids in a "shy bladder"[1] situation (see §40.193(b),[2] you may conduct a collection for another employee. *[(1)**GCMA Comment:** "Shy bladder" = unable to urinate immediately. (2)We added 49 CFR §40.193(b)*
to the end of this paper for your reference.]

(d)(2) To the greatest extent you can, keep an employee's collection container within view of both you and the employee between the time the employee has urinated and the specimen
is sealed.[1] *[(1)**GCMA Comment:** You must do this because you will not have any meaningful opportunity to do it later. Keep your eyes on your specimen as you would your wallet...it is just as important!]*

(d)(3) Ensure you are the only person in addition to the employee who handles the specimen before it is poured into the bottles and sealed with tamper-evident seals.

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

(d)(5) Maintain personal control over each specimen and CCF throughout the collection process.[1] *[(1)**GCMA Comment:** Be sure you understand every single mark made on your custody and control form.]*

(e) If you are operating a collection site, you must implement a policy and procedures to prevent unauthorized personnel from entering any part of the site in which urine specimens are collected or stored.

(e)(1) Only employees being tested, collectors and other collection site workers, DERs, employee and employer representatives authorized by the employer (e.g., employer policy, collective bargaining agreement[1]), and DOT agency representatives are authorized persons for purposes of this paragraph (e). *[(1)**GCMA Comment:** A Collective Bargaining Agreement is a union contract. Your union representative may be authorized to monitor the collection process to see that you are treated according to the agreement.]*

(e)(2) Except for the observer in a directly observed collection or the monitor in the case of a monitored collection, you must not permit anyone to enter the urination facility in which employees provide specimens.

(e)(3) You must ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(e)(4) You or the collector may remove any person who obstructs, interferes with, or causes a delay in the collection process.

(f) If you are operating a collection site, you must minimize the number of persons handling specimens.
[65 FR 79462, Dec. 19, 2000]

49 CFR §40.45 What Form Is Used To Document A DOT Urine Collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every urine collection required by the DOT drug testing program. The CCF must be a five-part carbonless manifold form. You may view this form on the Department's web site (http://www.dot.gov/ost/dapc) or the HHS web site (http://www.workplace.samhsa.gov).

(b) You must not use a non-Federal form or an expired Federal form to conduct a DOT urine collection. As a laboratory, C/TPA or other party that provides CCFs to employers, collection sites, or other customers, you must not provide copies of an expired Federal form to these participants. You must also affirmatively notify these participants that they must not use an expired Federal form (e.g., that beginning August 1, 2001, they may not use the old 7-part Federal CCF for DOT urine collections).

(c) As a participant in the DOT drug testing program, you are not permitted to modify or revise the CCF except as follows:

(c)(1) You may include, in the area <u>outside the border of the form</u>, other information needed for billing or other purposes necessary to the collection process.

(c)(2) The CCF must include the names, addresses, telephone numbers and fax numbers of the employer and the MRO,[1] which may be preprinted, typed, or handwritten. The MRO information must include the specific physician's name and address, as opposed to only a generic clinic, health care organization, or company name. This information is required, and it is prohibited for an employer, collector, service agent or any other party to omit it. In addition, a C/TPA's name, address, fax number, and telephone number may be included, but is not required. The employer may use a C/TPA's address in place of its own, but must continue to include its name, telephone number, and fax number. *[(1)**GCMA Comment:** MRO = Medical Review Officer (MRO). An MRO is a <u>licensed physician</u> who is responsible for receiving and reviewing laboratory results generated by a drug testing program and evaluating medical explanations for certain drug test results.]*

(c)(3) As an employer, you may add the name of the DOT agency under whose authority the test occurred as part of the employer information.

(c)(4) As a collector, you may use a CCF with your name, address, telephone number, and fax number preprinted, but under no circumstances may you sign the form before the collection event.

(d) <u>Under no circumstances may the CCF transmit personal identifying information about an employee (other than a social security number (SSN) or other employee identification (ID) number) to a laboratory</u>.[1] *[(1)**GCMA Comment:** You must <u>never</u> be identified by name to the drug lab, only by a social security number. This reflects your right to privacy and precludes possible racial or ethnic bias in testing.]*

(e) As an employer, you may use an equivalent foreign-language version of the CCF approved by ODAPC.[1] You may use such a non-English language form only in a situation where both the employee and collector understand and can use the form in that language.
*[65 FR 79462, Dec. 19, 2000; 66 FR 41944, Aug. 9, 2001. (1)**GCMA Comment:** ODAPC = Office of Drug and Alcohol Policy in the office of the Secretary of Transportation. This office coordinates drug and alcohol testing program matters within the DOT.]*

49 CFR §40.47 May Employers Use The CCF For Non-Federal Collections Or Non-Federal Forms For DOT Collections?

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

(b)(1) In the rare case where the collector, either by mistake or as the only means to conduct a test under difficult circumstances (e.g., post-accident or reasonable suspicion test with insufficient time to obtain the CCF), uses a non-Federal form for a DOT collection, the use of a non-Federal form does not present a reason for the laboratory to reject the specimen for testing or for an MRO to cancel the result.

(b)(2) The use of the non-Federal form is a "correctable flaw." As an MRO, to correct the problem you must follow the procedures of §40.205(b)(2).

[65 FR 79462, Dec. 19, 2000; 66 FR 41944, Aug. 9, 2001]

49 CFR §40.49 What Materials Are Used To Collect Urine Specimens?

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

*[65 FR 79462, Dec. 19, 2000. [(1)]**GCMA Comment:** We added Appendix A to the end of this paper.]*

49 CFR §40.51 What Materials Are Used To Send Urine Specimens To The Laboratory?

(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory.

(b) You are not required to use a shipping container if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

[59 FR 7357, Feb. 15, 1994, as amended at 60 FR 19679, Apr. 20, 1995; 65 FR 79462, Dec. 19, 2000]

TITLE 49 CFR PART 40, SUBPART E URINE SPECIMEN COLLECTIONS

49 CFR §40.61 What Are The Preliminary Steps In The Collection Process?

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

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's work site, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing and the employee does not appear, the C/TPA must notify the employee that he or she has refused to test[(1)] (see §40.191(a)(1)). *[[(1)]**GCMA Comment:** Refusal to test is a very serious matter. We have inserted 49 CFR §40.191(a)(1) at the end of this paper to emphasize this point!]*

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

(b)(1) If the employee is also going to take a DOT alcohol test, you must, to the greatest extent practicable, ensure that the alcohol test is completed before the urine collection process begins.

Example to Paragraph (b)(1): An employee enters the test site for both a drug and an alcohol test. Normally, the collector would wait until the BAT[(1)] had completed the alcohol test process before beginning the drug test process. However, there are some situations in which an exception to this normal practice would be reasonable. One such situation might be if several people were waiting for the BAT to conduct alcohol tests, but a drug testing collector in the same facility were free. Someone waiting might be able to complete a drug test without unduly delaying his or her alcohol test. Collectors and BATs should work together, however, to ensure that post-accident and reasonable suspicion alcohol tests happen as soon as possible (e.g., by moving the employee to the head of the line for alcohol tests). *[[(1)]BAT = Breath Alcohol Technician. A person who instructs and assists employees in the alcohol testing process and operates an evidential breath testing device. USCG regulations for testing for alcohol appear in 33 CFR Part 95.]*

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

(b)(3) You[(1)] must not collect, by catheterization or other means, urine from an unconscious employee to conduct a drug test under this part. Nor may you catheterize[(2)] a conscious employee. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner. *[[(1)]**GCMA Comment: [(1)]You, the collector. [(2)]Vocabulary: Catheterize** = *inserting a hollow tube inserted to drain fluids from body cavities.]*

(b)(4) If, as an employee, you normally void through self-catheterization, and decline to do so, this constitutes a refusal to test.[(1)] *[[(1)]Remember, refusal to test is an absolute "no-no"!]*

(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employed individual) or a Federal, state, or local government (e.g., a driver's license). You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

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

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

(f) Direct the employee to remove outer clothing (e.g., coveralls, jacket, coat, hat) that could be used to conceal items or substances that could be used to tamper with a specimen.

You must also direct the employee to leave these garments and any briefcase, purse, or other personal belongings with you or in a mutually agreeable location. You must advise the employee that failure to comply with your directions constitutes a refusal to test.

(f)(1) If the employee asks for a receipt for any belongings left with you, you must provide one.[1] *[(1)**GCMA Comment:** Notice how the rules cover just about everything — and they do not leave anything to chance. This is why you must know the rules!]*

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

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

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

(f)(5) If, in your duties under paragraph (f)(4) of this section, you find any material that could be used to tamper with a specimen, you must:

(f)(5)(i) Determine if the material appears to be brought to the collection site with the intent to alter the specimen, and, if it is, conduct a directly observed collection using direct observation procedures (see §40.67); or

(f)(5)(ii) Determine if the material appears to be inadvertently brought to the collection site (e.g., eye drops), secure and maintain it until the collection process is completed and conduct a normal (i.e., unobserved) collection.

(g) You must instruct the employee **not** to list medications that he or she is currently taking on the CCF. (The employee may make notes of medications on the back of the employee copy of the form for his or her own convenience, but these notes must **not** be transmitted to anyone else.) *[65 FR 79462, Dec. 19, 2000. [(1)]The MRO will ask you some very direct questions about your medications and how and when you use them in the event you have a "positive" (i.e., bad) drug test. Be alert to this procedure.]*

49 CFR §40.63 What Steps Does The Collector Take In The Collection Process Before The Employee Provides A Urine Specimen?

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

(a) Complete Step 1 of the CCF.

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

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

(d) Direct the employee to go into the room used for urination, provide a specimen of at least 45 mL, **not** flush the toilet, and return to you with the specimen as soon as the employee has completed the void.

(d)(1) Except in the case of an observed or a monitored collection (see §§40.67 and 40.69), neither you nor anyone else may go into the room with the employee.

(d)(2) As the collector, you may set a reasonable time limit for voiding.

(e) You must pay careful attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute). If you detect such conduct, you must require that a collection take place immediately under direct observation (see §40.67) and note the conduct and the fact that the collection was observed in the "Remarks" line of the CCF (Step 2). You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

[59 FR 7357, Feb. 15, 1994, as amended at 59 FR 43001, Aug. 19, 1994; 60 FR 19679, Apr. 20, 1995; 65 FR 79462, Dec. 19, 2000]

49 CFR §40.65 What Does The Collector Check For When The Employee Presents A Specimen?

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

(a) **Sufficiency of specimen**. You must check to ensure that the specimen contains at least 45 mL of urine.

(a)(1) If it does not, you must follow "shy bladder" procedures (see §40.193(b)).[1] *[(1)This regulation, 49 CFR §40.193(b), appears at the end of this paper.]*

(a)(2) When you follow "shy bladder" procedures, you must discard the original specimen, unless another problem (i.e., temperature out of range, signs of tampering) also exists.

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

(a)(4) You must discard any excess urine.

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

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

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

(b)(3) If the specimen temperature is within the acceptable range, you must mark the "Yes" box on the CCF (Step 2).

(b)(4) If the specimen temperature is outside the acceptable range, you must mark the "No" box and enter in the "Remarks" line (Step 2) your findings about the temperature.

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

(b)(6) In a case where a specimen is collected under direct observation because of the temperature being out of range, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but the temperature is out of range. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(b)(7) In a case where the employee refuses to provide another specimen (see §40.191(a)(3)) or refuses to provide another specimen under direct observation (see §40.191(a)(4)), you must notify the DER. As soon as you have notified the DER, you must discard any specimen the employee has provided previously during the collection procedure.

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

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

(c)(2) In a case where a specimen is collected under direct observation because of showing signs of tampering, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but it shows signs of tampering. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(c)(3) In a case where the employee refuses to provide a specimen under direct observation (see §40.191(a)(4)), you must discard any specimen the employee provided previously during the collection procedure. Then you must notify the DER as soon as practicable.

[59 FR 7357, Feb. 15, 1994, as amended at 59 FR 43002, Aug. 19, 1994; 60 FR 19679, Apr. 20, 1995; 65 FR 79462, Dec. 19, 2000; 66 FR 41944, Aug. 9, 2001]

49 CFR §40.67 When And How Is A Directly Observed Collection[(1)] Conducted? ***[GCMA Comment:*** *A "directly observed" and a "monitored" collection as described in 49 CFR 40.69 refer to two slightly different procedures.]*

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

(a)(1) The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to you that there was not an adequate medical explanation for the result; or

(a)(2) The MRO reported to you that the original positive, adulterated, or substituted test result had to be cancelled because the test of the split specimen could not be performed.

(a)(3) The laboratory reported to the MRO that the specimen was substituted with a creatinine concentration greater than or equal to 2 mg/dl, and less than 5 mg/dl, and the MRO reported the specimen to you as negative and dilute (see §§40.145(a)(1) and 401.97).

(b) As an employer, you may direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.

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

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

(c)(2) You observed materials brought to the collection site or the employee's conduct clearly indicates an attempt to tamper with a specimen (see §§40.61(f)(5)(i) and 40.63(e)); or

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

(c)(4) The original specimen appeared to have been tampered with (see §40.65(c)(1)).

(d)(1) As the employer, you must explain to the employee the reason for a directly observed collection under paragraph (a) or (b) of this section.

(d)(2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed collection under paragraphs (c)(1) through (3) of this section.

(e) As the collector, you must complete a new CCF for the directly observed collection.

(e)(1) You must mark the "reason for test" block (Step 1) the same as for the first collection.

(e)(2) You must check the "Observed, (Enter Remark)" box and enter the reason (see §40.67(b)) in the "Remarks" line (Step 2).

(f) In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the specimen at the collection site, enter on the "Remarks" line of the CCF (Step 2) for each specimen a notation to this effect (e.g., collection 1 of 2, or 2 of 2) and the specimen ID number of the other specimen.

(g) As the collector, you must ensure that the observer is the same gender[(1)] as the employee. You must never permit an opposite gender person to act as the observer. The observer can be a different person from the collector and need not be a qualified collector. *[[(1)]**GCMA Comment:** Gender = male or female.]*

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

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

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

(k) As the collector, when someone else has acted as the observer, you must include the observer's name in the "Remarks" line of the CCF (Step 2).

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

(m) As the collector, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

[65 FR 79462, Dec. 19, 2000; 66 FR 41944, Aug. 9, 2001]

49 CFR §40.69 How Is A Monitored Collection Conducted.

(a) As the collector, you must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

(b) As the collector, you 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 to practice in the jurisdiction in which the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.

(c) As the collector, if someone else is to monitor the collection (e.g., in order to ensure a same-gender monitor), you must verbally instruct that person to follow the procedures of paragraphs (d) and (e) of this section. If you, the collector, are the monitor, you must follow these procedures.

(d) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation (see §§40.63(e), 40.65(c), and 40.67(b)).

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

(f) As the collector, when someone else has acted as the monitor, you must note that person's name in the "Remarks" line of the CCF (Step 2).

(g) As the employee being tested, if you decline to permit a collection authorized under this section to be monitored, it is a refusal to test.

[65 FR 79462, Dec. 19, 2000; 66 FR 41944, Aug. 9, 2001]

49 CFR §40.71 How Does The Collector Prepare The Specimens?

(a) All collections under DOT agency drug testing regulations must be split specimen collections.

(b) As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you. You must take these steps in the presence of the employee.

(b)(1) Check the box on the CCF (Step 2) indicating that this was a split specimen collection.

(b)(2) You, not the employee, must first pour at least 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.

(b)(3) You, not the employee, must then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.

(b)(4) You, not the employee, must place and secure (i.e., tighten or snap) the lids/caps on the bottles.

(b)(5) You, not the employee, must seal the bottles by placing the tamper-evident bottle seals over the bottle caps/lids and down the sides of the bottles.

(b)(6) You, not the employee, must then write the date on the tamper-evident bottle seals.

(b)(7) You must then ensure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the specimens he or she provided. If the employee fails or refuses to do so, you must note this in the "Remarks" line of the CCF (Step 2) and complete the collection process.

(b)(8) You must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: you may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT agency regulation. Neither you nor anyone else may conduct further testing (such as adulteration testing) on this excess urine and the employee has no legal right to demand that the excess urine be turned over to the employee.

[65 FR 79462, Dec. 19, 2000; 66 FR 41944, Aug. 9, 2001]

49 CFR §40.73 How Is The Collection Process Completed?

(a) As the collector, you must do the following things to complete the collection process. You must complete the steps called for in paragraphs (a)(1) through (a)(7) of this section in the employee's presence.

(a)(1) Direct the employee to read and sign the certification statement on Copy 2 (Step 5) of the CCF and provide date of birth, printed name, and day and evening contact telephone numbers.[(1)] If the employee refuses to sign the CCF or to provide date of birth, printed name, or telephone numbers, you must note this in the "Remarks" line (Step 2) of the CCF, and complete the collection. If the employee refuses to fill out any information, you must, as a minimum, print the employee's name in the appropriate place. *[(1)**GCMA Comment:** So the MRO can contact you with the results of your test or with any further questions he or she may have.]*

(a)(2) Complete the chain of custody on the CCF (Step 5) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory,

(a)(3) Ensure that all copies of the CCF are legible and complete.

(a)(4) Remove Copy 5 of the CCF and give it to the employee.

(a)(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(a)(6) Secure both pouches of the plastic bag.

(a)(7) Advise the employee that he or she may leave the collection site.

(a)(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(a)(8)(i) Place the sealed plastic bag in a shipping container (e.g., standard courier box) designed to minimize the possibility of damage during shipment. (More than one

sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(a)(8)(ii) Seal the container as appropriate.

(a)(8)(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

(a)(9) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations.

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

[65 FR 79462, Dec. 19, 2000]

TITLE 49 CFR PART 40, SUBPART H SPLIT SPECIMEN TESTS

49 CFR §40.171 How Does An Employee Request A Test Of A Split Specimen?

***[GCMA Comment:** You left your urine specimen with the collector and watched it as it was sealed for shipment to the drug lab. You also signed the seal and the Custody and Control Form (CCF) and handed it over for shipment. The Medical Review Officer (MRO) is on the telephone and says you have a "Verified Positive Drug Test." You have a problem! If you are a drug user, you have been caught. If you "Do the crime, serve the time." But, if you did not use drugs, you have only one final safeguard to prove that the lab made some kind of a technical mistake. Read these regulations carefully!]*

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

(b)(1) If, as an employee, you have not requested a test of the split specimen within 72 hours, you may present to the MRO[(1)] information documenting that serious injury, illness, lack of actual notice of the verified test result, inability to contact the MRO (e.g., there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented you from making a timely request. *[(1)**GCMA Comment:** Just by taking a drug test, you have placed your career and your livelihood in other peoples' hands. Be sure you or someone reliable is available to receive the MRO's phone call or to receive the written notification at the address you gave on the Custody and Control form. Until the MRO contacts yoy, consider this test as "unfinished business." Don't just pack up, leave town or go to sea. Be available and be prepared to act promptly if the unexpected happens.]*

(b)(2) As the MRO, if you conclude from the employee's information that there was a legitimate reason for the employee's failure to contact you within 72 hours, you must direct that the test of the split specimen take place, just as you would when there is a timely request.[(1)] *[(1)**GCMA Comment:** This is a safeguard built into the system for your benefit.]*

(c) When the employee makes a timely request for a test of the split specimen under paragraphs (a) and (b) of this section, you must, as the MRO, immediately provide written notice to the laboratory that tested the primary specimen, directing the laboratory to forward the split specimen[(1)] to a second HHS-certified laboratory. You must also document the date and time of the employee's request. *[65 FR 79462, Dec. 19, 2000. [(1)]**GCMA Comment:** This will be a second test of the other half of your original urine specimen. It will be performed by a different laboratory. This part of the procedure will not require you to provide a second specimen.]*

49 CFR §40.173 Who Is Responsible For Paying For The Test Of A Split Specimen?

(a) As the employer, you are responsible for making sure (e.g., by establishing appropriate accounts with laboratories for testing split specimens) that the MRO, first laboratory, and second laboratory perform the functions noted in §§40.175-40.185 in a timely manner, once the employee has made a timely request for a test of the split specimen.[(1)] ***[GCMA Comment:** Your employer **must** pay to have the second half of your specimen tested. This is a very important point if you even suspect that the first laboratory incorrectly tested the first part of your original split specimen. It is very important that the second half of the split sample be tested by another laboratory or you will never be able to prove the first lab made a mistake!]*

(b) As the employer, you must not condition your compliance with these requirements on the employee's direct payment to the MRO or laboratory or the employee's agreement to reimburse you for the costs of testing. For example, if you ask the employee to pay for some or all of the cost of testing the split specimen, and the employee is unwilling or unable to do so, you must ensure that the test takes place in a timely manner, even though this means that you pay for it.[(1)] *[(1)**GCMA Comment:** Don't let anyone talk you out of your rights!]*

(c) As the employer, you may seek payment or reimbursement of all or part of the cost of the split specimen from the employee (e.g., through your written company policy[(1)] or a collective bargaining agreement[(2)]). This part takes no position on who ultimately pays the cost of the test, so long as the employer ensures that the testing is conducted as required and the results released appropriately. *[65 FR 79462, Dec. 19, 2000. **GCMA Comment:** [(1)]Most new employees are required to read company policy manuals and letters. Know where the company stands on paying for split-sample tests before you run into the problem. Also know that drug tests generally cost no more than $40.00. Your investment in your career is much greater than that! Your career is at risk here; protect it. [(2)]A union collective bargaining agreement will generally provide details...and you are expected to read and understand your rights.]*

49 CFR §40.175 What Steps Does The First Laboratory[(1)] Take With A Split Specimen? *[(1)**GCMA Comment:** The "First Laboratory" is the laboratory the collector sent one-*

half of your split sample (i.e., the "primary" sample) to for testing. They do not know your name, only a number. If the first laboratory tests your primary specimen as "positive," then you can request the other part of your split sample to be sent to a second HHS/SAMSHA-approved laboratory for an independent test.]

(a) As the laboratory at which the primary and split specimen first arrive, you[1] must check to see whether the split specimen is available for testing. *[[1]**GCMA Comment:** In this section, "you" refers to the first laboratory.]*

(b) If the split specimen is unavailable[1] or appears insufficient,[2] you must then do the following: *[**GCMA Comment:** [1] "Unavailable" could cover a variety of excuses such as spilled specimen, lost bottles, etc. The test of the available sample can go on, but the problem may reappear in some cases later. [2]"Insufficient" means there is not enough urine to test, possibly as a result of leakage. Possibly you did not provide enough urine for two complete samples...something you should have been aware of at the time of collection.]*

(b)(1) Continue the testing process for the primary specimen as you would normally. Report the results for the primary specimen without providing the MRO information regarding the unavailable split specimen.[1] *[[1]**GCMA Comment:** This means that the Medical Review Officer will talk to you only about the "primary" specimen. At this point, the MRO will not know of possible problems in testing the second half of your split sample.]*

(b)(2) Upon receiving a letter from the MRO instructing you to forward the split specimen to another laboratory for testing, report to the MRO that the split specimen is unavailable for testing. Provide as much information as you can about the cause of the unavailability.

(c) As the laboratory that tested the primary specimen, you are not authorized to open the split specimen under any circumstances (except when the split specimen is redesignated as provided in §40.83).

(d) When you receive written notice from the instructing you to send the split specimen to another HHS-certified laboratory, you must forward the following items to the second laboratory:

(d)(1) The split specimen in its original specimen bottle, with the seal intact;

(d)(2) A copy of the MRO's written request; and

(d)(3) A copy of Copy 1 of the CCF, which identifies the drug(s)/metabolite(s) or the validity criteria to be tested for.

(e) You must not send to the second laboratory any information about the identity of the employee. Inadvertent disclosure does not, however, cause a fatal flaw.[1] *[[1]**GCMA Comment:** A "fatal flaw" is one that destroys the validity of the entire test. A wide assortment of Commandant Decisions on Appeal decided upon over the years have reduced the chances of a "fatal flaw" occurring and are reflected in the latest regulations.]*

(f) This subpart does not prescribe who gets to decide which HHS-certified laboratory is used to test the split specimen. That decision is left to the parties involved. *[65 FR 79462, Dec. 19, 2000]*

49 CFR §40.177 What Does The Second Laboratory Do With The Split Specimen When It Is Tested To Reconfirm The Presence Of A Drug Or Drug Metabolite?

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) detected in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of §40.87.

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported positive in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in §40.91.

(d) In addition, if the test fails to reconfirm the presence of the drugs/drugs metabolites or validity criteria that were reported in the primary specimen, you may transmit the specimen or an aliquot of it to another HHS-certified laboratory that will conduct another reconfirmation test. *[65 FR 79462, Dec. 19, 2000]*

49 CFR §40.179 What Does The Second Laboratory Do With The Split Specimen When It Is Tested To Reconfirm An Adulterated Test Result?

As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the criteria of §40.95 just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria. *[65 FR 79462, Dec. 19, 2000]*

49 CFR §40.181 What Does The Second Laboratory Do With The Split Specimen When It Is Tested To Reconfirm A Substituted Test Result?

As the laboratory testing the split specimen, you must test the split specimen using the criteria of §40.93(b) , just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria. *[65 FR 79462, Dec. 19, 2000]*

49 CFR §40.183 What Information Do Laboratories Report To MROs Regarding Split Specimen Results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the "Reconfirmed" box or the "Failed to Reconfirm" box (Step 5(b)) on Copy 1 of the CCF.

(b) If you check the "Failed to Reconfirm" box, one of the following statements must be included (as appropriate) on the "Reason" line (Step 5(b)):

(b)(1) "Drug(s)/Drug Metabolite(s) Not Detected."

(b)(2) "Adulterant not found within criteria."

(b)(3) "Specimen not consistent with substitution criteria [specify creatinine, specific gravity, or both]"

(b)(4) "Specimen not available for testing."

(c) As the laboratory certifying scientist, enter your name, sign, and date the CCF. *[65 FR 79462, Dec. 19, 2000]*

49 CFR §40.185 Through What Methods And To Whom Must A Laboratory Report Split Specimen Results?

(a) As the laboratory testing the split specimen, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or another service agent (e.g., a C/TPA).

(b) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF, which has been signed by the certifying scientist.

(c) You must transmit the laboratory result to the MRO immediately, preferably on the same day or next business day as the result is signed and released. *[65 FR 79462, Dec. 19, 2000]*

49 CFR §40.187 What Does The MRO Do With Split Specimen Laboratory Results?

As an MRO, you must take the following actions when a laboratory reports the following results of split specimen tests:

(a) **Reconfirmed**. (1) In the case of a reconfirmed positive test for a drug or drug metabolite, report the reconfirmation to the DER and the employee.

(a)(2) In the case of a reconfirmed adulterated or substituted result, report to the DER and the employee that the specimen was adulterated or substituted, either of which constitutes a refusal to test. Therefore, "refusal to test" is the final result.

(a)(3) In the case of a reconfirmed substituted result, in which the creatinine concentration for the primary specimen was less than 2 mg/dl and the creatinine concentration of the split specimen is between 2 and 5 mg/dl inclusive, report the result to the employer as ñdiluteò and instruct the employer to conduct an immediate recollection under direct observation.

(b) **Failed to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected**. (1) Report to the DER and the employee that both tests must be cancelled.

(b)(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(c) **Failed to Reconfirm: Adulteration or Substitution** (as appropriate) Criteria Not Met. (1) Report to the DER and the employee that both tests must be cancelled.

(c)(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(d) **Failed to Reconfirm: Specimen not Available for Testing**. (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(d)(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(d)(3) Using the format in Appendix D to this part, notify ODAPC of the failure to reconfirm.

(e) **Failed to Reconfirm: Specimen Results Invalid**. (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(e)(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(e)(3) Using the format in Appendix D to this part, notify ODAPC of the failure to reconfirm.

(f) **Failed to Reconfirm: Split Specimen Adulterated**. (1) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated.

(f)(2) Follow the procedures of §40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration.

(f)(3) If you determine that there is a legitimate medical explanation for the adulterated test result, report to the DER and the employee that the test is cancelled. Using the format in Appendix D to this part, notify ODAPC of the result.

(f)(4) If you determine that there is not a legitimate medical explanation for the adulterated test result, take the following steps:

(f)(4)(i) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen also is present in the primary specimen.

(f)(4)(ii) Except that the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of §§40.153, 40.171, 40.173, 40.179, and 40.185.

(f)(4)(iii) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF .

(f)(4)(iv) If the test of the primary specimen reconfirms the adulteration finding of the split specimen, as the MRO you must report the test result as a refusal as provided in §40.187(a)(2).

(f)(4)(v) If the test of the primary specimen fails to reconfirm the adulteration finding of the split specimen, as the MRO you cancel the test. Follow the procedures of paragraph (e) of this section in this situation.

(g) Enter your name, sign and date (Step 7) of Copy 2 of the CCF.

(h) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see §40.163) to the employer and keep a copy for your records. Transmit the document as provided in §40.167. *[65 FR 79462, Dec. 19, 2000; 66 FR 41944, Aug. 9, 2001]*

49 CFR §40.189 Where Is Other Information Concerning Split Specimens Found In This Regulation?

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

§40.3ð Definition.

§40.65ð Quantity of split specimen.

§40.67ð Directly observed test when split specimen is unavailable.

§§40.71-40.73ð Collection process for split specimens.

§40.83ð Laboratory accessioning of split specimens.

§40.99ð Laboratory retention of split specimens

§40.103ð Blind split specimensð MRO notice to employees on tests of split specimen.

§§40.193 and 40.201ð MRO actions on insufficient or unavailable split specimens.

Appendix D to Part 40ð Report format for split specimen failure to reconfirm. *[65 FR 79462, Dec. 19, 2000]*

ADDENDA

49 CFR §40.191 What Is A Refusal To Take A DOT Drug Test, And What Are The Consequences?

(a) As an employee, you have refused[(1)] to take a drug test if you: *[[(1)]**GCMA Comment:** Be careful! The Coast Guard interpretation of "refusal" to test covers a wide*

assortment of cases settled by Commandant Decisions on Appeal (CDOA) that have closed just about every possible loophole. Dozens of failed legal opinions advanced by lawyers at great expense to mariners and decided years ago litter the landscape!]

(a)(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see §40.61(a));

(a)(2) Fail to remain at the testing site until the testing process is complete; Provided, That an employee who leaves the testing site before the testing process commences (see §40.63(c)) for a pre-employment test is not deemed to have refused to test;

(a)(3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations;[(1)] Provided, That an employee who does not provide a urine specimen because he or she has left the testing site before the testing process commences (see §40.63(c)) for a pre-employment test is not deemed to have refused to test; *[[(1)]**GCMA Comment:** The reference is to USCG "Chemical Testing" regulations in 46 CFR Part 16 or 33 CFR Part 95.]*

(a)(4) In the case of a directly observed or monitored collection in a drug test, fail to permit the observation or monitoring of your provision of a specimen (see §§40.67(l) and 40.69(g));

(a)(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see §40.193(d)(2));

(a)(6) Fail or decline to take a second test the employer or collector has directed you to take (see, for instance §40.193(d)(2));

(a)(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under §40.193(d). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment; or

(a)(8) Fail to cooperate with any part of the testing process (e.g., refuse to empty pockets when so directed by the collector, behave in a confrontational way that disrupts the collection process).

(b) As an employee, <u>if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test</u>.

(c) As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations.

(d) As a collector or an MRO, when an employee refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the CCF (including, in the case of the collector, printing the employee's name on Copy 2 of the CCF), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating a "shy bladder" condition or a claim of a legitimate medical explanation in a validity testing situation), you must notify the MRO, who in turn will notify the DER.

(d)(1) As the collector, you must note the refusal in the "Remarks" line (Step 2), and sign and date the CCF.

(d)(2) As the MRO, you must note the refusal by checking the "refused to test because" box (Step 6) on Copy 2 of the CCF, and add the reason on the "Remarks" line. You must then sign and date the CCF.

(e) As an employee, <u>when you refuse to take a non-DOT test or to sign a non-DOT form</u>, you have **<u>NOT REFUSED</u>** to take a DOT test. <u>There are no consequences under DOT agency regulations for refusing to take a non-DOT test</u>.

[65 FR 79462, Dec. 19, 2000; 66 FR 41944, Aug. 9, 2001]

49 CFR §40.193 What Happens When An Employee Does Not Provide A Sufficient Amount Of Urine For A Drug Test?

(a) This section prescribes procedures for situations in which an employee does not provide a sufficient amount of urine to permit a drug test (i.e., 45 mL of urine).

(b) As the collector, you must do the following:

(b)(1) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see §40.65(b) and (c)).

(b)(2) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. <u>It is not a refusal to test if the employee declines to drink</u>. Document on the Remarks line of the CCF (Step 2), and inform the employee of, the time at which the three-hour period begins and ends.

(b)(3) If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER. <u>This is a refusal to test</u>.

(b)(4) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER.

(b)(5) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.

(c) As the DER, when the collector informs you that the employee has not provided a sufficient amount of urine (see paragraph (b)(4) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(c)(1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(c)(1)(i) That the employee was required to take a DOT drug test, but was unable to provide a sufficient amount of urine to complete the test;

(c)(1)(ii) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(c)(1)(iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.

(c)(2) [Reserved]

(d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(d)(1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:

(d)(1)(i) Check "Test Cancelled" (Step 6) on the CCF; and

(d)(1)(ii) Sign and date the CCF.

(d)(2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must:

(d)(2)(i) Check "Refusal to test because" (Step 6) on the CCF and enter reason in the remarks line; and

(d)(2)(ii) Sign and date the CCF.

(e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of "situational anxiety" or dehydration.

(f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(g) If, as the referral physician making this evaluation in the case of a pre-employment test, you determine that the employee's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of §40.195, where applicable.

(h) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. You must report your determination to the DER in writing as soon as you make it.

(i) As the employer, when you receive a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. The employee remains in the random testing pool.

[65 FR 79462, Dec. 19, 2000; 66 FR 41944, Aug. 9, 2001]

49 CFR Appendix A To Part 40—DOT Standards For Urine Collection Kits

The Collection Kit Contents:

1. **Collection Container**

a. Single-use container, made of plastic, large enough to easily catch and hold at least 55 mL of urine voided from the body.

b. Must have graduated volume markings clearly noting levels of 45 mL and above.

c. Must have a temperature strip providing graduated temperature readings 32-38°C/90-100°F, that is affixed or can be affixed at a proper level on the outside of the collection container. Other methodologies (e.g., temperature device built into the wall of the container) are acceptable provided the temperature measurement is accurate and such that there is no potential for contamination of the specimen.

d. Must be individually wrapped in a sealed plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system.

e. May be made available separately at collection sites to address shy bladder situations when several voids may be required to complete the testing process.

2. **Plastic Specimen Bottles**

a. Each bottle must be large enough to hold at least 35 mL; or alternatively, they may be two distinct sizes of specimen bottles provided that the bottle designed to hold the primary specimen holds at least 35 mL of urine and the bottle designed to hold the split specimen holds at least 20 mL.

b. Must have screw-on or snap-on caps that prevent seepage of the urine from the bottles during shipment.

c. Must have markings clearly indicating the appropriate levels (30 mL for the primary specimen and 15 mL for the split) of urine that must be poured into the bottles.

d. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit with no damage to the seal when the employee initials it nor with the chance that the seal overlap would conceal printed information.

e. Must be wrapped (with caps) together in a sealed plastic bag or shrink wrapping separate from the collection container; or must be wrapped (with cap) individually in sealed plastic bags or shrink wrapping; or must have peelable, sealed lid or other easily visible tamper-evident system.

f. Plastic material must be leach resistant.

3. **Leak-Resistant Plastic Bag**

a. Must have two sealable compartments or pouches which are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.

b. The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident.

4. **Absorbent material**

Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. **Shipping Container**

a. Must be designed to adequately protect the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory (e.g., standard courier box, small cardboard box, plastic container).

b. May be made available separately at collection sites rather than being part of an actual kit sent to collection sites.

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimen bottles in the plastic leak-proof bags from the collection site to the laboratory.

[59 FR 43002, Aug. 19, 1994, as amended at 60 FR 19537, Apr. 19, 1995; 65 FR 79462, Dec. 19, 2000]