Urine Specimen Collection Guidelines

United States
Department of Transportation

Office of Drug and Alcohol Policy and Compliance

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DOT Urine Specimen Collection Guidelines

for the

U.S. Department of Transportation Workplace

Drug Testing Programs
(49 CFR Part 40)

Revised July 3, 2014 [previous editions become obsolete].

These guidelines apply only to employers and individuals who come under the regulatory authority of the U.S. Department of Transportation (DOT) and those individuals who conduct urine specimen collections under DOT regulations. The term "employee" is used throughout this document and has the same meaning as "donor" as used on the Federal Drug Testing Custody and Control Form (CCF).

These guidelines are a complete revision of the DOT Urine Specimen Collection Procedures Guidelines, 49 CFR Part 40, for Transportation Workplace Drug Testing Programs.

It contains minimal graphics and formatting to ease transmission and downloading of the document from the Internet.

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This document may be updated or modified based on additional interpretations or other procedural changes. Collectors and service agents should check the ODAPC web site periodically to ensure that they have the latest version: www.dot.gov/odapc .

INTRODUCTION

The Department of Transportation's (DOT) Operating Administrations – Federal Aviation Administration, Federal Motor Carrier Safety Administration, Federal Railroad Administration, Federal Transit Administration, Pipeline and Hazardous Materials Safety Administration – and United States Coast Guard *(now with the Dept. of Homeland Security)* have issued regulations requiring anti-drug programs in the aviation, highway, railroad, transit, pipeline, and maritime industries. The DOT Agencies' rules require that employers conduct drug testing according to provisions of 49 CFR Part 40, "Procedures for Transportation Workplace Drug Testing Programs."

The procedures for collection of urine under these rules are very specific and must be followed whenever a DOT-required urine specimen collection is performed. (The only exception is the Federal Railroad Administration's Post-Accident Toxicological Testing Program in which a railroad representative will provide the collector specific instructions and a testing kit.) These procedures, including use of the Federal Drug Testing Custody and Control Form (CCF), apply only to DOT-required testing.

While employers may use our collection and testing procedures for testing under employer or state authority, they must not use a Federal CCF, nor can they imply that company tests are conducted using DOT authority.

The collector has a major role in the success of the DOT's drug testing program. The collector is the one individual in the testing process with whom all employees have direct, face-to-face contact. Without the collector assuring the integrity of the specimen and collection process, the test itself may lose validity. Without the collector's sensitivity to an employee's privacy, the entire testing program may be subject to criticism. It is imperative that collectors fully understand and follow these procedures. These guidelines, together with 49 CFR Part 40 and the DOT operating administrations' rules, will provide collectors with the information needed in the performance of their collection duties.

The information in this document addresses *and provides guidance concerning* normal collection procedures and some of the more common problems or situations encountered. However, information contained in this publication should not be used to interpret or *be viewed as adding to or modifying* the legal requirements of the actual rule.

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SECTION 1. COLLECTOR

Part 40 defines a collector as a trained person who instructs and assists employees at a collection site, who receives and makes an initial inspection of the urine specimen provided by those employees, and who initiates and completes the Federal Drug Testing Custody and Control Form (CCF).

> **Note:** DOT does not require or provide collector certification. Collectors need to have documentation reflecting that they have met appropriate training requirements at Appendix A.

Any individual, who has received training specified in 49 CFR Part 40 (§40.33) for conducting the required collection procedure, may serve as a collector except in the following situations:

> 1. The immediate supervisor of a particular employee may not act as the collector when that employee is tested, unless no other collector is available and the supervisor is permitted to do so under a DOT operating administration's drug and alcohol regulation. (The immediate supervisor may act as a monitor or observer (same gender) if there is *no one else available* at the collection site to conduct a monitored or observed collection.);
>
> 2. An employee who is in a safety-sensitive position and subject to the DOT drug testing rules should not be a collector, an observer, or a monitor for co-workers who are in the same testing pool or who work together with that employee on a daily basis. This is to preclude any potential appearance of collusion or impropriety;
>
> 3. An individual working for an HHS-certified drug testing laboratory (e.g., as a technician or accessioner) may not act as a collector if that individual can link the employee with the specimen drug test result or laboratory report; and,
>
> 4. The employee may not be the collector of his or her own urine specimen.
>
> **Note:** 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., fiancée).

A collector should have appropriate identification, which includes the collector's name and the name of the Collection Company or clinic. The collector is required to provide his or her identification if requested by the employee. There is no requirement for the collector to have a picture I.D. or to provide his or her driver's license with an address or telephone number. Also, the collector is not required to provide any certification or other documentation to the employee documenting the collector's training. However, the collector must provide this documentation on request to DOT agency representatives and to employers and service agents (SA) or *Consortium*/Third Party Administrators (C/TPAs) who are using or negotiating to use that collector's services.

The employer must provide the collector with the name and telephone number of the appropriate Designated Employee Representative (DER) and C/TPA, where applicable, to contact about any problems or issues that may arise during the collection process.

SECTION 2. COLLECTION SITE

A collection site is a place (permanent or temporary) selected by the employer where employees present themselves for the purpose of providing a urine specimen for a DOT-required drug test.

Generally, there are two types of collection facilities:

1. A single-toilet restroom, with a full-length privacy door, or

2. A multi-stall restroom, with partial-length doors.

A collection site must have:

1. A restroom or stall with a toilet for the employee to have privacy while providing the urine specimen. Whenever available, a single toilet restroom, with a full-length privacy door, is preferred. All types of restrooms including a mobile facility (e.g., a vehicle with an enclosed toilet) are acceptable.

2. A source of water for washing hands that, if practical, is external to the restroom where urination occurs. If the only source of water available is inside the restroom, the employee may wash his or her hands, and then the collector must secure the water source (e.g., use tamper-evident tape, cut off the water supply) before the collection takes place. If water is not available at the collection site, the collector may provide moist towelettes outside the restroom.

3. A suitable clean surface for the collector to use as a work area and for completing the required paper work.

A second type of facility for urination, which can be used as a collection site, is a multi-stall restroom. Such a site must provide substantial visual privacy (e.g., a toilet stall with a partial-length door) and meet all other requirements listed above (2 and 3). Additionally, if a multi-stall restroom is used, the collector must either:

1. 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

2. Conduct all collections as monitored collections (See Section 10).

No one but the employee may be present in the multi-stall restroom during the collection, except the monitor in the event of a monitored collection or the observer in the event of a directly observed collection.

Note: 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.

All collection sites must meet *the requirement of §40.43 including the* following security requirements:

1. Procedures or restrictions to prevent unauthorized access to the site during the collection;

2. Procedures to prevent the employee or anyone else from gaining unauthorized access to the collection materials/supplies. The collector must also ensure that the employee does not have access to items that could be used to adulterate or dilute the specimen (e.g., soap, disinfectants, cleaning agents, water);

Note: See "DOT's 10 Steps to Collection Site Security and Integrity" at Appendix B.

3. Procedures to ensure that all authorized persons are under the supervision of a collector or appropriate site personnel at all times when permitted into the site; and,

4. Procedures to provide for the secure handling and storage of specimens.

Note: The testing site is that portion of the facility where the collector performs the paper work, seals the specimens, and where urination occurs. It does not necessarily include the total physical facility (e.g., clinic). Additionally, unauthorized personnel are any individuals that are not specifically authorized by the regulation, the collector, or employer to be present at the collection site.

SECTION 3. COLLECTION SUPPLIES

The following items must be available at the collection site in order to conduct proper collections:

1. For each DOT drug test, a collection kit meeting the requirements listed at Appendix C of these guidelines.

2. Federal Drug Testing Custody and Control Forms (CCF).

3. Bluing (coloring) agent to add to the toilet bowl/water tank to prevent an employee from diluting the specimen.

4. The collector should have available tamper-evident tape for securing faucets, toilet tank tops, and other appropriate areas, and signs, when necessary, that can be posted to prevent entry into collection areas.

Note: Single use disposable gloves are recommended for use by collectors while handling specimens.

SECTION 4. FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

The 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. This form may be viewed on the DOT web site [http://www.dot.gov/odapc/] or the Department of Health and Human Services (HHS) web site [http://workplace.samhsa.gov/]. CCFs are also available from a number of different sources (e.g., laboratories, service agents) although they are usually part of the urine collection kits provided by a laboratory.

The CCF consists of the following five copies:

Copy 1.	Test Facility Copy - accompanies the specimen to the laboratory
Copy 2.	Medical Review Officer Copy - sent to the MRO
Copy 3.	Collector Copy - retained by the collector
Copy 4.	Employer Copy - sent to the employer
Copy 5.	Employee Copy - given to the employee

The CCF is completed as follows:

Step 1 (Copy 1). This step is completed by the collector or employer representative prior to the employee providing a urine specimen. The employer and MRO names, addresses, and telephone and fax numbers may be preprinted or handwritten. If the employer has designated a service agent to receive the results from the MRO, the employer's address may be omitted and the service agent's address may be used. However, in all cases, the specific employer's name, telephone and fax numbers must be included. A clinic or collection site name may not be used in lieu of an employer name. The collector enters the employee's social security number or employee's ID number after verifying the employee's identity. The collector also marks the appropriate box to indicate the reason for the test and the appropriate box for the type of drug tests to be performed (all DOT drug tests are for five drugs). The collector is to check the DOT Agency whose authority the specimen is collected. For example, if the employee's specimen is collected under the authority of the Federal Motor Carrier Safety Administration (FMCSA) regulation, the collector would check the "DOT" and "FMCSA" boxes. The collector then enters the information required for the collection site (this information may also be preprinted).

The collector's telephone number is critical, since the laboratory or the MRO may need to contact the collector if they have questions related to a collection.

Step 2 (Copy 1). This step is completed by the collector after receiving the specimen from the employee and observing the temperature of the specimen. This step requires the collector to mark the appropriate box to indicate if the temperature of the specimen *is* within the required temperature range. This step also requires the collector to indicate whether it is a split specimen or single specimen collection, to indicate if no specimen was collected and why, *and* to indicate if it was an observed collection and why.

> Note: Because all DOT collections are split specimen collections, *the collectors should ALWAYS check the split specimen box*.

Step 3 (Copy 1). This step instructs the collector to seal and date the specimen bottles, *to date the bottles seals after placing them on the bottles*, to have the employee initial the bottle seals after placing them on the bottles, and then instruct the employee to complete step 5 on the MRO copy (Copy 2).

Step 5 (Copy 2). This step is completed by the employee (listed as donor on the CCF). The employee reads the certification statement, prints his or her name, provides date of birth, daytime and evening telephone numbers, date of collection, and signs the form. After the employee completes this portion of the CCF, the collector reviews it to ensure that all the required information was provided.

Step 4 (Copy 1). This step is initiated by the collector and then completed by the laboratory after the laboratory accessions the specimen. This step requires the collector to sign the form to certify that the specimen was collected, labeled, sealed, and released for shipment to the laboratory in accordance with Federal requirements. The collector is also required to note the time of the collection, the date of collection, and the specific name of the delivery service to whom the specimen is released for shipment to the laboratory.

> Note: There is no requirement for couriers, express carriers, or postal service personnel to add additional documentation to the chain of custody for the specimens during transit because they do not have direct access to the specimens or the CCF. Chain of custody annotations resume when the shipping container/package is opened and accessioned at the laboratory.

Step 5(a) (Copy 1). This step is completed by the laboratory to report the test result of the primary specimen.

Step 5(b) (Copy 1). This step is completed by the laboratory to report the test result of the split specimen if the split specimen is tested.

Step 6 (Copy 2). This step is completed by the MRO in reporting the results of the primary specimen to the employer.

Step 7 (Copy 2). This step is completed by the MRO in reporting the results of the split specimen to the employer.

The bottom area of Copy 1 is reserved for the tamper-evident specimen bottle seals/labels. There must be two seals/labels *to accommodate collecting split specimens* (i.e., one marked with the letter "A" to designate the primary specimen and the other marked with the letter "B" to designate the split specimen) to accommodate collecting split specimens.

> **Note:** No one (including collection site personnel or the collector) is permitted to require an employee to sign a consent, release, or waiver of liability, or indemnification agreement with respect to any part of the drug testing process. Collection sites (clinics) may not use “generic” consent forms for DOT-required urine specimen collections, even if their clinic policy requires consent from the general patient population.

SECTION 5. INFORMATION EMPLOYERS PROVIDE TO COLLECTORS

49 CFR Part 40 requires the employer or *its* service agent – for example a C/TPA -- to ensure the collector has the following information when conducting a urine specimen collection for *it*:

(a) Full name of the employee being tested.

(b) Employee SSN or ID number.

(c) Laboratory name and address (can be pre-printed on the CCF).

(d) Employer name, address, phone number, and fax number (this can be pre-printed on the CCF at Step 1-A).

(e) DER name and telephone number (and C/TPA, where applicable).

(f) MRO name, address, phone number, and fax number (can be pre-printed on the CCF at Step 1-B).

(g) The DOT Agency that regulates the employee's safety-sensitive duties (the checkmark can pre-printed in the appropriate box on the CCF at Step 1-D)

(h) Test reason, as appropriate: Pre-employment; Random; Reasonable Suspicion/Reasonable Cause; Post-Accident; Return-to-Duty; and Follow-up.

(i) Whether the test is to be observed or not [see 40.67(a) & (b)].

(j) (Optional) C/TPA name, address, phone, and fax number (can be pre-printed on the CCF).

SECTION 6. EMPLOYEE IDENTIFICATION

The employee must provide appropriate identification to the collector *at the outset of the collection process*. Acceptable forms of identification include:

1. A photo identification (e.g., drivers license, employee badge issued by the employer, or any other picture identification issued by a Federal, state, or local government agency), or

2. Identification by an employer or employer representative, or
3. Any other identification allowed under an operating administration's rules.

Note: If the employee cannot produce positive identification, the collector must contact a DER to verify the identity of the employee. The collection should not proceed until positive identification is obtained. However, if an owner/operator or other self-employed individual does not have proper identification, the collector should record in the remarks section that positive identification is not available. The owner/operator or other self-

employed individual should be asked to provide two items of identification bearing his/her signature. The collector then proceeds with the collection. When the donor signs the certification statement, the collector should then compare the signature on the CCF with the signatures on the identification provided previously by the owner/operator or other self-employed individual. If the signatures appear consistent, the collection process continues. If the signature does not match signatures on the identification presented, the collector should make an additional note in remarks section stating "signature identification is unconfirmed."

Unacceptable forms of identification include:

1. Identification by a co-worker,

2. Identification by another safety-sensitive employee,

3. Use of a single non-photo identification card (e.g., social security card, credit card, union or other membership cards, pay vouchers, voter registration card), or

4. Faxed or photocopies of identification document.

SECTION 7. COLLECTION PROCEDURES

The collector must do the following before each collection to deter potential tampering, adulteration, alteration, or substitution of the specimens:

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

2. Ensure that the water in the toilet and tank (if applicable) has bluing (coloring) agent in it. Tape or otherwise secure shut any movable toilet tank *lid*, or put bluing in the tank;

3. Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;

4. Inspect the site to ensure that no foreign or unauthorized substances are present;

5. Ensure that undetected access (e.g., through a door *or window* not in your view) is not possible;

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

7. Recheck items (1) through (6) following each collection to ensure the site's continued integrity.

If the collection site uses a facility normally used for other purposes, such as a public restroom or hospital examining room, the collector must also ensure before the collection that:

1. Access to collection materials and specimens is effectively restricted; and
2. The facility is secured against access during the procedure to ensure privacy to the employee and prevent distraction of the collector. Limited-access signs must be posted.

Note: See "DOT's 10 Steps to Collection Site Security and Integrity" at Appendix B.

To avoid distraction that could compromise security, the collector is limited to conducting a collection for only one employee at a time. However, during the 3 hour *waiting period* that an employee can consume fluids (shy bladder), the collector may conduct a collection for another employee. In this case, the employee with the shy bladder must be monitored *to ensure the continued integrity of the test* (see Section *8*).

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, the collector must 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, the collector must notify the DER that the employee has not reported for testing.

Note: 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).

Note: There is no requirement for a collector to inform the employee that failure to remain at the collection site or otherwise fails to cooperate with the testing process constitutes a refusal. It is a best practice for the collector to inform the employee that such behavior could lead an employer to determine that a refusal occurred.

The following steps describe a typical urine collection conducted under the DOT-mandated procedures:

1. The collector prepares the collection site to collect urine specimens. All collection supplies must be available, the area properly secured, water sources secured, and bluing (coloring) agent placed in all toilets as *required by Part 40 and reiterated* in Sections 2 and 3 of these guidelines.

2. The collector begins the collection without delay after the employee arrives at the collection site. Do not wait because the employee is not ready or states he or she is unable to urinate. In most cases, employees who state they cannot provide a specimen will, in fact, provide sufficient quantity to complete the testing process.

Note: If an alcohol breath test is also scheduled, the alcohol test should be conducted first, if practicable, *though the rule (§40.61(b)(1)) example suggests some situations where there can be an exception to this normal process*.

3. The collector requests the employee to present an acceptable form of identification. If the employee cannot produce positive identification, the collector must contact the DER to verify the identity of the employee (see Section 6 *for further guidance*). If the employee asks the collector

to provide identification, the collector must show the employee some form of identification. It must include the collector's name and the *name of the collector's* employer. It does not have to be picture identification or include the collector's home address or telephone number.

4. The collector explains the basic collection procedures to the employee and *shows the employee the instructions on the back of the CCF*.

5. The collector ensures that the required information is provided at the top of the CCF (the laboratory name and address and a pre-printed specimen ID number which matches the ID number on the specimen bottle seals). If the information is not already preprinted, the collector begins entering the required information in Step 1 of the CCF:

- Employer's name, address, telephone and fax number, and I.D. number (if applicable);
- MRO name, address, telephone and fax number;
- Employee SSN or employee ID number (refusal by the employee to provide a SSN is not a refusal to test, but requires the collector to annotate this in the remarks *section*);
- Reason for test;
- Drug test to be performed; and
- Collection site information.

Note: Part 40 requires a specific MRO's name and address on the CCF rather than the name of the clinic or medical facility. An employer must provide to the collector the name and telephone number of the appropriate DER. This may be part of the CCF information that is pre-printed or may be *separately documented*. If there is no employer or DER telephone number on the CCF, the collector should write in the DER name and telephone number on the CCF (if this information is available) so that either the collector or the MRO may get in touch with a company representative when any problems arise related to that specimen.

Note: The CCF may be pre-printed with the DOT and Agency designation boxes already checked. If it is not, the employer must *ensure the collector has* this information.

6. The collector *directs* the employee to remove any unnecessary outer clothing (e.g., coat, jacket, hat, etc.) and to leave any briefcase, purse, or other personal belongings he or she is carrying with the outer clothing. The employee may retain his or her wallet. If the employee asks for a receipt for any belongings left with the collector, the collector must provide one.

Note: To safeguard employee's belongings, procedures may be established where the belongings 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 and 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 the envelope with tamper-evident tape and retain the envelope in a secure place.

Note: The collector may encourage the employee to also leave, with his or her other belongings, any other items that the employee will not need or may be prohibited from carrying into the restroom.

Note: The employee must not be asked to remove other articles of clothing, such as shirt, pants, dress, or under garments. Additionally, the employee must not be requested or required to remove all clothing in order to wear a hospital or examination gown. An exception may be made, if the employee is also undergoing a physical examination authorized by a DOT operating administration's rule, in conjunction with the drug test, which normally includes wearing a hospital gown. Work boots or cowboy boots do not have to be removed unless the collector has a reason to suspect that the employee has something in them *that* may be used to adulterate or substitute a specimen. When an employee is asked to remove his or her hat or head covering, and 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.

7. The collector directs the employee to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee places the items back into the pockets and the collection procedure continues. If the employee refuses to empty his or her pockets, this is considered a refusal to cooperate in the testing process.

Note: If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, a directly observed collection procedure becomes a requirement. If the item appears to be inadvertently brought to the collection site, secure the item and continue with the normal collection procedure. For example, a bottle of eye drops may have been brought inadvertently and would have to be secured by the collector and the collection would proceed. However, a bottle of liquid or urine would suggest intent to tamper with the specimen and a directly observed collection would be required. 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 and the employer.

8. The collector instructs the employee to wash and dry his or her hands, under the collector's observation, and informs the employee not to wash his or her hands again until after the employee provides the specimen to the collector. The employee must not be allowed any further access to water or other materials that could be used to put into the specimen. If the employee refuses to wash his or her hands – after being directed to do so – this is a refusal to test.

Note: 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 and subsequently use them to attempt to adulterate the specimen.

9. The collector either gives *to* the employee or allows the employee to select the collection kit or collection container (if it is separate from the kit) from the available supply. Either the collector or the employee, with both present, then unwraps or breaks the seal of the kit or collection container.

> **Note:** Ensure the employee takes only the collection container into the room used for urination. The sealed specimen bottles remain with the collector.

> **Note:** 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. Do not unwrap or break the seal on any specimen bottle at this time. Unwrap only the collection container.

10. The collector directs the employee to go into the room used for urination, provide a specimen of at least 45 mL, not to flush the toilet, and return with the specimen as soon as possible after completing the void. (In many restrooms, a toilet tank into which bluing agent may be placed is not accessible to the collector. When the employee flushes the toilet, he or she can use the clear (un-blued) water to potentially dilute the specimen. 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.) The collector may set a reasonable time limit for the employee to be inside the bathroom and this time frame should be explained to the employee.

> **Note:** The collector should also tell the employee that the temperature of the specimen is a critical factor and that the employee should bring the specimen to the collector as soon as possible after urination. The collector should inform the employee that if it is longer than 4 minutes from the time the employee urinates into the container and the collector takes the specimen temperature, the potential exists that the specimen may be out of range and an observed collection may be required.

> **Note:** The collector *must* pay close attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to substitute or adulterate a specimen. If the collector detects such conduct, *the collector must complete the collection and immediately begin* a new collection under direct observation using a second CCF and a new kit. The collector then provides an appropriate comment on the "Remarks" line in Step 2 on the first CCF and second CCF indicating that this is the first of two or second of two (i.e., 1 of 2, 2 of 2) collections, the specimen ID numbers of the first and second CCF, the reason for the second collection, and that the second collection was *conducted* under direct observation (check appropriate box in Step 2 of the CCF). This will ensure that the laboratory and the MRO know that two separate specimens are being submitted for testing; the first one possibly being adulterated or substituted. Additionally, the collector must inform the collection site supervisor and the DER that a collection took place under direct observation and the reason for having done so.

11. After the employee gives the specimen to the collector, the collector must check the temperature of the specimen, check the specimen volume, and inspect the specimen for adulteration or substitution, *as described below*:

- The collector should check the temperature of the specimen as soon as the employee hands over the specimen, but no later than four minutes after the employee comes out of the restroom. The acceptable temperature range is 32°-38°C/ 90°-100°F. Temperature is determined by reading the temperature strip originally affixed to or placed on the outside of the collection container. If the temperature is within the acceptable range, the "Yes" box is marked in Step 2 on the CCF and the collector proceeds with the collection procedure. (If the temperature is out of range, the collector marks the "No" box in Step 2 and initiates an observed collection.)

- The collector then checks to make sure that the specimen contains a sufficient amount of urine (a minimum of 45 mL for all DOT collections). If the volume is sufficient, the collector checks the box on the CCF (Step 2) indicating that this was a split specimen collection. (This may be done at the same time that the collector checks the temperature box.)

- The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering or adulteration. If it is apparent from this inspection that the employee has adulterated or substituted the specimen (e.g., the specimen is blue, exhibits excessive foaming when shaken, has smell of bleach), a second collection using direct observation procedures must be conducted immediately.

If the temperature is outside the acceptable range, the volume is less than 45 mL, or the specimen may have been adulterated, the collector follows procedures in Section 11- Problem Collections.

12. After the employee hands the collection container to the collector, 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.) Bottles may be shrink-wrapped or secured by other easily discernable tamper-evident methodology and may be wrapped separately or together.

Note: Both the collector and 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. 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 and the collector can still maintain visual control of the specimen collection container.

Note: The following are considered refusals to test:

- The employee admits to the collector that he or she adulterated or substituted their specimen.

- The employee behaves in a confrontational way that disrupts the collection process.

In either of these refusal situations, the collector discards any specimen the employee provided previously and notifies the DER as soon as possible.

13. The collector, not the employee, then pours at least 30 mL of urine from the collection container into a specimen bottle and places the lid/cap on the bottle. This will be the primary specimen or "A" bottle. The collector, not the employee, then pours at least 15 mL into a second bottle and places the lid/cap on the bottle. This will be the "B" bottle used for the split specimen. (The collector may first pour the requisite amount of specimen into each bottle and then secure the lids/caps on each bottle.)

> **Note:** The collector should not fill the primary or split specimen bottle up to the cap because a completely full bottle is more likely to leak in transit. Additionally, when a split specimen bottle is full and subsequently frozen, it may cause the bottle material to crack and then leak during transit as the specimen thaws.

14. The collector, not the employee, must then remove the tamper-evident seals from the CCF and place them on each bottle. *The collector should also ensure* that the seal labeled as "A" is placed on the primary bottle with at least 30 mL of urine and that the seal labeled as "B" is placed on the bottle with *at least* 15 mL of urine. The seal must be centered over the lid/cap and down the sides of the bottle to ensure that the lid/cap cannot be removed without destroying the seal. The collector, not the employee, writes the date on the seals. The employee is then requested to initial the seals. The employee must be present to observe the sealing of the specimen bottles. If the employee fails or refuses to initial the seals, the collector must note this in the "Remarks" line of the CCF and complete the collection process; this is not considered a refusal to test.

> **Note:** The collector must not ask the employee to initial the labels/seals while they are still attached to the CCF; they must be initialed after they are placed on the bottles. The collector should also inform the employee to use care during the initialing process to avoid damaging the labels/seals.

> **Note:** Occasionally, the tamper-evident label/seal provided with the CCF will not properly adhere to the specimen bottle because of environmental conditions (e.g., moisture, temperature, specimen bottle material) or may be damaged or broken during the collection process. When this occurs, the collector should use the following corrective procedures:

> (a) If the seal is broken while being removed from the chain of custody form or during the application of the first seal on the primary bottle, the collector should transfer the information to a new CCF and use the seals from the second form.

> (b) If one seal is already in place on a bottle and the second seal is broken while being removed from the CCF or is broken during application on the second bottle or while the employee is initialing either seal, the collector should initiate a new CCF and 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 and must be initialed by the employee (both sets of employee initials should match). The collector should draw a line through the Specimen ID number and bar code (if present) on the original seals to ensure that the

laboratory does not use that number for reporting the results. The collector should not pour the specimen into new bottles.

(c) In both cases, the collector should ensure that all copies of the original (first) *CCF* are destroyed or disposed of properly (e.g., shredded, torn into pieces).

(d) If the collector inadvertently reverses the seals (i.e., places the "A" bottle seal on the split bottle and vise-versa) and the collector subsequently notices this, the collector should note this in the "Remarks" line and continue the collection process. Laboratories have procedures that permit them to "re-designate" the bottles.

Note: There is no corrective procedure available if the seal is broken after the employee leaves the collection site.

Note: Since the specimen bottle is now sealed with tamper-evident tape and does not have to be under the employee's direct observation, the employee is allowed to wash his or her hands if he or she desires to do so.

15. The collector directs the employee to read, sign, and date the certification statement, and provide date of birth, printed name, and day and evening contact telephone numbers in Step 5 of Copy 2 of the CCF.

Note: If the employee refuses to sign the form or provide date of birth, printed name, or telephone numbers, the collector must make a notation on the "Remarks" line to that effect and complete the collection. If the employee refuses to fill out any information, the collector must, as a minimum, print the employee's name in the appropriate place. This does not constitute a refusal to test.

16. The collector completes the collector's portion *in Step 4* on the CCF (Copy 1) by printing his or her name (the name may be pre-printed), recording the date and time of the collection, signing where indicated, and entering the specific name of the delivery or courier service transferring the specimens to the laboratory.

17. The collector then ensures that all copies of the CCF are legible and complete. The collector removes Copy 5 from the CCF and gives it to the employee.

Note: At this time, the collector can suggest that the employee list any prescription and over-the-counter medications he or she may be taking on the employee's copy (Copy 5) of the CCF, but not on any other copy. This information may help the employee remember what medications he or she may have taken if a *non-negative* result is reported by the laboratory to the MRO.

18. The collector places the specimen bottles and Copy 1 of the CCF inside the appropriate pouches of the leak-resistant plastic bag, and seals both pouches. If the employee has not had the opportunity to wash his or her hands, they may do so now. The collector then informs the employee that he or she may leave the collection site.

19. Any urine specimen left over in the collection container after both specimen bottles have been appropriately filled and sealed should be discarded at this time. Excess urine may be used to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT operating administration's regulation. No further testing (e.g., adulteration testing, DNA, additional drugs) may be conducted on this excess urine and the employee has no right to demand that the excess urine be turned over to the employee.

20. The collector places the sealed plastic bag in an appropriate shipping container (e.g., box, express courier mailer) designed to minimize the possibility of damage during shipment. More than one sealed plastic bag can be placed into a single shipping container if there are multiple collections. The collector seals the shipping container as appropriate. If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, the collector prepares the shipment as directed by the courier service. In this case, the plastic bag may not need to be placed into a shipping container, but still needs to be transported by the courier in a manner that protects the bottles from damage.

> **Note:** If the laboratory courier does not hand-deliver the specimens to the laboratory, but subsequently places the specimens into a commercial delivery system, the specimens must be placed into a shipping container to minimize damage in transit.

21. The collector then sends Copy 2 of the CCF to the MRO and Copy 4 to the DER (or service agent if authorized by the employer). The collector must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day and keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT operating administration's regulations.

> **Note:** The MRO copy (Copy 2) may be faxed to the MRO's secure fax machine, it may be scanned and the image sent to the MRO's secure computer, or it may be mailed or sent by courier to the MRO. (It is recommended that the MRO copy be faxed, since it is critical for the MRO to have this document to expeditiously conduct the verification process.) In the case where the MRO copy (Copy 2) is faxed or the scanned image is sent securely to the MRO, the collector or the collection site should maintain the MRO copies together with the collector's copies for 30 days. Retention is *necessary* in case the MRO's copy is lost in the mail or the faxed or scanned copy is not legible and another copy is required by the MRO. The transmission process must be coordinated between the collection site and the MRO to ensure that transmission procedures meet the MRO's requirements (e.g., MROs must provide secure fax numbers to collection sites, some MROs may want hard copies mailed; others may want only faxed copies).

22. The collector or collection site must ensure that each specimen collected is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

23. If the specimen will not be shipped immediately, the collector is responsible for ensuring its integrity and security. Specimens in plastic bags, which have not been placed into shipping containers or which are awaiting a laboratory courier, must be kept in a secure location. *Access to the specimens must be effectively restricted*.

Note: After specimens are placed into shipping containers that are subsequently sealed, the shipping containers may be placed with other containers or packages that the collection site has waiting to be picked up by a courier. It is expected that collection sites will use reasonable security to ensure that all of their packages are relatively secure and not subject to damage, theft, or other actions that would potentially raise questions related to the integrity of the specimens.

Note: Couriers, postal employees, and other personnel involved in the transportation of the sealed shipping container are not required to make, and should not attempt to make, additional chain of custody entries on the custody and control form.

The *entire* collection process is now complete.

SECTION 8. SHY BLADDER PROCEDURES

The term "shy bladder" refers to a situation when the employee does not provide a sufficient amount of urine (45 mL) for a DOT-required drug test. 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, and direct the employee to make the attempt to provide the specimen.

At the point in the collection procedure where the collector and employee unwrap/open a collection container, the collector does the following:

1. The collector requests the employee to go into the rest room and try to provide a specimen.

Note: 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.

2. If the employee provided an initial insufficient specimen, the collector discards the insufficient specimen. The collector then annotates in the “Remarks” line the time when the employee provided the insufficient specimen. This is the time when the “shy bladder” collection process starts.

Note: If there was actually no specimen provided on an attempt, the same collection container may be used for the next attempt (the employee may keep possession of the container during the waiting period). The collector uses the same CCF and continues to document subsequent collections on the same form.

Note: If the insufficient specimen is also out of temperature range (assuming there was sufficient specimen to activate the temperature strip) or shows evidence of adulteration or tampering, the collector completes the collection process, *does not discard the specimen, but instead* sends the insufficient specimen (temperature out of range or adulterated) to the laboratory and immediately initiates another collection under direct observation.

3. The collector explains to the employee the process for a shy bladder collection and urges the employee to drink up to 40 ounces of fluids, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink.

> **Note:** 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, although in total, the amount would have been at least 45 mL. In this case, the collector needs to determine if a longer time is needed for the employee to consume fluids and produce a sufficient volume of specimen. If the employee refuses to drink fluids, this is not considered a refusal to test, although the collector should explain to the employee that not drinking sufficient fluids may result in the employee's inability to provide a sufficient specimen and would require a medical evaluation. Under no circumstances can a collector "combine" urine collected from separate voids to create one specimen of sufficient volume.

4. If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is completed, the collector must discontinue the collection, note the fact on the "Remarks" line of the CCF (Step 2), and immediately notify the DER. This is a refusal to test.

> *Note: As with other collections situations, there is no requirement for the collector to inform the employee in a shy bladder situation that failure to remain at the collection site or otherwise fails to cooperate with the testing process constitutes a refusal. It is a best practice for the collector to inform the employee that such behavior could lead an employer to determine that a refusal occurred.*

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

> **Note:** The collector should maintain a record in the "Remarks" line on the CCF of the time of each attempt, whether there was any specimen provided or the quantity of specimen provided, and the amount of fluids that the employee was given to drink. During the waiting *period that the employee can consume fluids*, the employee must be monitored *to ensure the continued integrity of the test*. *While, as noted above, there is no requirement for the collector to do so, it is a good practice for the collector to inform* the employee that he or she is not permitted to leave the collection site and *that doing so could lead an employer to determine that a refusal occurred*.

6. The collector then sends Copy 2 of the CCF to the MRO and Copy 4 to the DER. This is done even if the employee did not provide any specimen in order to notify the MRO and the employer of the problem. The collector must send or fax these copies to the MRO and DER within 24 hours or the next business day.

SECTION 9. DIRECTLY OBSERVED COLLECTIONS

A directly observed collection procedure is the same as a routine collection procedure with the additional requirement that an observer *directly watches the urine go from the employee's body* into the collection container. The observer must be the same gender as the employee; there are no exceptions to this requirement.

> **Note:** See "DOT's Direct Observation Procedures" at Appendix D.

An observed collection is required when:

1. The employer or DER directs the collector (or collection site) to conduct a collection under direct observation.

> Note: The employer is required to conduct a directly observed collection, *with no advance notice to the employee* when:
>
> 1. The laboratory reports an invalid specimen and the MRO reports that there was not an adequate medical explanation for the result.
>
> 2. Because the split specimen test could not be performed (e.g., split lost, inadequate volume).
>
> 3. The MRO reports a negative-dilute result with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL.
>
> 4. The test is a return-to-duty or follow-up test.
>
> Note: An employee may not "volunteer" to have his or her specimen collected under direct observation.

2. The collector observed materials brought to the collection site or the employee's conduct clearly indicated an attempt to tamper with a specimen.

3. The temperature on the original specimen was out of range or the specimen appeared to have been tampered with.

> **Note:** The collector may serve as the observer when the collector is the same gender as the employee. If not, the collector must call upon another individual (who is the same gender as the employee) to act as the observer. The collector must verbally instruct the observer as to the procedures the observer must follow and specifically inform the observer not to take the specimen from the employee, but have the employee bring it to the collector. It is recommended that the collector have a short written outline of the *direct observation procedures to provide to and review with the observer.*

An observed collection is conducted in the following manner:

1. The collector must explain to the employee why a directly observed collection is being conducted. If the directly observed collection is requested by the employer, the collector may state the reason (if known) or may only state that the employer requested a directly observed collection.

2. The collector must complete a new CCF for the directly observed collection and 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).

3. The collector then checks the "Observed, (Enter Remark)" box and enters the reason in the "Remarks" line (Step 2) and the name of the observer if it is someone other than the collector.

4. In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the first specimen, the collector enters 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 CCF specimen ID number of the other specimen.

5. The collector, if the same gender as the employee, or the same gender observer enters the restroom or facility where urination occurs with the employee. The observer must request the employee to raise his or her shirt, blouse, or dress/skirt, as appropriate, above the waist *or navel*, and lower clothing and underpants *sufficient* to show the observer – by turning around – that the employee does not have a prosthetic device. After the observer has determined that the employee does not have such a device, the observer may permit the employee to return clothing to its proper position and then conduct the observed collection.

> **Note:** There are three basic types of devices employees could "wear." [Of course, there could be other devices, *here are examples of some* devices]:
>
> 1. One device has a long plastic tube connected to a bottle containing heated urine.
>
> 2. Another device consists of a short plastic tube attached to a battery-heated plastic bag.
> 3. One device goes a step further by replacing the tube with very realistic prosthetic genitalia designed to match the employee's skin tone.

6. The observer must watch the employee urinate into the collection container. Specifically, the observer must personally and directly watch the urine go from the employee's body into the collection container (use of mirrors or video cameras is not permitted).

> Note: If it is a multi-stall restroom, the observer must enter the stall with the employee.
>
> Note: With respect to direct observation collections, the following situations are considered refusals to test:

- The employee declines to allow a directly observed collection required or permitted by Part 40 to occur.

- The employee fails to follow the observer's instructions to raise and lower their clothing and to turn around to permit the observer to determine if the employee has a prosthetic or other device that could be used to interfere with the collection process.

- The employee possesses or wears a prosthetic or other device that could be used to interfere with the collection process.

In either of these situations, the collector discards any specimen the employee provided previously and notifies the DER as soon as possible.

7. After the employee has completed urinating into the collection container, the employee and observer leave the enclosed toilet stall/restroom and the employee hands the collection container directly to the collector. The observer must maintain visual contact of the collection container until the employee hands the container to the collector. If the observer is the collector, the collector may receive the collection container from the employee while they are both in the enclosed toilet stall/restroom.

8. If the collector learns that a directly observed collection should have taken place, but was not, the collector must inform the employer that the employee must be directed to return for an immediate recollection under direct observation.

SECTION 10. MONITORED COLLECTIONS

A monitored collection is one that is conducted under less than completely private conditions, utilizing a multi-stall restroom. If there is no practicable work place outside of the restroom, the collector may set up an area within the multi-stall restroom to be used as a work area and for finalizing the required paper work. (A collection which is not monitored may also be conducted in a multi-stall restroom, provided that the collector secures all of the stalls (bluing agent, etc.), secures all water sources and other potential sources of adulterants (soap dispensers) in the restroom, and posts signs or otherwise secures the restroom from entry by unauthorized personnel.)

A monitored collection is conducted in the following manner:

1. The collector must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

2. The monitor must be 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.

3. If someone other than the collector is to monitor the collection procedure (i.e., the collector is not a medical professional), the collector must verbally instruct that person to use the following procedures (if the collector is the monitor, the collector must also follow these procedures):

(a) A monitor stands outside the stall and does not watch the employee urinate. If the monitor hears sounds or makes other observations indicating an attempt to tamper with a specimen by the employee, there must be an additional collection conducted under direct observation.

(b) A monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

4. When someone besides the collector has acted as the monitor, the collector must note that person's name in the "Remarks" line of the CCF (Step 2).

5. If the employee declines to permit a collection authorized under Part 40 to be monitored, it is a refusal to test.

SECTION 11. PROBLEM COLLECTIONS

CATHETERIZATION.
If an employee needs medical attention (e.g., an injured employee in an emergency medical facility who is required to have a post-accident test), treatment takes priority and should not be delayed to collect a specimen. If an employee is catheterized as part of a medical procedure (following an accident), once the employee's medical condition is stabilized and the employee can give his or her consent to the collection (e.g., understand that a DOT collection is required, can sign the CCF), a urine specimen should be obtained from that employee. Procedures similar to those listed below may be used when an external urine bag is involved. A urine specimen must not be collected, by catheterization or other means, from an unconscious employee to conduct a DOT-required drug test. Catheterization of a conscious employee to obtain a urine specimen for a DOT-required test is also not authorized.

However, an employee who normally voids through intermittent or self-catheterization is required to provide a specimen in that manner if he or she is required to produce a specimen for a DOT test. If able to, the employee may provide the specimen directly from the catheter into the collection container in the privacy of a restroom. If an employee, who normally voids through self-catheterization, declines to do so, this would constitute a refusal to test.

EXTERNAL URINE BAG.
The following procedures should be used in the collection of a urine specimen from an employee who has a medical condition requiring an indwelling catheter or excretion of urine into an external bag. The urine specimen should be a freshly voided specimen. *An* employee with an indwelling catheter may urinate directly into a collection container. In the case of an employee with an external bag, the employee should be asked to empty his or her bag in the privacy of a bathroom, show the empty bag to the collector, and then drink sufficient fluids at the collection site 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. In this case, the temperature of the specimen would not be a critical factor. *If the specimen temperature is out of range, a direct*

observation collection would not necessarily be required because of the nature of the collection. The collector should be keenly aware of the potential embarrassment that this type of collection can cause the employee and should conduct the collection with appropriate decorum.

This procedure would not have to be done in a medical environment/health clinic or by a collector of the same gender, although the collector may try to accommodate the employee (e.g., conduct the collection at a medical facility, have the same gender collector) if the employee requests this and if it would not significantly delay the collection process. If the employer is aware of this situation prior to the actual collection (e.g., because the employee had previously expressed a desire to provide the specimen in a medical setting, requested a same gender collector, told the employer about the medical condition and its impact on urine collection for drug testing), the employer (collection site) may establish or modify procedures as needed to permit the employee to provide a specimen in a way consistent with the employee's privacy while still meeting regulatory requirements. In the case of a collection based on a post-accident or reasonable suspicion requirement, the collector may attempt to honor the employee's request (for the collection to be conducted in a medical setting or for the collector to be the same gender) if the collection can be accomplished within a reasonable time frame.

The above scenario assumes that the employee's medical condition is not one that decreases or completely prohibits renal output, and that the employee can produce normal amounts of urine that is excreted into an external bag. Therefore, an employee with this or similar medical conditions would be subject to the same testing requirements (e.g., pre-employment, random) and to the "shy bladder" protocol (three hours and 40 ounces of fluids) as an employee with no medical condition. If an employee who normally voids in this manner declines to provide a urine specimen under these conditions, it would constitute a refusal to test.

TEMPERATURE. The collector should check the temperature of the specimen as soon as the employee hands over the specimen, but no later than four minutes after the employee comes out of the restroom. The acceptable temperature range is 32°-38°C/ 90°-100°F. Temperature is determined by reading the temperature strip originally affixed to or placed on the outside of the collection container after the employee hands the specimen to the collector.

(a) If the temperature is within the acceptable range, the "Yes" box is marked in Step 2 on the CCF and the collector proceeds with the collection procedure.

(b) If the temperature is outside the acceptable range, the "No" box is marked in Step 2 on the CCF and if the temperature was below or above the acceptable range should be noted in the "Remarks" line. The collector completes the collection process for the "first" specimen and immediately begins a "second" collection under direct observation using a second CCF and a new kit. The collector then provides an appropriate comment on the "Remarks" line in Step 2 on the first CCF and second CCF indicating that this is the first of two or second of two collections, the specimen ID numbers of the first and second CCF, the reason for the second collection, and that the second collection was under direct observation. This will ensure that the laboratory and the MRO know that two separate specimens are being submitted for testing; the first one possibly being adulterated or substituted. Additionally, the collector must inform the collection site supervisor and the DER that a collection took place under direct observation and the reason for doing so.

Note: There is no requirement to take the employee's body temperature if the specimen temperature is out of range. If the collector suspects that the temperature strip was not activated, the collector should pour the urine specimen into another collection container with a temperature strip or into a specimen bottle which has a temperature strip attached, and use this method to determine the specimen temperature. Collectors should not introduce any other object (e.g., litmus paper, testing strips, etc.) into the specimen in the collection container or the bottles.

SPECIMEN VOLUME. The collector checks to make sure that the specimen contains a sufficient amount of urine (a minimum of 45 mL for all DOT collections). If the volume is sufficient, the collector checks the box on the CCF (Step 2) indicating that this was a split specimen collection. (This may be done at the same time that the collector checks the temperature box.)

If the volume is less than 45 mL, the action taken will depend on whether the temperature of the specimen is in or outside the acceptable temperature range.

(a) If the temperature is in the acceptable range, the specimen is discarded and a second specimen is collected. The collector may use the original CCF for the second specimen, but should annotate in the "Remarks" line the time that the first insufficient specimen was provided by the employee and the fact that this is a second collection (the time annotation is important since this may become a "shy bladder" situation). The collector should use a new specimen collection container, if these are available separately or a new kit.

(b) If the temperature is outside the acceptable range, a second specimen must be collected under direct observation and both specimens are sent to the laboratory for testing. The collector must use a separate CCF and kit for each specimen and provide an appropriate comment on each CCF to indicate why two specimens were collected.

ADULTERATION OR SUBSTITUTION. The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering or adulteration. If it is apparent from this inspection that the employee has adulterated or substituted the specimen (e.g., the specimen is blue, exhibits excessive foaming when shaken, has smell of bleach), a second collection using direct observation procedures must be conducted immediately. The first specimen and the second specimen collected using direct observation are both sent to the laboratory for testing. The first specimen is always sent to the laboratory even though it may have had an insufficient volume, but showed signs of tampering.

If the employee does not provide the required amount of urine for the second collection using direct observation, the collector annotates the time the second specimen was not provided and initiates the shy bladder procedures. If after 3 hours the employee still cannot provide a sufficient amount of specimen, the collector ends the collection process and informs the DER. The collector must send or fax Copy 2 of the CCF to the MRO and Copy 4 to the DER within 24 hours or the next business day. The collector must send the original specimen to the laboratory 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.

Note: In a case where the employee refuses to provide another specimen, refuses to provide a specimen under direct observation, or admits to the collector that he or she adulterated or substituted their specimen, the collector discards any specimen the employee provided previously during the collection and then notifies the DER that the employee refused to comply with a DOT test.

SECTION 12. BLIND QUALITY CONTROL SAMPLES

An employer or *Consortium*/Third Party Administrator (C/TPA) with an aggregate of 2000 or more DOT-covered employees, must send blind quality control samples to laboratories they use. If the employer or C/TPA *has* an aggregate of fewer than 2000 DOT-covered employees, they are not required to provide blind quality control samples.

To each laboratory to which an employer or C/TPA sends at least 100 specimens in a year, they must transmit a number of blind quality control samples equivalent to one percent of the specimens sent to that laboratory, up to a maximum of 50 blind quality control samples in each quarter (i.e., January-March, April-June, July-September, October-December). A C/TPA must apply this percentage to the total number of DOT-covered employees' specimens it sends to the laboratory. Blind quality control sample submissions must be evenly spread throughout the year.

Note: In general, the employer determines who will conduct the regulatory requirement for the employer to submit blind quality control samples. It may be the employer itself, the collection site, MRO, or the C/TPA. However, regardless of who purchases the blind quality control samples, they must be submitted through the normal collection procedures used by the employer and must be indistinguishable by the laboratory from normal specimens sent by the collection site for DOT testing.

The collector always submits the blind quality control sample using the same CCF as that used for an employee specimen. The collector provides the required information to ensure that the CCF has been properly completed as well as providing fictitious initials on the specimen bottle labels/seals. Since there is no employee, the collector must indicate that the sample is a "blind quality control" on the MRO copy where the employee would normally provide a signature (Step 5 on Copy 2 of the CCF).

Note: For a blind quality control sample, Copies 4 and 5 of the CCF (the employer and employee copy) may be discarded by the collector, unless the employer or the service agent requires the employer copy (in this case, the collector must ensure that the employer copy has the same “blind quality control” annotation as the MRO copy). All blind quality control samples must be submitted as DOT split specimen collections. Blind quality control samples may be obtained from companies listed on the HHS Internet web site (http://workplace.samhsa.gov/).

SECTION 13. CORRECTING COLLECTION PROBLEMS

The collector has the responsibility of trying to successfully complete a collection procedure for each employee.

1. If, during or shortly after the collection process, the collector becomes aware of any event that prevents the completion of a valid test or collection (e.g., a procedural or paperwork error), the collector must try to correct the problem promptly, if doing so is practicable. The collector may initiate another collection as part of this effort. 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.

2. If another collection is necessary, the collector must begin the new collection procedure as soon as possible, using a new CCF and a new collection kit.

> **Note:** If the collector becomes aware of a problem that can be corrected, but which has not already been corrected, the collector must take all practicable actions to correct the problem so that the test is not cancelled.

3. If the problem resulted from the omission of required information, the collector must, as the person responsible for providing that information, supply in writing the missing information and a statement that it is true and accurate. For example, suppose the collector forgot to make a notation on the "Remarks" line of the CCF that the employee did not sign the certification. The collector would, when the problem is called to his or her attention, supply a signed statement that the employee failed or refused to sign the certification and that the collector's signed statement is true and accurate. The collector must supply this information on the same business day on which he or she is notified of the problem, transmitting it by fax or courier.

4. If the problem is the use of a non-Federal CCF or an expired Federal form, the collector must provide a signed statement (e.g., a memorandum for record). The documentation must state that the incorrect form contains all the information needed for a valid DOT drug test, and that the incorrect CCF was used inadvertently or as the only means of conducting a test, in circumstances beyond the collector's control. The memorandum must also list the steps the collector took to prevent future use of non-Federal or expired Federal CCFs for DOT tests. This information must be supplied to the laboratory on the same business day that the collector is notified of the problem, and may be transmitted by fax or courier. The use of a non-Federal form does not, in and of itself, present a reason for the laboratory to reject the specimen for testing or for the MRO to cancel the test.

5. The collector must maintain a copy of the written and dated documentation of correction with the appropriate CCF. The collector must also mark the CCF in such a way (e.g., stamp noting correction, written notation) that it would be obvious on the face of the CCF that the corrected (missing) information was supplied.

When an HHS certified laboratory receives specimen bottles and the associated CCF, it checks to see if the specimen ID number on the specimen bottle labels/seals matches the number on the CCF, that the specimen bottle seals are intact, that there is sufficient specimen volume, and that the CCF has been properly completed by the collector. If there is any discrepancy and/or error of omission (i.e., the collector did not sign the chain of custody, the collector did not check the temperature box), the laboratory will contact the collector to determine if the discrepancy and/or

missing information can be recovered. That is, the collector can provide a *signed* statement attesting to the fact that he or she inadvertently forgot to properly document the CCF.

Note: If a fatal flaw exists in the collection process or a memorandum for record or other written statement cannot be provided by the collector to related to a correctable flaw, the laboratory will report "Rejected for Testing" to the MRO and provide an appropriate comment as to why the specimen was not tested. If the reason for rejecting the test was a collector error, when a test is cancelled by the MRO, the collector who collected the specimen will need to go through an error correction training process within 30 days addressing the specific problem that caused the specimen to be cancelled.

Note: Once contacted by the laboratory or the MRO, the collector should immediately provide a statement or memorandum to recover the discrepancy and/or error of omission. Laboratories are required by HHS to retain these specimens for a minimum of 5 business days before they may be discarded; therefore, it is critical that the collector respond immediately to the laboratory's request for corrective action.

APPENDIX A – TRAINING REQUIREMENTS FOR COLLECTORS

To be permitted to act as a collector in the DOT drug testing program, you must meet the following requirements:

(a) Basic information. You must be knowledgeable about 49 CFR Part 40, 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, U.S. Department of Transportation, 1200 New Jersey Ave, SE, W62-300, Washington DC, 20590, 202-366-3784, or on the ODAPC web site: http://www.dot.gov/odapc.

(b) Qualification training. You must receive qualification training *that* provides instruction on the following subjects:

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

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

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

(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;

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

(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.

(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 by --

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

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

(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:

(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.

(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.

(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) above, you must complete refresher training that meets all the requirements of paragraphs (b) and (c).

(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.

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

(ii) 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.

(iii) 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 who are using or negotiating to use your services.

APPENDIX B – COLLECTION SITE SECURITY AND INTEGRITY

DOT's 10 Steps to Collection Site Security and Integrity

Office of Drug and Alcohol Policy and Compliance
U.S. Department of Transportation

1. Pay careful attention to employees throughout the collection process.

2. Ensure that there is no unauthorized access into the collection areas and that undetected access (e.g., through a door not in view) is not possible.

3. Make sure that employees show proper picture ID.

4. Make sure employees empty pockets; remove outer garments (e.g., coveralls, jacket, coat, hat); leave briefcases, purses, and bags behind; and wash their hands.

5. Maintain personal control of the specimen and CCF at all times during the collection.

6. Secure any water sources or otherwise make them unavailable to employees (e.g., turn off water inlet, tape handles to prevent opening faucets, secure tank lids).

7. Ensure that the water in the toilet and tank (if applicable) has bluing (coloring) agent in it. Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank.

8. Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present.

9. Inspect the site to ensure that no foreign or unauthorized substances are present.

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

APPENDIX C – DOT STANDARDS FOR URINE COLLECTION KITS

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 º C / 90-100 º 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.

APPENDIX D – DIRECT OBSERVATION PROCEDURES

DOT's Direct Observation Procedures
Office of Drug and Alcohol Policy and Compliance
U.S. Department of Transportation

1. DOT's 49 CFR Part 40 directly observed collections are authorized and required only when:

- **The employee attempts to tamper with his or her specimen at the collection site.**

  -- The specimen temperature is outside the acceptable range;

  -- The specimen shows signs of tampering ~ unusual color / odor / characteristic; or

  -- The collector finds an item in the employee's pockets or wallet which appears to be brought into the site to contaminate a specimen; or the collector notes conduct suggesting tampering.

- **The Medical Review Officer (MRO) orders the direct observation because:**

  -- The employee has no legitimate medical reason for certain atypical laboratory results; or

  -- The employee's positive or refusal [adulterated / substituted] test result had to be cancelled because the split specimen test could not be performed (for example, the split was not collected).

- **The test is a Follow-Up test or a Return-to-Duty test.**

2. The observer must be the same gender as the employee.

3. If the collector is not the observer, the collector must instruct the observer about the procedures for checking the employee for prosthetic or other devices designed to carry "clean" urine and urine substitutes AND for watching the employee urinate into the collection container.

- **The observer requests the employee to raise his or her shirt, blouse or dress / skirt, as appropriate, above the waist, just above the navel; and lower clothing and underpants to mid-thigh and show the observer, by turning around, that the employee does not have such a device.**

- ***If The Employee Has A Device*: The observer immediately notifies the collector; the collector stops the collection; and the collector thoroughly documents the circumstances surrounding the event in the remarks section of CCF. The collector notifies the DER. This is a refusal to test.**

- ***If The Employee Does Not Have A Device*: The employee is permitted to return clothing to its proper position for the observed collection. The observer must watch the urine go from the employee's body into the collection container. The observer must watch as the employee takes the specimen to the collector. The collector then completes the collection process.**

4. Failure of the employee to permit any part of the direct observation procedure is a refusal to test.

APPENDIX E – QUESTIONS AND ANSWERS

Periodically, DOT will publish questions and answers specific to the collector and the collection process. These will be posted on the ODAPC web site: www.dot.gov/odapc . All collectors are encouraged to check the site to ensure that they have the most current information to help them conduct DOT-required specimen collections appropriately. Collectors who do not have access to the Internet may obtain copies of the questions and answers from ODAPC by calling 1-202-366-3784.

APPENDIX F – OPERATING ADMINISTRATIONS' RULES (SUMMARY)

49 CFR Part 40 (§40.33(a)) states that collectors must be knowledgeable about the DOT agency regulations applicable to the employers for whom the collectors conduct urine specimen collections. The following is a list of regulations which govern an employer's implementation of the DOT drug and alcohol testing rules:

The FMCSA regulation is 49 CFR Part 382.

The FRA regulation is 49 CFR Part 219.

The FAA regulation is 14 CFR Part 120.

The FTA regulation is 49 CFR Part 655.

The PHMSA regulation is 49 CFR Part 199.

The USCG regulation is 46 CFR Parts 4, 5, and 16.

Drug and alcohol testing (including collection) procedures are 49 CFR Part 40.

The following pages contain a short summary of some of the operating administrations' requirements. Copies of the complete rule texts are available on the ODAPC web site: http://www.dot.gov/odapc.

Federal Motor Carrier Safety Administration - (FMCSA)

Covered employee: A person who **operates** (**i.e., drives**) a Commercial Motor Vehicle(CMV) with a gross vehicle weight rating (gvwr) of 26,001 or more pounds; or is designed to transport 16 or more occupants (to include the driver); or is of any size and is used in the transport of hazardous materials that require the vehicle to be placarded.

Types of tests for drugs: Pre-employment, random, reasonable suspicion, post-accident, return-to-duty, and follow-up.

Types of tests for alcohol: Pre-employment (optional), random, reasonable suspicion, post-accident, return-to-duty, and follow-up.

Definition of accident requiring testing: Any accident involving a fatality requires testing. Testing is also required in accidents in which one or more motor vehicles are towed from the scene or in which someone is treated medically away from the scene; **and** a citation is issued to the CMV driver.

Reasonable-suspicion determination: One trained supervisor or company official can make the decision based upon specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the employee.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of duty.

Actions for BACs 0.02 – 0.039: The employee cannot be returned to duty until the next day or the start of the employee's next regularly scheduled duty period, but not less than 24 hours following the test.

Employee training: Employer must provide educational materials explaining drug and alcohol regulatory requirements and employer's policies and procedures for meeting regulation requirements. Distribution to each employee of these educational materials and the employer's policy regarding the use of drugs and alcohol is mandatory.

Supervisor training: One-hour of training is required on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use. One-hour of training is also required on the specific, contemporaneous physical, behavioral, and performance indicators of probable alcohol use.

Reportable employee drug and alcohol violations: No requirements to report violations to FMCSA.

Other: Drivers are prohibited from using alcohol for eight hours following an accident (as described above) or until they have undergone a post-accident alcohol test, whichever occurs first.

Federal Railroad Administration - (FRA)

Covered employee: A person who performs hours of service functions at a rate sufficient to be placed into the railroad's random testing program. Categories of personnel who normally perform these functions are **locomotive engineers, trainmen, conductors, switchmen, locomotive hostlers/helpers, utility employees, signalmen, operators,** and **train dispatchers.**

Types of tests for drugs: Pre-employment, random, reasonable suspicion, reasonable cause, post-accident, return-to-duty, and follow-up.

Types of tests for alcohol: Pre-employment (optional), random, reasonable suspicion, reasonable cause, post-accident, return-to-duty, and follow-up.

Definition of accident requiring testing: FRA's post-accident testing rule requires urine and blood specimen collection from surviving employees and also tissue from deceased employees (these collection procedures go well beyond the normal Part 40 procedures). For surviving employees, these specimens are collected at an independent medical facility. FRA regulation, 49 CFR Part 219 Subpart C, stipulates the level of events requiring testing and who has to be tested. The collected specimens are analyzed only at FRA's contract laboratory. Post-accident testing provides FRA with accident investigation and usage data.

Reasonable-suspicion determination: One trained supervisor can make the decision for alcohol testing based upon specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the employee. A decision to conduct a drug test requires two supervisors (only the on-site supervisor must be trained).

Reasonable-cause determination: Employers are authorized to use federal authority to test covered employees after specific operating rule violations or accidents/incidents which meet the criteria in 49 CFR Part 219 Subpart D.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of duty or after receiving notice to report for covered service, whichever is the shorter period.

Actions for BACs 0.02 – 0.039: The employee cannot be returned to duty until the start of the employee's next regularly scheduled duty period, but not less than 8 hours following the test. Railroads are prohibited from taking further disciplinary action under their own authority.

Employee training: Employer must provide education materials that explain the requirements of the FRA rules as well as railroad policies and procedures with respect to meeting these requirements.

Supervisor training: A total of three hours of training is required: one-hour on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use; one-hour of similar training on probable indicators of alcohol use; and one-hour of training on how to determine if an accident qualifies for post-accident testing.

FRA (continued)

Reportable employee drug and alcohol violations: No requirements to report violations to FRA. Engineers, who are the only certificate holders in the rail industry, will have their certificates reviewed for suspension or revocation by the employer when a FRA violation occurs. Note that a FRA alcohol violation occurs at 0.04 percent or greater. When a locomotive engineer is in a voluntary referral program, the counseling professional must report the engineer's refusal to cooperate in the recommended course of counseling or treatment.

Other:
Anyone with direct or immediate supervisory authority over an employee may not collect that person's urine, saliva, or breath.

Refusal to test results in a mandatory minimum nine-month removal from covered service. During this nine-month period, there is no prohibition against the employee working a non-covered service position if agreeable to the employer.

Locomotive engineers (or other employees certified as a locomotive engineer at the time of the alcohol or drug violation) required both alcohol and drug return-to-duty tests; and both alcohol and drug follow-up tests.

Locomotive engineers who have a DUI are required by Part 240 to be evaluated to determine whether they have an active substance abuse disorder. A DUI is not considered to be a violation of FRA regulations if it occurred during the employee's off-duty time; therefore, any testing would be conducted under employer authority.

Employers must provide a voluntary referral program which allows an employee to self-refer for treatment, and a co-worker report program which allows one employee to refer another for treatment before the employer identifies a problem. Both of these employee assistance programs guarantee that employees will retain their jobs if they cooperate and complete the required rehabilitation program. For an engineer who is in a voluntary referral program, the counseling professional must report the engineer's refusal to cooperate in the recommended course of counseling or treatment to the employer.

Federal Aviation Administration - (FAA)

Covered employee: A person who performs **flight crewmember duties, flight attendant duties, flight instruction duties, aircraft dispatch duties, aircraft maintenance or preventive maintenance duties; ground security coordinator duties; aviation screening duties; air traffic control duties,** and ***operations control specialist duties***. Note: Anyone who performs the above duties directly or by contract for a part 119 certificate holder authorized to operate under parts 121 and/or 135, **air tour operators** defined in 14 CFR part 91.147, and **air traffic control** facilities not operated by the Government are considered covered employees.

Types of tests for drugs: Pre-employment, random, reasonable cause, post-accident, return to duty, and follow-up.

Types of tests for alcohol: Pre-employment (optional), random, reasonable suspicion, post-accident, return to duty, and follow-up.

Definition of accident requiring testing: Accident means an occurrence associated with the operation of an aircraft which takes place between the time any person boards the aircraft with the intention of flight and all such persons have disembarked, and in which any person suffers death or serious injury, or in which the aircraft receives substantial damage. Testing must occur if employee's performance either contributed to the accident or cannot be completely discounted as a contributing factor of the accident. The decision not to test an employee must be based on a determination, using the best information available at the time of the determination that the employee's performance could not have contributed to the accident.

Reasonable cause determination (drugs): Two of the employee's supervisors, one of whom is trained, shall substantiate and concur in the decision to test the employee. If the employer is not an air carrier operating under 14 CFR part 121 and has 50 or fewer employees, a single trained supervisor can make the determination. A trained supervisor makes the determination based upon specific contemporaneous physical, behavioral or performance indicators of probable drug use.

Reasonable suspicion determination (alcohol): One trained supervisor makes the determination based upon specific, contemporaneous, articulable observations concerning the employee's appearance, behavior, speech, or body orders.

Pre-duty alcohol use prohibitions: Eight (8) hours prior to performance of flight crewmember duties, flight attendant duties, and air traffic controller duties. Four (4) hours prior to performance of other duties.

Actions for BACs 0.02 - 0.039: If the employer chooses to return the employee to covered services within 8 hours, the BAC retest must be below 0.02.

FAA (continued)

Employee training (drugs): An employer must train all employees who perform safety-sensitive duties on the effects and consequences of prohibited drug use on personal health, safety, and work environment, and on the manifestations and behavioral cues that may indicate drug use and abuse. Employers must also implement an education program for safety-sensitive employees by displaying and distributing informational materials, a community service hot-line telephone number for employee assistance and the employer's policy regarding drug use in the work place which must include information regarding the consequences under the rule of using drugs while performing safety-sensitive functions, receiving a verified positive drug test result, or refusing to submit to a drug test required under the rule.

Employee training (alcohol): Employers must provide covered employees with educational materials that explain the alcohol misuse requirements and the employer's policies and procedures with respect to meeting those requirements. The information must be distributed to each covered employees and must include such information as the effects of alcohol misuse on an individual's health work, personal life, signs and symptoms of an alcohol problem; and the consequences for covered employees found to have violated the regulatory prohibitions.

Supervisor training (drugs): One-hour of training is required on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use. In addition, supervisors must receive employee training as defined above. Reasonable recurrent training is also required.

Supervisor training (alcohol): One-hour of training is required on the physical, behavioral, speech, and performance indicators of probable alcohol misuse.

Reportable employee drug and alcohol violations:

Each employer must notify the FAA about any covered employee who holds a certificate issued under 14 CFR Parts 61 (pilots and flight and ground instructors), 63 (flight engineers and navigators), or 65 (air traffic control tower operators, aircraft dispatchers, airframe or power plant mechanics, and repairmen) who has refused to take a drug or alcohol test. The MRO may report a positive or refusal (i.e. adulterated, substituted results or no medical explanation for providing an insufficient specimen) on behalf of the employer.

Each employer must notify the FAA about any safety-sensitive employee who is required to hold an airman medical certificate issued under 14 CFR Part 67 who has a positive drug test result, an alcohol test result of 0.04 or greater, or who has refused to submit to testing. The MRO may report a positive or refusal (i.e. adulterated, substituted results or no medical explanation for providing an insufficient specimen) on behalf of the employer.

Each employer must not permit an employee who is required to hold a medical certificate under part 67 to perform a safety-sensitive function to resume that duty until the employee has received a new medical certificate issued by the FAA Federal Air Surgeon **and** the employer has ensured that the employee meets the return to duty requirements of Part 40. (Medical certificates are not operating certificates but employees cannot continue to perform airman duties without a medical certificate.)

FAA (continued)

According to FAA's regulation 14 CFR part 120, Subpart E, section 120.113(d), when a MRO verifies a drug test result or a SAP performs the initial evaluation, they must ask the employee whether he or she holds or would be required to hold an airman medical certificate issued under 14 CFR part 67 of this chapter to perform a safety-sensitive function for the employer. [This requirement only applies to MROs and SAPs who provide services for FAA regulated employers.] If the employee answers in the affirmative, the employee must obtain an airman medical certificate issued by the Federal Air Surgeon dated after the drug and/or alcohol violation date.

The SAP must wait until the employee obtains their airman medical certificate before reporting to an employer that the employee demonstrated successful compliance with the SAP's treatment and/or education recommendations.

Federal Transit Administration - (FTA)

Covered employee: A person who performs a **revenue vehicle operation; revenue vehicle and equipment maintenance; revenue vehicle control or dispatch (optional); Commercial Drivers License non-revenue vehicle operation;** or **armed security duties.**

Types of tests for drugs: Pre-employment, random, reasonable suspicion, post-accident, return-to-duty, and follow-up.

Types of tests for alcohol: Pre-employment (optional), random, reasonable suspicion, post-accident, return-to-duty, and follow-up.

Definition of accident requiring testing: Any accident involving a fatality requires testing. Testing following a non-fatal accident is discretionary: If the employer can show the employee's performance could not have contributed to the accident, no test is needed. Non-fatal accidents that may require testing must have disabling damage to any vehicle or immediate medical attention away from the scene to meet the testing threshold.

Reasonable-suspicion determination: One trained supervisor or company official can make the decision based upon specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the employee.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of duty.

Actions for BACs 0.02 – 0.039: If the employer chooses to return the employee to covered service within 8 hours, the BAC re-test must be below 0.02.

Employee training: Employer must provide education with display and distribution of informational materials and a community service hot-line telephone number, if available. One-hour of training on the effects and consequence of prohibited drug use on personal health, safety, and the work environment, and on the signs and symptoms that may indicate prohibited drug use. Distribution to each employee of the employer's policy regarding the use of drugs and alcohol with signed receipt is mandatory.

Supervisor training: One-hour of training is required on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use. One-hour of training is also required on the specific, contemporaneous physical, behavioral, and performance indicators of probable alcohol use.

Reportable employee drug and alcohol violations: No requirements to report violations to FTA.

Other: Anyone with direct or immediate supervisory authority over an employee may not collect that person's urine, saliva, or breath.

Pipeline and Hazardous Materials Safety Administration - (PHMSA)

Covered employee: A person who performs on a pipeline or liquefied natural gas (LNG) facility an **operation, maintenance, or emergency-response** function.

Types of tests for drugs: Pre-employment, random, reasonable cause, post-accident, return-to-duty, and follow-up.

Types of tests for alcohol: Post-accident, reasonable suspicion, return-to-duty, and follow-up.

Definition of accident requiring testing: An accident is one involving gas pipeline facilities or LNG facilities or involving hazardous liquid or carbon dioxide pipeline facilities.

Reasonable-suspicion determination: One trained supervisor can make the decision based upon signs and symptoms.

Reasonable-cause determination: One trained supervisor can make the decision based upon reasonable and articulable belief that the employee is using prohibited drugs on the basis of specific, contemporaneous physical, behavioral, or performance indicators of probable drug use.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of duty.

Actions for BACs 0.02 – 0.039: If the employer chooses to return the employee to covered service within 8 hours, the BAC retest must be below 0.02.

Employee training (Drugs): Employer must provide EAP education with display and distribution of informational materials; display and distribution of a community service hot-line telephone number; and display and distribution of the employer's policy regarding the use of prohibited drugs.

Employee Training (Alcohol): Employer must develop materials that explain policies and procedures (as well as names of those who can answer questions about the program) and distribute them to each covered employee.

Supervisor training: One-hour of training is required on the specific, contemporaneous physical, behavioral, and performance indicators of probable drug use. One-hour of training is also required on the specific, contemporaneous physical, behavioral, and performance indicators of probable alcohol use.

Reportable employee drug and alcohol violations: No requirements to report violations to PHMSA.

United States Coast Guard - (USCG)

Covered employee: A person who is **on board a vessel** acting under the authority of a **license, certificate of registry, or merchant mariner's document**. Also, a person **engaged or employed on board a U.S. owned vessel** and such vessel is required to engage, employ or be operated by a person holding a license, certificate of registry, or merchant mariner's document.

Types of tests for drugs: Pre-employment, periodic, random, reasonable cause, and post-serious marine incident (SMI), return-to-duty, and follow-up.

Types of tests for alcohol: 49 CFR Part 40 alcohol-testing requirements do not apply to the Maritime Industry. 46 CFR Part 4.06 requires post-SMI chemical testing for alcohol use. 33 CFR Part 95.035 allows for a marine employer or a law enforcement officer to direct an individual to undergo a chemical test for intoxicants when reasonable cause exists or a marine casualty has occurred.

Definition of incident requiring testing: An SMI is defined in 46 CFR 4.03-2. In general, an SMI is: A discharge of 10,000 gallons or more of oil into the navigable waters of the United States, whether or not resulting from a marine casualty; a discharge of a reportable quantity of a hazardous substance into the navigable waters or into the environment of the United States, whether or not resulting from a marine casualty; or a marine casualty or accident required to be reported to the Coast Guard, involving a vessel in commercial service, and resulting in any of the following: One or more deaths; an injury to any person (including passengers) which requires professional medical treatment beyond first aid, and, in the case of a person employed on board a commercial vessel, which renders the person unable to perform routine vessel duties; damage to property in excess of $100,000; actual or constructive total loss of any inspected vessel; or actual or constructive total loss of any uninspected, self-propelled vessel of 100 gross tons or more.

Reasonable-cause determination (drugs): The marine employer must have a reasonable and articulable belief that the individual has used a dangerous drug. This belief should be based on the direct observation of specific, contemporaneous physical, behavioral, or performance indicators of probable use and where practicable based on the observation of two persons in supervisory positions.

Reasonable-cause determination (alcohol): The employee was directly involved in the occurrence of a marine casualty or the individual operated a vessel and the effect of the intoxicant(s) consumed by the individual on the person's manner, disposition, speech, muscular movement, general appearance or behavior is apparent by observation.

Pre-duty alcohol use prohibitions: Four (4) hours prior to performance of scheduled duty.

Employee training: Employer must provide education with display and distribution of informational materials and a community service hot-line telephone number. Distribution to each employee of the employer's policy regarding the use of drugs and alcohol is mandatory. Training must include the effects of drugs and alcohol on personal heath, safety, and work environment; and manifestations and behavioral cues that may indicate drug and alcohol use and abuse.

USCG (continued)

Supervisor training: One-hour of training is required on the effects of drugs and alcohol on personal heath, safety, and work environment; and manifestations and behavioral cues that may indicate drug and alcohol use and abuse.

Reportable employee drug and alcohol violations: Results of all post-SMI tests and positive drug test results for all mariners who hold a license, certificate of registry or merchant mariner's document must be reported to the nearest Coast Guard Officer in Charge, Marine Inspection.

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Office of the Secretary

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Changes from previous version [October 1, 2010]:

- Page 2: Removed the introductory statement from the Secretary of Transportation (now available on our web site)
- Page 41: Added a new FAA safety-sensitive employee category known as "Operations Control Specialist."
- Updated web site addresses/ hyperlinks, as needed.
- Modified language throughout the document to clarify concepts and to identify when actions are required versus simply permitted by the regulation. These edits are *italicized* throughout this document and the items *italicized*, underlined, and **bolded** from the 2010 revisions to this document were returned to normal text.
- Removed effective dates in Section 4 that have passed.
- Section 13 was reorganized.
- Removed Section 14.